# MONODUR® DURULES®

## Modified release tablets

*Isosorbide mononitrate*

**Consumer Medicine Information**

## What is in this leaflet

This leaflet answers some of the common questions people ask about MONODUR DURULES. It does not contain all the information that is known about MONODUR DURULES.

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 MONODUR DURULES 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 MONODUR DURULES are for

MONODUR DURULES are used to prevent angina. Angina is a pain or uncomfortable feeling in the chest, often spreading to the arms or the neck and sometimes to the shoulders and back. This is caused by too little blood and oxygen getting to the heart.

The pain of angina is usually brought on by exercise or stress.

MONODUR DURULES belong to a group of medicines called nitrates.

MONODUR DURULES work by relaxing the blood vessels, letting more blood and oxygen reach the heart.

Your doctor will have explained why you are being treated with MONODUR DURULES and told you what dose to take.

**Follow all directions given to you by your doctor carefully.**
They may differ from the information contained in this leaflet.

However, your doctor may prescribe this medicine for another use. Ask your doctor if you want more information.

MONODUR DURULES are not addictive.

## Before you use MONODUR DURULES

### *When you must not use it*

**Do not use MONODUR DURULES if you are allergic to it or food containing nitrates or nitrites or any ingredients listed at the end of the leaflet.**

**Do not use MONODUR DURULES if you have any of the following medical conditions:**

- Low blood pressure
- Shock including those caused by low blood pressure or failing heart
- Pericarditis (swelling around the heart)
- Weakened muscle of the heart

**You must not use MONODUR DURULES whilst taking sildenafil (Viagra*), vardenafil (Levitra=), tadalafil (Cialis+).**

**Do not use MONODUR DURULES if you are pregnant or breast feeding unless your doctor says it is safe. Ask your doctor about the risks and benefits involved.**
We do not know if it is safe for you to take it while you are pregnant. It may affect your baby.

It is not known if your baby can take in MONODUR DURULES from breast milk if you are breast feeding.

**Do not give MONODUR DURULES to children.**
There is no specific information about use in children, so MONODUR DURULES is not recommended for use in children. Always ask your doctor before giving medicines to children.

**Do not use after the use by (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 take this medicine, talk to your doctor.**

### *Before you start to use it*

**You must tell your doctor if:**

1. **you have any allergies to:**

- any medicine, foods, preservatives or dyes.

  If you have an allergic reaction you may get a skin rash, hayfever, asthma or feel faint.

2. **you have any of these medical conditions:**

- any illness affecting your liver or kidneys
- low blood pressure (this can make you feel faint, weak or

dizzy, especially when you stand up suddenly)
- heart and blood vessel problems

It may not be safe for you to take MONODUR DURULES if you have any of these conditions.

**Do not use MONODUR DURULES to treat acute angina.**

**MONODUR DURULES must be taken once daily.**

**Do not stop taking it abruptly.**

### *Taking other medicines*

**Tell your doctor if you are taking any other medicines, including**

- sildenafil (Viagra*), vardenafil (Levitra=), tadalafil (Cialis+)
- medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

These medicines may affect the way MONODUR DURULES work.

Your doctor or pharmacist can tell you what to do if you are taking any other medicines.

**If you have not told your doctor about any of these things, tell them before you take any MONODUR DURULES.**

## Using MONODUR DURULES

### *How to take it*

**Take one MONODUR DURULE modified release tablet every day, at about the same time.**

**If your doctor tells you to take two 60mg MONODUR DURULES each day, take both tablets at the same time.**
Taking MONODUR DURULES at 24 hour intervals makes sure they keep working properly.

**Swallow MONODUR DURULES modified release tablets whole, with half a glass of water or other liquid e.g. fruit juice, milk. Do not chew or crush the tablets.**

**The 60mg tablet can be broken in half if care is taken not to crumble them.**
MONODUR DURULES modified release tablets are designed to let the drug out over a number of hours. If they are crushed or chewed they won't work properly.

