

MedeList

MedeList for:

Consumer name Mr Hans MOLEMAN
(DOB 01/02/1950)

Address Wing: Wing 1
A nursing home
an address
Hobart TAS 7000



Created by:

Pharmacist name Mr Peter GEE



Address an address
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Allergies No allergies recorded

Notes

Medications

Medicine name	Image	Instructions	Doses AM NO EV BT	Reasons for use	Counselling
Lanoxin PG 62.5 microgram tablet: uncoated Brands: <i>Lanoxin PG</i>		Take ONE tablet in the MORNING	1	This medicine makes your heart beat regularly. It can also be used to help treat heart failure.	Avoid taking St John's Wort as it may decrease the amount of digoxin in your blood.
Noten 50 mg tablet: uncoated Brands: <i>Noten</i>		Take ONE tablet in the MORNING		For treatment of high blood pressure and angina, or to reduce your heart rate.	Do not suddenly stop taking this medicine unless your prescriber tells you to do so. May cause nausea, diarrhoea, cold fingers and toes, blurred vision, dizziness, faintness, sleep disturbances, bad dreams, or depression. May worsen diabetes or asthma, and may affect sex drive in some people. See your prescriber if any of these are a problem.

Medicine name	Image	Instructions	Doses AM NO EV BT	Reasons for use	Counselling
Diabex XR-1000 1 g tablet: modified release Brands: <i>Diabex XR-1000</i>		Swallow ONE tablet whole in the MORNING		This is used to treat diabetes - it will lower the sugar (glucose) level in your blood.	Tell your doctor immediately if you have loss of appetite, nausea, vomiting, abdominal pain, cramps, malaise, diarrhoea or weight loss. Taking with food will help minimise upset stomachs. Taking alcohol decreases your blood sugar and it can mask warning symptoms of hypoglycaemia. It can also increase the risk of serious side effects; limit your alcohol intake, avoid binge drinking and eat when you drink alcohol. Do not crush or chew these tablets, swallow them whole with a glass of water.
Renitec 20 mg tablet: uncoated Brands: <i>Renitec</i>		Take ONE tablet in the MORNING		This is used to treat heart failure, high blood pressure, kidney problems related to diabetes, and after a heart attack in some people.	May lower blood pressure and cause dizziness (especially the first time you take it), fatigue, nausea and kidney problems. Tell your doctor if you get a dry cough. Your doctor may like to test your blood to monitor your kidney function.

Disclaimer

*The information on this document has been created solely for use by **Mr Hans MOLEMAN**. At the time of printing, best efforts were taken to ensure this MedeList contains the most current information available.*

*The reasons for use and counselling points contain **general** information. In some cases the information provided may not be relevant to your case.*

This document is not intended to replace approved Consumer Medicines Information (CMI) leaflets, or the Approved Product Information. If you would like more information on the medicines you take, contact your pharmacist.

Abbreviations

AM: In the morning, NO: At noon, EV: In the evening, BT: At bedtime

LANOXIN[®] Tablets & Liquid

digoxin

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about LANOXIN. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits.

Your doctor has weighed the risks of you taking LANOXIN against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What is LANOXIN

LANOXIN belongs to a group of medicines known as cardiac glycosides. They work by slowing down the rate while increasing the force of your heart when it beats.

It is used to treat certain heart problems, such as:

Chronic Heart failure

Heart failure is when your heart can't pump strongly enough to supply blood needed through out the whole body. It is not the same as a heart attack and does not mean that your heart stops.

Certain type of irregular heart beats

Irregular heart rhythms caused by an electrical problem in the upper chamber of your heart. They cause your heart to beat too fast or in an uneven way.

Ask your doctor if you have any questions about why LANOXIN has been prescribed for you.

Your doctor may have prescribed LANOXIN for another reason.

There is no evidence that LANOXIN is addictive.

Before you take it

When you must not take it

Do not take LANOXIN if you have an allergy to:

- digoxin or other cardiac glycosides
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction to LANOXIN may include:

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- skin rash, itching or hives

Do not take LANOXIN if you have or have had any of the following medical conditions:

- intermittent or complete heart block or second degree atrioventricular block, (conditions where the heart

misses beats) especially if there is a history of Stokes-Adams attacks

- ventricular tachycardia and ventricular fibrillation (a type of irregular heart rhythm)
- irregular heart rhythm caused by cardiac glycoside overdose
- certain other irregularities of heart rhythm.

If you are not sure whether you should start taking LANOXIN, talk to your doctor or pharmacist.

Do not take LANOXIN after the expiry date (EXP) printed on the pack.

Do not take it if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to take it

Tell your doctor if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you are pregnant or intend to become pregnant.

Pregnant women may require an adjustment of the dose of LANOXIN during pregnancy. This medicine may have harmful effects on the developing baby if the dose is too high.

Tell your doctor if you are breast-feeding or plan to breast-feed.

Tell your doctor if you have or have had any medical conditions, especially the following:

- heart disease
- heart disease caused by lack of vitamin B, known as 'Beri-Beri disease'
- lung problems
- liver or kidney problems – effect of LANOXIN may be increased because of slower removal from the body
- thyroid disease – patients with low or high thyroid gland activity may be more or less sensitive to the effects of LANOXIN
- high or low levels of calcium, potassium in your blood
- low level of magnesium in your blood
- digestion problems.

If you have not told your doctor or pharmacist about any of the above, it is important to tell them before you start taking LANOXIN.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and LANOXIN may interfere with each other.

These include:

- amphetamine, appetite suppressants, medicines for colds, sinus problems, hay fever or other allergies – may increase the risk of heart rhythm problems
- medicines for heart problems, including high blood pressure (hypertension) and irregular heart beat (arrhythmia)
- diuretics (water tablets)
- potassium supplements
- medicines for cancer
- medicines for depression

- medicines for bacterial infection (antibiotics)
- medicines for fungal infections (antifungals)
- medicines for stomach problems, including for nausea, vomiting, diarrhoea or indigestion
- some laxatives
- medicines for relieving asthma attacks or other breathing problems
- corticosteroids (e.g. hydrocortisone, dexamethasone, prednisolone, prednisone)
- medicines for diabetes (e.g. insulin, glucagon)
- cholestyramine, a medicine used for high cholesterol
- phenytoin, a medicine used to control epilepsy
- indomethacin – medication used for inflammation, gout or arthritis
- St John's Wort.

These medicines may be affected by LANOXIN or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

If you not sure if any of the above apply to you, talk to your doctor or pharmacist before taking LANOXIN.

