

Duride

contains the active ingredient 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 benefits and risks. 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 the heart. The pain of angina is usually brought on by exercise or stress.

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

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

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

Duride is available only with a doctor's prescription.

There is no evidence that Duride is addictive.

Before you take Duride

When you must not take it

Do not take Duride if you are taking medicines used to treat impotence, namely; sildenafil (Viagra), tadalafil (Cialis) and vardenafil (Levitra).

Do not take Duride if you are allergic to medicines containing isosorbide mononitrate or any other nitrate medicine, or 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 Duride if you have:

- * extremely low blood pressure
- * swelling of the lining that surrounds the heart (pericarditis)
- * weakened muscle of the heart.

Do not take Duride to relieve a sudden attack of angina.

Duride is only for the prevention of angina.

Do not take Duride if you are pregnant or are breastfeeding unless your doctor says it is safe. Ask your doctor about the risks and benefits involved.

It is not known whether Duride is safe for you to take while you are pregnant. It may affect your baby. It is not known whether Duride can be passed into breast milk, therefore it is not recommended if you are breastfeeding.

Do not give Duride to children.

There is no specific information about use in children, so Duride is not recommended for use in children.

Do not take Duride if the expiry date (Exp.) printed on the pack has passed.

Do not take Duride if the packaging shows signs of tampering or the tablets do not look quite right.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

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. The safety of Duride in pregnancy has not been established.

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

The use of Duride in women who are breastfeeding is not recommended. Your doctor will discuss the risks and benefits of taking Duride when breastfeeding.

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.

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

- * liver problems
- * kidney problems
- * low blood pressure
- * heart or blood vessel disease.

Your doctor may want to take special care if you have any of these conditions.

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 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 may be affected by Duride, or may affect how well it works. These include:

- * any medicines that you buy with or without a prescription from a pharmacy, supermarket or health food shop
- * medicines used to treat high blood pressure and heart conditions, such as calcium antagonists.
- * medicines used to treat liver disease, namely, propranolol.
- * medicines used to treat impotence in men, eg. sildenafil (Viagra), tadalafil (Cialis) and vardenafil (Levitra),

Your doctor can tell you what to do if you are taking any of these 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 Duride.

How to take Duride

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.

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

How to take Duride

Swallow the 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 sustained 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 Duride

Duride can be taken with or without food.

Take your tablets at about the same time each day.

This helps them to control your angina properly.

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

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

If you forget to take Duride

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 the missed dose as soon as you remember, and then go back to taking your tablets 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 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 any questions about this, check with your doctor or pharmacist.

How long to take Duride for

To prevent angina, Duride must be taken every day.

Keep taking Duride for as long as your doctor recommends.

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

If you take too much Duride (overdose)

Immediately telephone your doctor, or the 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 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 have a throbbing 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 taking Duride

Things you must do

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

Before starting any new medicine, tell your doctor or pharmacist that you are taking Duride.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Duride.

If you become pregnant while taking Duride, tell your doctor.

Visit your doctor regularly so they can check on your progress.

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 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 use Duride to treat any other conditions unless your doctor tells you to.

Do not take medicines used to treat impotence in men, such as: sildenafil (Viagra), tadalafil (Cialis) and vardenafil (Levitra) if you are taking Duride.

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

Do not give Duride 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.

Duride may cause dizziness, lightheadedness or fainting in some people. If any of these occur, do not drive, operate machinery or do anything that could be dangerous.

Be careful getting up from a sitting or lying position.

Dizziness, lightheadedness or fainting may occur, especially when you get up quickly. Getting up slowly may help.

Be careful when drinking alcohol while taking Duride.

Combining Duride and alcohol can make you more sleepy, dizzy or lightheaded.

Side effects

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

Duride 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 treatment if you get some of the side effects.

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

You may not experience any of them.

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:

- * headache
- * dizziness, lightheadedness 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.

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

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

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 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 Duride 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 their 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 Duride or any other medicine in the bathroom or near a sink.

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

Heat and dampness can destroy some medicines.

Disposal

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

Medical Information

Phone: 1800 028 365

Australian registration number:

Aust R 60907.

This leaflet was prepared on:

8 August 2005.

Product description

What it looks like

Duride is a yellow, oval tablet, scored and marked IM60 on one side

Each pack contains 30 tablets.

Ingredients

The active ingredient in Duride is isosorbide mononitrate. Each Duride tablet contains 60 mg of isosorbide mononitrate.

The tablets also contain:

- * 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).

The tablets are gluten free.

Supplier

Duride is supplied by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

Phone: (02) 9298 3999