NEW ZEALAND CONSUMER MEDICINE INFORMATION

DURIDE

Isosorbide mononitrate Modified Release Tablet 60 mg



What is in this leaflet

Please read this leaflet carefully before you start taking Duride.

This leaflet answers some common questions about Duride.

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 Duride 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 Duride is used for

Duride is used to prevent angina.

Angina is a pain or uncomfortable feeling (tightness, pressure or heaviness) 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.

Duride contains the active ingredient Isosorbide mononitrate. It belongs to a group of medicines called nitrates. These medicines work by widening blood vessels, letting more blood and oxygen reach the heart. This means your heart does not need to do as much work.

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

Your doctor may have prescribed it for another reason.

Duride is not recommended for use in children, as there is not enough information available on its effects in children.

There is no evidence that Duride is addictive.

This medicine is available only with a doctor's prescription.

Before you take Duride

When you must not take it

Do not take Duride if you have an allergy to:

- any medicine containing isosorbide mononitrate or other nitrate medicines
- any of the ingredients listed at the end of this leaflet.

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 Duride if you are taking medicines used to treat erectile dysfunction, namely; sildenafil (Viagra/Avigra/Vedafil), tadalafil (Cialis) and vardenafil (Levitra).

Do not take Duride if you:

- have very low blood pressure
- shock including those caused by low blood pressure or failing
- heart

- have a condition that has caused swelling of the lining that surrounds the heart (pericarditis)
- have weakened muscle of the heart

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,

Before you start to take

talk to your doctor.

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

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

- heart or blood vessel problems (including thickening or hardening of blood vessels walls in the brain)low blood pressure (this can make you feel faint, weak or dizzy, especially when you stand up suddenly)
- kidney problems
- liver problems.

Duride should not be taken to relieve a sudden attack of angina. Duride is only for the prevention of angina.

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

Your doctor will discuss the risks and benefits of taking Duride during pregnancy. Duride may affect your developing baby if you take it during pregnancy.

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

Your doctor will discuss the risks and benefits of taking Duride when breastfeeding. It is not known whether Duride can pass into breast milk, therefore it is not recommended if you are breastfeeding

Tell your doctor if you are or have been an industrial worker.

You may have had long-term exposure to organic nitrates, which may affect how your body responds to Duride.

Tell your doctor if you are lactose intolerant.

This medicine contains lactose.

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

Taking other medicines

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

You should also tell any health professional who is prescribing a new medication for you that you are taking Duride.

Some medicines may interfere with Duride. These include:

- medicines used to treat high blood pressure and heart conditions, such as calcium channel blockers and propranolol
- erectile dysfunction in men, e.g. sildenafil (Viagra Avigra/ Vedafil), tadalafil (Cialis) and vardenafil (Levitra).

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

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

How to take Duride

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 box, ask your doctor or pharmacist for help.

How much to take

The usual dose is one tablet once a day. Some patients may need a different dose. Your doctor will decide the right dose for you.

How to take it

Swallow Duride tablets whole with half a glass of water.

Duride tablets can be broken in half if your doctor has prescribed half a tablet.

Do not crush or chew the tablets. Duride tablets are modified release. This means the medicine is released into the blood over an extended period of time. If you crush or chew Duride tablets, they will not work as well.

When to take it

Take Duride in the morning at about the same time each day.

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

If your doctor tells you to take two tablets each day, take both tablets at the same time in the morning.

Taking Duride at 24 hour intervals helps to keep them working properly.

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

How long to take it

Continue taking your medicine for as long as your doctor tells

you.

This medicine helps to control your angina, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take it

If it is more than 8 hours since you should have taken your dose, do not take the missed dose - wait until the right time the next day to take your next dose.

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 that you missed.

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

If you miss a dose of Duride, you may get attacks of angina and need to use the tablets or spray your doctor has given you for relieving angina attacks.

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.

While you are taking Duride

Things you must do

Tell your doctor if you continue to have angina attacks, or if they become more frequent while you are taking Duride

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

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

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

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

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not use Duride to relieve an attack of angina.

Duride is used to prevent angina. Your doctor will have given you other tablets or a spray to use if you have an attack of angina.

Do not take medicines used to treat erectile dysfunction in men, such as: sildenafil (Viagra/Avigra/Vedafil), tadalafil (Cialis) and vardenafil (Levitra) if you are taking Duride

Taking these medicines together with Duride may cause your blood pressure to drop to a dangerously low level. This may lead to fainting or even a heart attack.

Do not stop taking Duride, or change the dose, without checking with your doctor. Do not let yourself run out of tablets over the weekend or on holidays. Stopping Duride suddenly may worsen your angina.

Do not take Duride 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 Duride affects you.

This medicine may cause dizziness, light-headedness or fainting in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine.. If you drink alcohol, dizziness, tiredness, lightheadedness or fainting may be worse.

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

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 continues or gets worse, talk to your doctor.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Duride. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include a throbbing headache, a fast heartbeat, feeling dizzy or faint. You may feel excited, flushed, have cold sweats, feel sick or vomit.

Side effects

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

This medicine helps most people with angina 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 or pharmacist if you notice any of the following and they worry you:

- headache
- dizziness, light-headedness or feeling faint
- nausea
- vomiting
- poor appetite
- heartburn
- diarrhoea
- tiredness or sleep disturbances

Headache is the most common side effect with Duride. It can happen when you start treatment but usually goes away in a few days.

The above list includes the more common side effects of your medicine. They are usually mild.

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

- rapid or fast heart beat
- low blood pressure
- muscle tenderness or weakness not caused by exercise

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

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- skin rash, itching or hives on the skin
- swelling of the face, lips, tongue or other part of the body
- shortness of breath, wheezing or trouble breathing

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

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 people. 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 taking Duride

Be aware that the outer shell of Duride tablets passes through the body. This does not affect the way it works.

Duride tablets are made of a waxlike shell which does not dissolve in the body. After the active ingredient, isosorbide mononitrate, has been absorbed into the body, you may see this empty tablet shell in your faeces (bowel motions).

Storage

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 at or below 30°C.

Do not store Duride or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

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

Product description

What it looks like

Duride is a yellow, oval tablet, scored and marked IM | 60 on one side.

Ingredients

Active ingredient(s):

Duride contains 60 mg of isosorbide mononitrate as the active ingredient.

<u>Inactive ingredient(s):</u> Duride also contains:

- microcrystalline cellulose
- aluminium silicate
- magnesium stearate
- colloidal silicon dioxide
- paraffin wax blend
- hypromellose
- titanium dioxide
- · lactose monohydrate
- polyethylene glycol
- iron oxide yellow
- iron oxide black
- iron oxide red.

Contains lactose and sulfites.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Duride is supplied in New Zealand by:

Viatris Ltd,
PO Box 11-183,
Ellerslie,
Auckland
www.viatris.co.nz
Telephone 0800 168 169

Date of Preparation

27 June 2022 (Based on datasheet dated 27 June 2022)