How to take it

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

How much to take

Your doctor will tell you how much LANOXIN you will need to take each day. This depends on your condition and other factors such as your weight, age and other medicines you may be taking.

How to take it

Tablets:

Swallow LANOXIN tablets with a glass of water.

Liquid:

Accurately measure the dose with the calibrated dropper provided. Do not dilute.

Using the dropper will make sure that you get the correct dose.

Do not change your dose of LANOXIN unless your doctor tells you to do so.

After you begin taking LANOXIN, your doctor may sometimes check its level in your blood. This will help your doctor find out if your dose needs to be changed.

When to take it

Take LANOXIN at same time each day.

Taking LANOXIN at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take LANOXIN before or after food.

If you forget to take it

Take it as soon as you remember. However, if it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

How long to take it

Continue taking LANOXIN for as long as your doctor tells you.

LANOXIN helps control your condition, but does not cure it. Therefore, you must take LANOXIN every day.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much LANOXIN. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose to LANOXIN include some of the side effects listed below.

Some early warning signs of overdose are loss of appetite, nausea, vomiting, diarrhoea, or extremely slow heart beat.

In infants and small children, the earliest signs of overdose are changes in the rate and rhythm of the heart beat.

Carers should be aware that children may not show symptoms as soon as adults.

While you are taking it

Things you must do

Tell your doctor immediately if you notice any side effects from LANOXIN.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking LANOXIN.

Tell your doctor, dentist or pharmacist that you are taking LANOXIN before you start taking any medicines you buy from a pharmacy, health food shop or supermarket.

If you plan to have surgery that needs a general anaesthetic, tell your doctor or dentist that you are taking LANOXIN.

If you become pregnant while taking LANOXIN, tell your doctor immediately.

If you need to have any medical tests while you are taking LANOXIN, tell your doctor.

LANOXIN may affect the results of some tests.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Your doctor will check your progress and may want to take some blood tests from time to time. This helps to prevent unwanted side effects.

Things you must not do

Do not give LANOXIN to anyone else, even if their symptoms seem similar or they have the same condition as you.

Do not take LANOXIN to treat any other complaints unless your doctor tells you to.

Do not stop taking LANOXIN, or change the dose even if you are feeling better, without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how LANOXIN affects you.

LANOXIN may cause dizziness, blurred vision, and faintness in some patients. Make sure you know how you react to LANOXIN, before you drive a car, operate machinery, or do anything else that could be dangerous if this happens.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

If any of the following happen, tell your doctor or pharmacist immediately:

- nausea or vomiting, loss of appetite
- diarrhoea
- lower stomach pain
- slow or irregular heart beats (may be fast in children)
- unusual tiredness or extreme weakness
- general feeling of 'unwellness'
- blurred vision or visual disturbances (e.g. coloured halos around objects i.e. yellow, green, or white)
- depression
- headache
- mental disturbances, such as confusion or feeling indifferent
- skin rash
- painful, swollen breasts, or breast enlargement in men
- bleeding or bruising more easily than normal.

These may be serious side effects. You may need urgent medical attention. Serious side effects are rare or are caused by a dose of LANOXIN that is too high for you.

Tell your doctor immediately if you have:

- palpitations
- chest pain
- shortness of breath or sweating.

These can be symptoms of a serious heart problem caused by new irregular heart beats of a different type to those caused by atrial fibrillation (which LANOXIN is often used to treat).

Your doctor may do regular checks on your blood levels of digoxin and body salts, as well as your kidney function to make sure LANOXIN is working safely for you.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

This is not a complete list of side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking it

Storage

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep your LANOXIN tablets in the pack and the liquid in the bottle until it is time to take them.

If you take the tablets or liquid out of the pack, they will not keep well.

Store LANOXIN-PG tablets in a cool, dry place away from light and where the temperature stays below 30°C.

Store LANOXIN tablets and paediatric elixir in a cool, dry place away from light and where the temperature stays below 25°C.

Do not store LANOXIN or any other medicine in the bathroom or near a sink. Do not leave it in the car on hot days or on windowsills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking LANOXIN or the medicine has passed its expiry date, ask your pharmacist what to do with any that is left over.

Product description

What it looks like

LANOXIN-PG Tablet

Blue, biconvex, round tablet coded "U3A" on the upper face, bottom face plain; in bottles of 200.

LANOXIN Tablet

White, biconvex, uncoated round tablet scored and marked "X3A" on one side. Blister packs of 100 tablets.

LANOXIN Paediatric Elixir

Clear, bright yellow liquid with a characteristic odour, in 60 mL bottles with calibrated dropper. Do not dilute.

Ingredients

LANOXIN-PG tablet

Active ingredient:

Each tablet contains digoxin 62.5 micrograms.

Other ingredients:

- lactose
- starch-oxidised maize
- starch-maize
- starch-rice
- magnesium stearate
- povidone
- indigo carmine – CI73015.

LANOXIN-PG tablets do not contain sucrose, gluten, tartrazine or any other azo dyes.

LANOXIN tablet

Active ingredient:

Each tablet contains digoxin 250 micrograms.

Other ingredients:

- lactose
- starch-oxidised maize
- starch-maize
- starch-rice
- magnesium stearate.

LANOXIN tablets do not contain sucrose, gluten, tartrazine or any other azo dyes.

LANOXIN Paediatric Elixir

Active ingredient:

Each mL of oral liquid contains digoxin 50 micrograms.

Other ingredients:

- sucrose
- sodium phosphate - dibasic
- citric acid - anhydrous
- ethanol
- propylene glycol
- quinoline yellow – CI47005
- lime flavour NI No. 1 DF1167 (PI)
- methyl hydroxybenzoate
- water-purified.

LANOXIN Paediatric Elixir does not contain lactose, gluten, tartrazine or any other azo dyes.

The Australian Product Registration
Numbers for:

LANOXIN-PG digoxin 62.5
microgram tablet bottle:
AUST R 11108

LANOXIN digoxin 250 microgram
tablet blister pack: AUST R 15333

LANOXIN PAEDIATRIC ELIZIR
digoxin 50 microgram/mL oral
liquid bottle: AUST R 42757.

Sponsor

Aspen Pharma Pty Ltd
34-36 Chandos St
St Leonards NSW 2065
Australia

This leaflet was revised in May
2014

Noten

contains the active ingredient atenolol

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Noten.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Noten against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What Noten is used for

Noten is used to:

- * lower high blood pressure, also called hypertension
- * prevent angina
- * treat an irregular heart beat or rhythm, also called arrhythmia
- * reduce the risk of heart complications following a heart attack.

