

DURIDE

isosorbide mononitrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about DURIDE. 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 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, talk to your doctor or pharmacist.

Keep this leaflet with your 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 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 your heart. The pain of angina is usually brought on by exercise or stress.

This medicine belongs to a group of medicines called nitrates. These medicines work by widening blood vessels, letting more blood and oxygen reach the heart.

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.

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

This medicine is not addictive.

There is not enough information to recommend the use of this medicine for children.

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
- 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 impotence, including sildenafil (Viagra), tadalafil (Cialis) and vardenafil (Levitra).

Do not take DURIDE if you have:

- low blood pressure
- experienced shock, including it being caused by low blood pressure or heart failure
- swelling of the lining that surrounds the heart (pericarditis)
- a weakened heart muscle

Do not take DURIDE to relieve acute angina.

This medicine should only be used for the prevention of angina.

Do not take this medicine if you are pregnant.

It may affect your developing baby if taken during pregnancy.

Do not breast-feed if you are taking this medicine unless your doctor says it is safe.

It is not known whether DURIDE is passed into breast milk, therefore it is not recommended if you are breastfeeding.

Do not give this medicine to children.

Safety and effectiveness in children have not been established.

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, foods, preservatives or dyes.

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

- liver problems
- kidney problems
- low blood pressure (this can make you feel faint, weak or dizzy, especially when you stand up suddenly)
- heart or blood vessel disease

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

Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are or have been an industrial worker, as you may have had long-term exposure to organic nitrates, which may affect how your body responds to DURIDE.

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 any that you get without a prescription from your pharmacy, supermarket or health food shop.

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

- medicines used to treat high blood pressure and heart conditions, such as calcium antagonists
- medicines used to treat liver disease, such as propranolol
- medicines used to treat impotence in men, such as sildenafil (Viagra), 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.

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 and 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 the tablets whole with half a glass of water.

DURIDE tablets can be broken in half if care is taken not to crumble them. Break the tablet in half with care if your doctor has prescribed half a tablet.

Do not crush or chew the tablets.

DURIDE tablets are modified release tablets. This means that the medicine is released into the blood over an extended

period of time. If you crush or chew the tablets, they will not work as well.

When to take it

Take your medicine at about the same time each day.

Taking it 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 this medicine before or after food.

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

How long to take it for

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, 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 miss a dose of DURIDE, you may get attacks of angina.

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 of it (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 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.

If you take too much DURIDE, you may experience a headache, a fast heart beat and feel dizzy or faint. You may feel excited, flushed, have cold sweats, feel sick or vomit.

While you are using DURIDE

Things you must do

If you are about to be started on any new medicine, remind 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 become pregnant while taking this medicine, tell your doctor immediately.

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

If you continue to have angina attacks, or if they become frequent while you are taking DURIDE tell your doctor.

Things you must not do

Do not use DURIDE to relieve acute attacks of angina.

This medicine is used to prevent angina. Your doctor will have given you other medicines to use if you have an angina attack.

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.

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

If you stop taking it suddenly, your angina may worsen, or you may have unwanted side effects.

Things to be careful of

You will probably feel better when you start to take DURIDE but be careful not to overdo physical activities straight away.

You will need time to improve your physical fitness.

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 any have any of these symptoms, do not drive, operate machinery or do anything that could be dangerous.

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.

Be careful when drinking alcohol while taking DURIDE.

Combining DURIDE and alcohol can make you more sleepy, dizzy or lightheaded, due to a drop in your blood pressure.

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

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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
- feeling sick (nausea)
- rapid heart beat
- poor appetite
- vomiting
- heartburn
- diarrhoea
- rash, itching
- muscle tenderness or weakness not caused by exercise

- tiredness or sleep disturbances

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.

After using DURIDE

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

DURIDE tablets are made of a wax-like 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 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-and-a-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 shaped tablet, scored and marked IM|60 on one side

Each pack contains 30 tablets.

Ingredients

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

The tablets also contain the following inactive ingredients:

- colloidal anhydrous silica
- heavy kaolin
- magnesium stearate
- microcrystalline cellulose

- hard paraffin
- synthetic paraffin
- Opadry Yellow OY-LS-22814 (includes colours iron oxide red CI 77491, iron oxide black CI 77499, iron oxide yellow CI 77492, titanium dioxide CI 77891)

DURIDE contains lactose and sulfites. The tablets are gluten free.

Supplier

Alphapharm Pty Limited

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30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian registration number:

AUST R 60907

This leaflet was prepared in

May 2021.

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