MONODUR DURULES modified release tablets are composed of a waxy substance that does not dissolve in the body. You may find the outer shell of the tablets in your bowel motions. The medication in them has already been absorbed by the body.

### *If you forget to take it*

**If you forget to take a dose, take it as soon as you remember, as long as it is not more than 8 hours late.**
If it is more than eight hours after you should have taken MONODUR DURULES, wait until the right time the next day to take it.

**Do not double the dose.**

You may find that you will need to use the tablets or spray that your doctor has given you to use during angina attacks if you miss a dose of MONODUR DURULES.

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

### *Overdose*

**Telephone your doctor or the Poisons Information Centre (13 11 26), or go to casualty at your nearest hospital immediately if you think that you or anyone else may have taken too much MONODUR DURULES even if there are no signs of discomfort or poisoning.**

If you take too many MONODUR DURULES modified release tablets you will have a pulsing headache. You may also feel excited, flushed, have cold sweats, nausea (feeling sick) and vomit.

## While you are using MONODUR DURULES

### *Things you must do*

**You must take MONODUR DURULES regularly once every day.**
If you don't you will be more likely to get attacks of angina.

Tell your doctor if you continue to get angina attacks, or they become more frequent, while you are taking MONODUR DURULES.

### *Things you must not do*

**You must not use MONODUR DURULES to relieve acute attacks of angina.**

Your doctor will have given you other tablets or a spray to use when you get attacks of angina.

**Do not take medicines known as phosphodiesterase type 5 inhibitor used to treat impotence (or erectile dysfunction) whilst on MONODUR DURULES.**

**Do not stop taking MONODUR DURULES unless you have discussed it with your doctor.**

**Do not use MONODUR DURULES for 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*

**You will probably feel better when you start taking MONODUR DURULES, 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 MONODUR DURULES affects you.**
MONODUR DURULES may cause dizziness and fainting in some patients, especially when you first start to take it. Make sure you know how you feel when you are taking

MONODUR DURULES before you drive a car, operate machinery, or do anything else that could be dangerous if you are dizzy.

**Be careful when drinking alcohol while you are using MONODUR DURULES.**
If you drink alcohol while you are taking MONODUR DURULES, your blood pressure may drop, making you feel dizzy or faint.

Please talk to your doctor or pharmacist about these possibilities if you think they may bother you.

## Side effects

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

MONODUR DURULES 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 if you notice any of the following and they worry you:**

- headache
- feeling faint
- dizziness
- fatigue
- muscle tenderness or weakness, not caused by exercise.

Headache is the most common side effect while taking MONODUR DURULES. It can occur at the beginning of treatment, but usually goes away after a few days.

These are all mild side effects of MONODUR DURULES.

**Tell your doctor if you notice anything else that is making you feel unwell.**
Some people may get other side effects while taking MONODUR DURULES.

## After using it

### *Storage*

**Keep your MONODUR DURULES modified release tablets in the blister pack until it is time to take them.**
If you take MONODUR DURULES out of the blister pack it will not keep well.

**Keep it in a cool dry place where the temperature stays below 30 degrees C.**

**Do not store it 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 young 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*

**Ask your pharmacist what to do with any tablets you have left over if your doctor tells you to stop taking them, or you find that they have expired.**

## Product description

**What MONODUR DURULES look like**

MONODUR DURULES 60mg modified release tablets are yellow, oval tablets, scored on both sides, marked A/ID.

MONODUR DURULES 120mg modified release tablets are whitish, oval tablets marked A/IF.

### *Ingredients*

**Each MONODUR DURULE modified release tablet contains:**

Isosorbide mononitrate 60mg or 120mg as the active ingredient;

plus,

Aluminium silicate

Paraffin special

Magnesium stearate

Hydroxypropylcellulose

Colloidal silica.

in blister packs of 30 modified release tablets.

The coating on each modified release tablet contains hydroxypropylmethylcellulose (E464), propylene glycol (E1520); with colouring agents,

titanium dioxide (E171)

iron oxide yellow (E172).

## Sponsor

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120mg 64284

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