Noten belongs to a group of medicines called beta-blockers. It works by affecting the body's response to certain nerve impulses, especially in the heart. As a result, it decreases the heart's need for blood and oxygen and therefore reduces the amount of work the heart has to do. It widens the blood vessels in the body, causing blood pressure to fall.

It also helps the heart to beat more regularly.

Hypertension:

Everyone has blood pressure. This pressure helps to push blood all around your body. Your blood pressure changes during the day, depending on how busy you are or how you are feeling.

You have hypertension (high blood pressure) when your blood pressure stays higher than is needed, even when you are calm and relaxed.

There are usually no symptoms of hypertension. The only way of knowing that you have hypertension is to have your blood pressure checked on a regular basis. You may feel fine and have no symptoms, but if high blood pressure is not treated, it can lead to serious health problems.

Noten helps to lower your blood pressure.

Angina:

Angina is a pain or uncomfortable feeling in the chest, often spreading to the arms or neck and sometimes to the shoulders and back. This may be caused by too little blood and oxygen getting to the heart. The pain of angina is usually brought on by exercise or stress, but can also occur at rest.

Noten helps prevent angina. It is not used to relieve a sudden attack of angina.

Irregular heart beat (arrhythmia):

Irregular heart beat, also known as arrhythmia, means that there is a disturbance of the heart's normal rhythm or beat. Arrhythmias may be caused by a number of factors, including some heart diseases, an overactive thyroid gland, or chemical imbalances.

Noten helps restore the heart's normal rhythm.

Reducing heart complications after heart attack:

After a heart attack there is a chance of developing arrhythmias or of further heart attacks occurring.

Noten helps prevent these conditions from occurring.

Ask your doctor if you have any questions about why Noten has been prescribed for you.

Your doctor may have prescribed Noten for another reason.

Noten is not recommended for use in children, as there have been no studies of its effects in children.

Noten is available only with a doctor's prescription.

There is no evidence that Noten is addictive.

Before you take Noten

When you must not take it

Do not take Noten if you have an allergy to:

- * any medicine containing atenolol
- * any of the ingredients listed at the end of this leaflet
- * any other beta-blocker medicine.

Some of the symptoms of an allergic reaction may include shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take Noten if you have:

- * asthma, wheezing, difficulty breathing, or other lung problems; or have had them in the past
- * a history of allergic problems, including hayfever
- * a very slow heart beat, less than 45-50 beats per minute
- * other problems with your heart
- * low blood pressure, also called hypotension
- * phaeochromocytoma (a rare tumour of the adrenal gland) that is not already being treated with other medicines
- * a severe blood vessel disorder causing poor circulation in the arms and legs.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to:

- * any other medicines, including eye drops, or other beta-blocker medicines

- * any other substances, such as foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant.

Noten may affect your baby if you take it early in pregnancy or in the last weeks before your baby is due. Your doctor will discuss the risks and benefits of taking Noten during pregnancy.

Tell your doctor if you are breastfeeding or wish to breastfeed.

Noten passes into breast milk and may affect your baby. Your doctor will discuss the risks and benefits of taking Noten when breastfeeding.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- * diabetes
- * kidney problems
- * an overactive thyroid gland
- * certain types of angina, such as Prinzmetal angina or variant angina
- * any other heart problem
- * any blood vessel disorders causing poor circulation in the arms and legs
- * phaeochromocytoma (a rare tumour of the adrenal gland) that is being treated.

If you have not told your doctor about any of the above, tell them before you start taking Noten.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and Noten may interfere with each other. These include:

- * other medicines used to treat high blood pressure, angina or an irregular heart beat
- * digoxin, a medicine used to treat heart failure

- * medicines used to treat other heart conditions
- * insulin and other medicines used to treat diabetes
- * certain medicines used to treat arthritis, pain or inflammation such as indomethacin or ibuprofen
- * medicines commonly used during surgery or in emergency situations such as dopamine, adrenaline, noradrenaline and certain anaesthetics.

These medicines may be affected by Noten or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Noten.

How to take Noten

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

Hypertension:

The usual dose is from 50 mg (1 tablet) up to 200 mg (4 tablets) daily.

If your dose is 100 mg or less, take it once a day. If you need to take more than 100 mg (2 tablets), take half of your dose in the morning and the other half in the evening.

Angina or Arrhythmia (irregular heart beat):

The usual dose is from 50 mg (1 tablet) up to 100 mg (2 tablets) taken as a single dose or half the dose in the morning and half at night.

Heart attack

The usual dose is 50 mg (1 tablet) daily for 1 - 3 years following a heart attack.

The doses mentioned for arrhythmia and heart attack should be given after the condition is brought under control.

Certain people e.g. the elderly or those with kidney problems, may require a lower dose.

How to take it

Swallow the tablets with a glass of water.

When to take it

It does not matter if you take this medicine before or after food.

Take your tablet(s) at about the same time each day.

This will help you remember when to take the tablet.

How long to take it

Continue taking your medicine for as long as your doctor tells you to.

This medicine helps to treat high blood pressure, irregular heart beat, heart attacks and prevent angina but does not cure it. Therefore, Noten must be taken every day.

If you forget to take it

If it is less than six hours from when you missed your dose, take it as soon as you remember, and then go back to taking your tablets at the same time you would normally

If it is more than six hours since your last dose, skip the dose you missed and take your next dose when you would normally.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Noten. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much Noten, you may faint, feel dizzy or lightheaded, wheeze or have difficulty breathing. You may also have a very slow heart beat.

While you are taking Noten

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Noten.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you have a severe allergic reaction to foods, medicines or insect stings, tell your doctor immediately.

If you have a history of allergies, there is a chance that Noten may cause allergic reactions to be worse and harder to treat.

If you are going to have surgery (even at the dentist), tell your doctor or dentist that you are taking Noten.

This medicine may affect some of the medicines used during surgery.

If you are being treated for diabetes, make sure you check your blood sugar level regularly.

Noten may affect how well your diabetes is controlled. It may also cover up some of the symptoms of low blood sugar levels, such as a fast heart beat. It may also make low blood sugar last longer. Your doctor may need to change your dose of diabetic medicines, including insulin.

If you have angina and continue to have attacks or have more of them while you are taking this medicine, tell your doctor.

Noten is used to help prevent angina, so your angina attacks should become less severe and occur less often.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

You may feel light-headed or dizzy after taking Noten. This is because your blood pressure is falling suddenly.

If this problem gets worse or continues, talk to your doctor.

To help your body get used to the change in blood pressure, you may find the following hints useful:

- * Stand up slowly when getting up from a chair or bed. This will allow your body get used to the change in position and blood pressure.
- * If you feel dizzy, sit or lie down until you feel better.
- * If you feel faint, sit down and put your head between your knees.

Make sure you drink enough water in hot weather and during exercise while you are taking Noten, especially if you sweat a lot.

If you do not drink enough water while taking Noten, you may feel faint, lightheaded or sick. This is because your blood pressure is dropping suddenly. The recommended healthy minimum water intake is 6 - 8 glasses daily.

If you have to have any medical tests while you are taking Noten, tell your doctor.

Noten may affect the results of some tests.

Things you must not do

Do not stop taking Noten without checking with your doctor.

Stopping Noten suddenly may worsen your angina or cause other heart complications to occur. Your doctor may want you to gradually reduce the amount of Noten you are taking before stopping completely.

Do not take your medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how Noten affects you.

Noten may cause dizziness or tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Dress warmly during cold weather, especially if you will be outside for a long time (for example, when playing or watching sports in winter).

Noten, like other beta-blocker medicines, may make you more sensitive to cold temperatures, especially if you have blood circulation problems. Beta-blockers tend to decrease blood circulation in the skin, fingers and toes.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Noten.

Like all other medicines, Noten may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor if you notice any of the following and they worry you:

- * tiredness, headache
- * fatigue
- * feeling generally unwell
- * dry mouth
- * stomach upsets such as diarrhoea, constipation, abdominal pain or indigestion
- * hair loss
- * runny or blocked nose
- * sleep problems, nightmares, vivid dreams
- * problems with sexual function.

The above list includes the more common side effects of Noten. For the most part these have been mild.

Tell your doctor as soon as possible if you notice any of the following:

- * dizziness or lightheadedness, especially when getting up quickly
- * skin rash
- * worsening of psoriasis
- * unsteadiness when walking
- * abnormal thinking, hallucinations (seeing or hearing things that are not there)
- * depression or mood changes or a worsening of these
- * confusion
- * dry, red or sore eyes, blurred vision
- * pins and needles in the hands or feet
- * numbness, tingling and colour change in the fingers and toes when exposed to the cold
- * ringing in the ears.

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- * fast, slow or irregular heart beat
- * unusual bruising or bleeding
- * chest tightness, wheezing, difficulty breathing
- * shortness of breath (sometimes with tiredness, weakness and reduced ability to exercise), which may occur together with swelling of the feet or legs due to fluid build up
- * yellowing of the eyes or skin (jaundice) - this has been reported rarely
- * signs of an allergic reaction such as skin rash, itching or hives; swelling of the face, lips, tongue or other parts of the body; shortness of breath, wheezing or troubled breathing.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some patients.

After using Noten

Storage

Keep Noten where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30 degrees C.

Do not store Noten or any other medicine in the bathroom or near a sink.

Do not leave Noten in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Noten, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Noten is a white, oblong tablet marked AT/50 and a Greek alpha symbol.

Each pack contains 30 tablets.

Ingredients

The active ingredient in Noten is atenolol. Each Noten tablet contains 50 mg of atenolol.

The tablets also contain:

- * lactose
- * starch - maize
- * povidone
- * cellulose - microcrystalline
- * silica - colloidal anhydrous
- * hydrogenated vegetable oil
- * crospovidone
- * sodium starch glycollate
- * purified talc
- * magnesium stearate.

The tablets are gluten free.

Manufacturer

Noten is made in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999

www.alphapharm.com.au

Medical Information

Phone: 1800 028 365

Australian registration numbers:

Aust R 46250, 46251

This leaflet was prepared on
24 January 2007.

Diabex* XR

contains the active ingredient metformin hydrochloride

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Diabex XR.

It does not contain all the available information. It does not take the place of talking to your doctor, pharmacist or diabetes educator.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Diabex XR against the benefits expected for you.

If you have any concerns about taking this medicine, talk to your doctor, pharmacist or diabetes educator.

Keep this leaflet with your medicine.

You may need to read it again.

What Diabex XR is used for

Diabex XR is used to control blood glucose (sugar) in people with Type 2 diabetes mellitus, especially in those who are overweight. It is used when diet and exercise are not enough to control high levels of blood glucose.

Diabex XR can be used alone, or in combination with other medicines for treating diabetes.

TYPE 2 DIABETES MELLITUS

Type 2 diabetes mellitus is also called non-insulin dependent diabetes mellitus (NIDDM) or maturity onset diabetes.

Insulin is a hormone that enables body tissues to take up glucose from

the blood and to use it for energy or fat storage for future use.

People with Type 2 diabetes are unable to make enough insulin or their body does not respond properly to the insulin it does make. This causes a build up of glucose in the blood (hyperglycaemia), which can lead to serious medical problems.

Long-term hyperglycaemia can lead to heart disease, blindness, kidney damage, poor blood circulation and gangrene.

Signs of hyperglycaemia may include:

- tiredness or lack of energy
- headache
- thirst
- passing large amounts of urine
- blurred vision

How Diabex XR works

Diabex XR belongs to a group of medicines called biguanides. It lowers high blood glucose levels by:

- improving your body's sensitivity to insulin and restoring the way it normally uses glucose
- reducing the amount of glucose your liver makes
- delaying the amount of glucose your intestine absorbs

Ask your doctor if you have any questions about why Diabex XR has been prescribed for you.

Diabex XR is not recommended in children as its safety and effectiveness have not been established in this age group.

Diabex XR is available only with a doctor's prescription.

There is no evidence that Diabex XR is addictive.

This medicine has been prescribed for you personally and you should not pass it onto others even if their symptoms are the same as yours.

Before you take Diabex XR

When you must not take it

Do not take Diabex XR if you are allergic to:

- medicines containing metformin (such as Diaformin, Glucophage) or any other biguanide
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

Do not take Diabex XR if you have any of the following medical conditions:

- Type 1 diabetes mellitus that is well controlled by insulin alone
- Type 2 diabetes that is already well controlled by diet alone
- serious complications with your diabetes or diabetic ketoacidosis (a symptom of uncontrolled diabetes, in which substances called ketone bodies accumulate in the blood - you may notice this as an unusual fruity odour on your breath)
- kidney failure or severe kidney disease

- dehydration (for instance due to persistent or severe vomiting or diarrhoea)
- shock from severe injury or blood loss
- severe liver disease
- acute alcohol intoxication, chronic alcohol dependence
- certain heart or blood circulation problems, including a recent heart attack or heart failure (when the heart fails to pump blood effectively)
- blood clots in the lungs (symptoms include coughing, shortness of breath, chest pain and a fast heart rate), severe breathing difficulties
- inflammation of the pancreas (symptoms include severe upper stomach pain, often with nausea and vomiting) if associated with severe infection or hypoxia (lack of oxygen)
- a severe infection or gangrene.

Do not take Diabex XR if you need to have major surgery or an examination such as an X-ray or a scan requiring an injection of iodinated contrast (dye).

You must stop taking Diabex XR for a certain period of time before and after the examination or the surgery. Your doctor will decide whether you need any other treatment for this time. It is important that you follow your doctor's instructions precisely.

Do not take this medicine if you are pregnant or plan to become pregnant.

Insulin is more suitable for controlling blood glucose during pregnancy. Your doctor will replace Diabex XR with insulin while you are pregnant.

Do not take Diabex XR if you are breastfeeding.

Your doctor will discuss the options available to you.

Do not take this medicine after the expiry date (EXP) printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking Diabex XR, ask your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, dyes or preservatives.

Before starting Diabex XR your doctor will ask you to have a blood test to check your kidney function.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney problems
- liver problems
- heart or blood vessel problems including heart failure.

Tell your doctor if you drink alcohol.

Alcohol can affect the control of your diabetes. Drinking excessive amounts of alcohol while you are being treated with Diabex XR may also lead to serious side effects.

Your doctor may suggest you stop drinking or reduce the amount of alcohol you drink.

If you have not told your doctor about any of the above, tell him/her before you start taking Diabex XR.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and Diabex XR may interfere with each other.

These include:

- other medicines used to treat diabetes such as insulin, glitinides (Novonorm), and sulfonylureas (e.g. Amaryl, Daonil, Diamicon, Glimel, Glyade, Melizide, Minidiab)
- iodinated contrast agents (dyes)

- medicines that contain alcohol, such as cough and cold syrups
- corticosteroids such as prednisone (Panafacort, Sone) and cortisone (Cortate)
- tetracosactrin, a medicine used in people with multiple sclerosis, and in young children to treat some types of seizures (fits)
- danazol, a medicine used to treat endometriosis
- medicines used to treat high blood pressure and some heart conditions, such as beta-blockers, metoprolol (e.g. Betaloc, Minax), calcium channel blockers such as nifedipine (e.g. Adalat, Adefin), ACE inhibitors such as captopril (e.g. Capoten, Acenorm), enalapril (e.g. Alphapril, Amprace, Renitec) fosinopril (Monopril), lisinopril (e.g. Lisodur, Prinivil, Zestril), perindopril (Coversyl), quinapril (Accupril, Asig).
- Some medicines used to treat asthma such as salbutamol (Ventolin) or terbutaline (Bricanyl).
- diuretics, also called fluid tablets, such as amiloride (Midamor, Kaluril), bumetanide (Burinex), frusemide (Lasix, Uremide, Urex), hydrochlorothiazide (Dithiazide), spirinolactone (Aldactone, Spiractin).
- Chlorpromazine, a medicine used to treat schizophrenia and other mental illnesses
- NSAIDs (non-steroidal anti-inflammatory drugs), medicines used to relieve pain, swelling and other symptoms of inflammation, including arthritis such as aspirin (e.g. Disprin, Solprin), diclofenac (e.g. Voltaren, Fenac), ibuprofen (e.g. Actiprofen, Brufen, Rafen), meloxicam (Mobic), naproxen (e.g. Naprogesic, Naprosyn, Inza) and piroxicam (e.g. Feldene, Mobilis)
- medicines used to treat ulcers and reflux, such as cimetidine (e.g. Tagamet, Magicul)

- medicines used to prevent blood clots such as warfarin (e.g. Coumadin, Marevan)
- thyroid hormones, such as thyroxine (e.g. Oroxine, Eutroxsig)

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Diabex XR.

How to take Diabex XR

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist.

How much to take

Diabex XR comes in two strengths Diabex XR 500 (500 mg Tablets) and Diabex XR 1000 (1000 mg Tablets).

The dose varies from person to person. Your doctor will decide the right dose for you.

The usual starting dose is 1 tablet (500 mg) once daily with the evening meal. Your doctor may increase the dose slowly, depending on your blood glucose levels.

The maximum recommended dose is 2 grams once per day.

The elderly and people with kidney problems may need smaller doses.

How to take Diabex XR

Swallow the tablets whole with a glass of water.

Do not break, crush or chew the tablets.

If you break, crush or chew Diabex XR, they will not work as well. Diabex XR are extended release tablets. This means they have a special coating which allows the

active ingredient, metformin, to be released slowly over time.

When to take Diabex XR

Take your medicine everyday with the evening meal.

Taking Diabex XR during or with your evening meal will reduce the chance of a stomach upset.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take Diabex XR for

Keep taking Diabex XR for as long as your doctor recommends.

Diabex XR will help control diabetes but will not cure it. Most people will need to take Diabex XR for long periods of time.

When you start treatment with Diabex XR, it can take up to some weeks for your blood glucose levels to be properly controlled.

If you forget to take Diabex XR

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much Diabex XR (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Diabex XR. Do this even if there are no signs of discomfort or poisoning.

If you take too much Diabex XR, you may feel very tired, sick, vomit, have trouble breathing and have unusual muscle pain, stomach pain or diarrhoea. These may be early signs of a serious condition called lactic acidosis (build up of lactic acid in the blood).

You may also experience symptoms of hypoglycaemia (low blood glucose). This usually only happens if you take too much Diabex XR together with other medicines for diabetes or with alcohol.

If you do experience any signs of hypoglycaemia, raise your blood glucose quickly by eating jelly beans, sugar or honey, drinking a non-diet soft drink or taking glucose tablets.

While you are taking Diabex XR

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Diabex XR .

Tell all the other doctors, dentists and pharmacists who are treating you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor.

Tell your doctor if you plan to have:

- surgery with general anaesthesia
- any x-ray procedures requiring an injection of an iodinated contrast agent (dye).

Your doctor will advise you when to stop taking Diabex XR before you have these procedures and when to start again.

HYPOGLYCAEMIA

Diabex XR does not normally cause hypoglycaemia (low blood sugar), although you may experience it while

taking other medicines for diabetes such as insulin, sulfonylureas or glinide.

Make sure that you, your friends, family and work colleagues can recognise the symptoms of hypoglycaemia (low blood sugar) and know how to treat them.

Hypoglycaemia can occur suddenly. Initial signs may include:

- weakness, trembling or shaking
- sweating
- lightheadedness, dizziness, headache or lack of concentration
- irritability, tearfulness or crying
- hunger
- numbness around the lips and tongue.

If not treated promptly, these may progress to:

- loss of co-ordination
- slurred speech
- confusion
- fits or loss of consciousness.

If you experience any of the symptoms of hypoglycaemia, you need to raise your blood glucose immediately.

You can do this by doing one of the following:

- eating 5 to 7 jelly beans
- eating 3 teaspoons of sugar or honey
- drinking half a can of non-diet soft drink
- taking 2 to 3 concentrated glucose tablets.

Unless you are within 10 to 15 minutes of your next meal or snack, follow up with extra carbohydrates such as plain biscuits, fruit or milk.

Taking this extra carbohydrate will prevent a second drop in your blood glucose level.

HYPERGLYCAEMIA

If you experience any of the signs of hyperglycaemia (high blood

sugar), contact your doctor immediately.

The risk of hyperglycaemia is increased in the following situations:

- uncontrolled diabetes
- illness, infection or stress
- taking less Diabex XR than prescribed
- taking certain other medicines
- too little exercise
- eating more carbohydrates than normal.

Tell your doctor if any of the following happen:

- you become ill
- you become dehydrated (for instance due to persistent or severe diarrhoea or recurrent vomiting)
- you are injured
- you have a fever
- you have a serious infection such as an influenza, respiratory tract infection or urinary tract infection
- you are having major surgery
- you are having an examination such as an X-ray or a scan requiring an injection of an iodinated contrast agent (dye).
- you become pregnant.

Your blood glucose may become difficult to control at these times. You may also be more at risk of developing a serious condition called lactic acidosis. At these times, your doctor may replace Diabex XR with insulin.

Visit your doctor regularly for check ups.

Your doctor may want to check your kidneys, liver, heart and blood levels while you are taking Diabex XR.

Make sure you check your blood glucose levels regularly.

This is the best way to tell if your diabetes is being controlled properly. Your doctor or diabetes educator will show you how and when to do this.

Carefully follow the advice of your doctor and dietician on diet, drinking alcohol and exercise.

Things you must not do

Do not use Diabex XR to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not skip meals while taking Diabex XR.

Do not stop taking your medicine or change the dose without checking with your doctor.

Things to be careful of

If you have to be alert, for example when driving, be especially careful not to let your blood glucose levels fall too low.

Low blood glucose levels may slow your reaction time and affect your ability to drive or operate machinery. Drinking alcohol can make this worse. However, Diabex XR by itself is unlikely to affect how you drive or operate machinery.

Things to be aware of

After the active ingredient metformin is absorbed into your body, you may see the empty tablet shell in your faeces (bowel motions). This is normal and does not affect the way Diabex XR works.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Diabex XR.

Diabex XR helps most people with diabetes but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Tell your doctor if you notice any of the following and they worry you:

- stomach upset such as feeling sick (nausea), vomiting
- diarrhoea
- stomach pain
- taste disturbance, loss of appetite
- skin reactions such as redness of the skin, itching or an itchy rash (urticaria).

These are generally mild side effects which disappear after the first few weeks. Taking Diabex XR with meals can help reduce nausea and diarrhoea.

Tell your doctor as soon as possible if you notice any of the following:

Symptoms of liver disease such as nausea, vomiting, loss of appetite, feeling generally unwell, fever, yellowing of the skin and eyes (jaundice) and dark coloured urine

TELL YOUR DOCTOR IMMEDIATELY OR GO TO ACCIDENT AND EMERGENCY AT THE NEAREST HOSPITAL IF YOU NOTICE ANY OF THE FOLLOWING SYMPTOMS OF LACTIC ACIDOSIS (BUILD UP OF LACTIC ACID IN THE BLOOD):

- **nausea, vomiting, stomach pain**
- **trouble breathing**
- **feeling weak, tired or generally unwell**
- **unusual muscle pain**
- **sleepiness**
- **dizziness or lightheadedness**
- **shivering, feeling extremely cold**
- **slow heart beat.**

LACTIC ACIDOSIS IS A VERY RARE BUT SERIOUS SIDE

EFFECT REQUIRING URGENT MEDICAL ATTENTION OR HOSPITALISATION.

ALTHOUGH RARE, IF LACTIC ACIDOSIS DOES OCCUR, IT CAN BE FATAL. THE RISK OF LACTIC ACIDOSIS IS HIGHER IN THE ELDERLY, THOSE WHOSE DIABETES IS POORLY CONTROLLED, THOSE WITH PROLONGED FASTING, THOSE WITH CERTAIN HEART CONDITIONS, THOSE WHO DRINK ALCOHOL AND THOSE WITH SEVERE KIDNEY OR LIVER PROBLEMS.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell. It is very important that you speak to your doctor immediately if a side effect is severe, occurred suddenly or gets worse rapidly.

Other side effects not listed above may also occur in some people.

Some side effects (e.g. reduced vitamin B12 level) can only be found when your doctor does tests from time to time to check your progress.

After taking Diabex XR

Storage

Keep Diabex XR where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the blister pack they may not keep well.

Keep your Diabex XR tablets in a cool, dry place where the temperature stays below 25°C.

Do not store Diabex XR or any other medicine in the bathroom or near a sink.

Do not leave Diabex XR in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking this medicine, or your tablets have passed their expiry date, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Diabex XR comes in 2 strengths. Diabex XR 500 (500 mg Tablets) and Diabex XR 1000 (1000 mg Tablets).

- Diabex XR 500 is a white to off-white, capsule-shaped tablet, marked "500" on one side. It is available in blister packs of 90 and 120 tablets.
- Diabex XR 1000 is a white to off-white, capsule-shaped tablet, marked on one side with "SR1000". It is available in blister packs of 60 tablets.

Ingredients

The active ingredient in Diabex XR is metformin hydrochloride.

Each extended release tablet contains 500 mg of metformin hydrochloride.

The tablets also contain the following inactive ingredients:

- carmellose sodium
- hypromellose
- microcrystalline cellulose
- magnesium stearate.

The tablets do not contain sucrose, lactose, gluten, tartrazine or any other azo dyes.

Each extended release tablet contains 1000 mg of metformin hydrochloride.

The tablets also contain the following inactive ingredients:

- carmellose sodium
- hypromellose

- magnesium stearate.

The tablets do not contain sucrose, lactose, gluten, tartrazine or any other azo dyes.

Supplier

Diabex XR 500 and Diabex XR 1000 are supplied in Australia by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2

Cnr. Wentworth Park Road & Bay Street

Glebe NSW 2037

Phone: (02) 9298 3999

Medical Information

Phone: 1800 028 365

www.alphapharm.com.au

Australian registration numbers are:

Diabex XR 500 - AUST R 98982

Diabex XR 1000 - AUST R 153699

This leaflet was prepared on

26th February 2010

* Registered trade mark of

Merck Sante s.a.s.

RENITEC®

Enalapril maleate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about RENITEC. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking RENITEC against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What RENITEC is used for

RENITEC lowers high blood pressure, which doctors call hypertension. It is also used to treat heart failure.

Hypertension:

Everyone has blood pressure. This pressure helps get your blood all around your body. Your blood pressure may be different at different times of the day, depending on how busy or worried you are. You have hypertension (high blood pressure) when your blood pressure stays higher than is needed, even when you are calm and relaxed.

There are usually no symptoms of hypertension. The only way of knowing that you have hypertension is to have your blood pressure checked on a regular basis. If high

blood pressure is not treated it can lead to serious health problems. You may feel fine and have no symptoms, but eventually hypertension can cause stroke, heart disease and kidney failure. RENITEC helps to lower your blood pressure.

Heart Failure:

Heart failure means that the heart muscle cannot pump blood strongly enough to supply all the blood needed throughout the body. Heart failure is not the same as heart attack and does not mean that the heart stops working. Heart failure may start off with no symptoms, but as the condition progresses, patients may feel short of breath or may get tired easily after light physical activity such as walking. Some patients may wake up short of breath at night. Fluid may collect in different parts of the body, often first noticed as swollen ankles and feet.

RENITEC helps to treat heart failure, whether you have symptoms or not. In many patients with heart failure who have symptoms, RENITEC may slow the progression of heart failure and reduce the need to go to hospital as a result of heart failure. RENITEC may help some of these patients live longer.

In many patients with heart failure who have no symptoms, RENITEC may help to stop the heart muscle from getting weaker. RENITEC may also slow down the development of symptoms, such as shortness of breath, tiredness after light physical activity, or swelling of the ankles and feet. These patients may be less likely to have hospital stays due to heart failure.

By taking RENITEC, heart failure patients may have less chance of having a heart attack.

When used to treat heart failure, RENITEC is almost always used with other medicines called diuretics or fluid tablets. These medicines help the kidney get rid of excess fluid from the body.

How RENITEC works

One of the ways RENITEC helps lower blood pressure and treat heart failure is that it widens blood vessels. This means that blood is able to pass through them more easily and the heart doesn't have to pump as hard to move blood around the body. This also means that when you place extra demands on your heart, such as during exercise, the heart may cope better so you may not get short of breath as easily.

RENITEC belongs to a group of medicines called Angiotensin Converting Enzyme (ACE) inhibitors.

Your doctor may prescribe RENITEC for another reason. Ask your doctor if you have any questions about why RENITEC has been prescribed for you.

RENITEC is not addictive.

Before you take RENITEC

When you must not take it

Do not take RENITEC if:

- **you have taken any other 'ACE inhibitor' medicines for high blood pressure or heart failure**

before, which caused your face, lips, tongue, throat, hands or feet to swell up, or made it hard for you to breathe

If you have had an allergic reaction to an ACE inhibitor before, you may be allergic to RENITEC.

- **you have an allergy to RENITEC, Amprace® or other brands of enalapril maleate, or any of the ingredients listed at the end of this leaflet**

Symptoms of an allergic reaction to RENITEC or other brands of enalapril maleate may include skin rash, itchiness, shortness of breath, swelling of the face, lips or tongue, muscle pain or tenderness or joint pain.

- **you have a history of swelling of the face, lips, tongue, throat, hands or feet, for no apparent reason.**
- **you have diabetes and are taking a medicine called aliskiren to reduce blood pressure.**

Do not take RENITEC if you are pregnant or breast-feeding.

Your baby may absorb this medicine in the womb or from breast milk and therefore there is a possibility of harm to the baby.

Do not take RENITEC if:

- **the packaging is torn or shows signs of tampering**
- **the expiry date on the pack has passed.**

If you take this medicine after the expiry date has passed, it may not work.

If you are not sure whether you should start taking RENITEC, talk to your doctor.

Before you start to take it

Tell your doctor if:

1. **you are or intend to become pregnant or intend to breast-feed**

RENITEC should not be used during pregnancy or while breast-feeding.

2. **you have any medical conditions, especially the following:**
 - kidney disease, or are undergoing dialysis
 - diabetes
 - heart problems
3. **you have recently suffered from excessive vomiting or diarrhoea**
4. **you are following a very low salt diet**
5. **you have had an allergy to any other medicines or any other substances, such as foods, preservatives or dyes.**
6. **if you suffer from low blood pressure (you may notice this as faintness or dizziness, especially when standing).**
7. **surgery and anaesthesia (even at the dentist office) are scheduled, as there may be a sudden fall in blood pressure associated with anaesthesia.**

If you have not told your doctor about any of the above, tell them before you take any RENITEC.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. Some medicines and RENITEC may interfere with each other. These include:

- **other blood pressure medicines**
- diuretic tablets - also called fluid or water tablets
- lithium, a medicine used to treat mood swings and some types of depression
- potassium tablets
- potassium-containing salt substitutes

- potassium-sparing agents (e.g. spironolactone, eplerenone, triamterene, amiloride)
- non-steroidal anti-inflammatory medicines (NSAIDs or Coxibs/ COX-2 inhibitors), used to relieve pain, swelling and other symptoms of inflammation
- arthritis medicines including gold therapy
- insulin or oral antidiabetic medicines. You should be closely monitored for low blood glucose levels, especially during the first month of treatment with RENITEC.

These medicines may be affected by RENITEC, or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to avoid while taking RENITEC.

How to take RENITEC

How much to take

Your doctor will tell you how many tablets you need to take each day. This depends on your condition and whether you are taking other medicines. Take RENITEC only when prescribed by your doctor.

For high blood pressure:

For most patients, the usual starting dose is 5 mg taken once a day. Some patients may need a lower starting dose. The dose may need to be increased depending on your blood pressure. Most patients take between 10 to 40 mg each day.

For heart failure:

The usual starting dose is 2.5 mg taken once a day. Depending on your response, this dose may need to be increased up to 20 mg each day. This dose may be taken once a day or divided into two doses per day.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How to take it

Take your RENITEC at about the same time each day.

Taking your tablet(s) at the same time each day will have the best effect. It will also help you remember when to take the tablets.

It does not matter if you take RENITEC before or after food.

Swallow RENITEC with a glass of water.

How long to take it

RENITEC helps control your high blood pressure and helps improve your heart failure, but does not cure it. Therefore RENITEC must be taken every day. Continue taking RENITEC for as long as your doctor prescribes.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your tablet(s) as you would normally.

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

Do not take a double dose to make up for the dose that you missed.

If you have trouble remembering to take your tablets, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26), or go to accident and emergency at your

nearest hospital, if you think that you or anyone else may have taken too much RENITEC. Do this even if there are no signs of discomfort or poisoning.

If you take too many tablets, you will probably feel light-headed or dizzy, or you may faint.

While you are using RENITEC

Things you must do

Have your blood pressure checked when your doctor says, to make sure RENITEC is working.

If you feel any light-headedness or dizziness after you take your first dose of RENITEC or if your dose is increased, tell your doctor immediately. This is especially important if you are taking RENITEC for heart failure.

If you feel light-headed, dizzy or faint, get up slowly when getting out of bed or standing up.

You may feel light-headed or dizzy, especially if you are also taking a diuretic (fluid tablet). This may be because your blood pressure is falling suddenly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem gets worse or continues, talk to your doctor.

If you become pregnant while taking RENITEC, tell your doctor immediately.

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking RENITEC.

If you plan to have surgery (even at the dentist) that needs a general anaesthetic, tell your doctor or dentist that you are taking RENITEC.

Your blood pressure may drop suddenly.

Make sure you drink enough water during exercise and hot weather when you are taking RENITEC, especially if you sweat a lot.

If you do not drink enough water while taking RENITEC, you may faint or feel light-headed or sick. This is because your blood pressure is dropping suddenly. If you continue to feel unwell, tell your doctor.

If you have excessive vomiting and/or diarrhoea while taking RENITEC, tell your doctor.

This can also mean that you are losing too much water and salt, and may drop your blood pressure too much.

Go to your doctor regularly for a check-up.

Your doctor may occasionally do a blood test to check your potassium level in the blood and to see how your kidneys are working.

Things you must not do

Do not give RENITEC to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how RENITEC affects you.

RENITEC may cause dizziness or light-headedness in some people, especially after the first dose or if the dose is increased. Make sure you know how you react to RENITEC before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy or light-headed. If you drink alcohol, dizziness or light-headedness may be worse.

Things that would be helpful for your blood pressure or heart failure

Some self-help measures suggested below may help your condition. Talk to your doctor or pharmacist about these measures and for more information.

- **Alcohol -**

your doctor may advise you to limit your alcohol intake.

- **Diet -**

eat a healthy diet which includes plenty of fresh vegetables, fruit, bread, cereals and fish. Also eat less fat and sugar.

- **Exercise -**

regular exercise helps to reduce blood pressure and helps the heart get fitter, but it is important not to overdo it. Walking is good exercise, but try to find a route that is fairly flat. Before starting any exercise, ask your doctor about the best kind of programme for you.

- **Salt -**

your doctor may advise you to watch the amount of salt in your diet. To reduce your salt intake you should avoid using salt in cooking or at the table.

- **Smoking -**

your doctor may advise you to stop smoking or at least cut down.

- **Weight -**

your doctor may suggest losing some weight to help lower your blood pressure and help lessen the amount of work your heart has to do. Some people may need a dietician's help to lose weight.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking RENITEC.

RENITEC helps most people with high blood pressure and heart failure, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- light-headedness or dizziness because blood pressure is too low
- headache
- fatigue
- dry cough
- mild stomach upsets such as feeling sick, diarrhoea, or stomach pains
- muscle cramps

These are usually mild side effects of RENITEC, but may be serious.

Tell your doctor immediately if you notice any of the following:

- changes in the way your heart beats, for example, if you notice it beating faster
- fainting
- yellowing of the skin and eyes, also called jaundice
- itchy skin rash or other skin problems
- signs of worrying or frequent infections such as fever, severe chills, sore throat or mouth ulcers
- passing less urine than is normal for you
- signs of dehydration such as nausea, vomiting, muscle cramps, headache, drowsiness and tiredness. If untreated, mental confusion and fits may develop. Your doctor may need to monitor your blood sodium levels.

These may be serious side effects. You may need urgent medical attention.

Serious side effects are rare.

If any of the following happen, stop taking RENITEC and tell your doctor immediately or go to accident and emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat which may cause

difficulty in swallowing or breathing

- swelling of the hands, feet, or ankles
- pinkish, itchy swellings on the skin, also called hives or nettle rash
- chest pain, angina
- wheeziness due to tightness in the chest
- collapse, numbness or weakness of arms or legs

These are serious side effects. You may need urgent medical attention or hospitalisation.

All of these side effects are rare.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using RENITEC

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the blister pack and store them in another container they will not keep well and they may become soft and crumbly.

RENITEC Tablets should be kept in a cool dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking RENITEC or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

RENITEC comes in three types of tablets:

- RENITEC M - white, barrel-shaped tablet with RENITEC marked on one side and scored on the other side.
- RENITEC - rust-red, barrel-shaped tablet with RENITEC marked on one side and scored on the other side.
- RENITEC 20 - peach coloured, barrel-shaped tablet with MSD714 marked on one side.

A box of RENITEC contains 30 tablets.

Ingredients

Active ingredient:

- RENITEC M - 5 mg enalapril maleate per tablet
- RENITEC - 10 mg enalapril maleate per tablet
- RENITEC 20 - 20 mg enalapril maleate per tablet

Inactive ingredients:

- lactose
- sodium bicarbonate
- maize starch
- pregelatinised maize starch
- magnesium stearate
- iron oxide red CI77491 (RENITEC 10 mg and RENITEC 20 mg)
- iron oxide yellow CI77492 (RENITEC 20 mg)

RENITEC does not contain gluten, sucrose, tartrazine or any other azo dyes.

Manufacturer/Supplier

RENITEC is supplied in Australia by:

Merck Sharp & Dohme (Australia) Pty Limited

Level 1 Building A, 26 Talavera Road, Macquarie Park NSW 2113

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Australian Register Numbers:

RENITEC M - AUST R 10514

RENITEC - AUST R 10521

RENITEC 20 - AUST R 10515

RNT-042008

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