

MONODUR®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using MONODUR®?

MONODUR contains the active ingredient isosorbide mononitrate. MONODUR is used to prevent angina.

For more information, see Section [1. Why am I using MONODUR?](#) in the full CMI.

2. What should I know before I use MONODUR®?

Do not use if you have ever had an allergic reaction to MONODUR or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use MONODUR?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with MONODUR and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use MONODUR®?

- Take one MONODUR modified release tablet every day, at about the same time.
- If your doctor tells you to take two 60mg MONODUR modified release tablets each day, take both tablets at the same time.

More instructions can be found in Section [4. How do I use MONODUR?](#) in the full CMI.

5. What should I know while using MONODUR®?

Things you should do	<ul style="list-style-type: none">• Take MONODUR modified release tablets regularly once every day• Remind any doctor, dentist or pharmacist visit that you are using MONODUR.
-----------------------------	---

<p>Things you should not do</p>	<ul style="list-style-type: none"> ● Do not stop using this medicine suddenly ● Do not use MONODUR modified release tablets to relieve acute attacks of angina.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> ● Be careful driving or operating machinery until you know how MONODUR affects you. ● MONODUR may cause dizziness and fainting in some patients
<p>Drinking alcohol</p>	<ul style="list-style-type: none"> ● Be careful when drinking alcohol while you are using MONODUR ● If you drink alcohol while you are taking MONODUR, you may feel dizzy or faint.
<p>Looking after your medicine</p>	<ul style="list-style-type: none"> ● Keep it in a cool dry place where the temperature stays below 30°C. ● Keep your MONODUR modified release tablets in the blister pack until it is time to take them

For more information, see Section [5. What should I know while using MONODUR?](#) in the full CMI.

6. Are there any side effects?

Headache is the most common side effect while taking MONODUR. You may also experience feeling faint, dizziness, fatigue, and muscle tenderness or weakness.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

MONODUR®

Active ingredient(s): Isosorbide mononitrate

Consumer Medicine Information (CMI)

This leaflet provides important information about using MONODUR. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using MONODUR.**

Where to find information in this leaflet:

- [1. Why am I using MONODUR®?](#)
- [2. What should I know before I use MONODUR®?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use MONODUR®?](#)
- [5. What should I know while using MONODUR®?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using MONODUR®?

MONODUR contains the active ingredient Isosorbide mononitrate. MONODUR is belongs to a group of medicines called nitrates.

MONODUR is 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 works 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 and told you what dose to take.

2. What should I know before I use MONODUR®?

Warnings

Do not use MONODUR if:

- You are allergic to isosorbide mononitrate or food containing nitrates or nitrites or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- You have one of the following 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 are taking sildenafil (Viagra), vardenafil (Levitra), tadalafil (Cialis).

Check with your doctor if 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.
- 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 if you have any of these conditions.

Do not use MONODUR to treat acute angina.

MONODUR modified release tablets must be taken once daily.

Do not stop taking it abruptly.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not use MONODUR if you are pregnant or breast feeding unless your doctor says it is safe.

Check with your doctor if you are pregnant or intend to become pregnant.

It is not know if it is safe for you to take it while you are pregnant. It may affect your baby.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

Ask your doctor about the risks and benefits involved.

Use in children

Do not give MONODUR to children.

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

3. What if I am taking other medicines?

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

Some medicines may interfere with MONODUR and affect how it works.

- Phosphodiesterase inhibitors such as sildenafil (Viagra*), vardenafil (Levitra=), tadalafil (Cialis+) can result in serious side-effects such as syncope or myocardial infarction
- Calcium antagonists, which can cause orthostatic hypotension

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MONODUR.

4. How do I use MONODUR®?

How much to take

- Take one MONODUR modified release tablet every day, at about the same time.
- If your doctor tells you to take two 60mg MONODUR modified release tablets each day, take both tablets at the same time.
- Taking MONODUR modified release tablets at 24-hour intervals makes sure they keep working properly.
- Swallow MONODUR 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 modified release tablet can be broken in half if care is taken not to crumble them.

- MONODUR 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 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
- Follow the instructions provided and use MONODUR until your doctor tells you to stop.

If you forget to take MONODUR

If you forget to take a dose, take it as soon as you remember, as long as it is not more than eight (8) hours late.

If it is more than eight (8) hours after you should have taken MONODUR, 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.

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

If you take too much MONODUR

If you think that you have taken too much MONODUR, you may need urgent medical attention.

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

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using MONODUR®?

Things you should do

Take MONODUR regularly once every day.

If you don't you will be more likely to get attacks of angina.

Call your doctor straight away if you:

- Continue to get angina attacks, or they become more frequent, while you are taking MONODUR.

Remind any doctor, dentist or pharmacist you visit that you are using MONODUR.

Things you should not do

- Do not use MONODUR 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.
- Do not stop taking MONODUR unless you have discussed it with your doctor.
- Do not use MONODUR 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 but be careful not to overdo physical activities straight away.

You will need time to improve your physical fitness.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how MONODUR affects you.

MONODUR 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 before you drive a car, operate machinery,

or do anything else that could be dangerous if you are dizzy.

Drinking alcohol

Tell your doctor if you drink alcohol.

If you drink alcohol while you are taking MONODUR, 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.

Looking after your medicine

- Keep your MONODUR modified release tablets in the blister pack until it is time to take them.
- If you take MONODUR out of the blister pack it will not keep well.
- Keep it in a cool dry place where the temperature stays below 30°C.
- Keep it where young children cannot reach it.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Side effects

Side effects	What to do
Heart related <ul style="list-style-type: none">• Hypotension• Tachycardia Head and body related <ul style="list-style-type: none">• Headache• Vertigo• Fainting• Fatigue	Speak to your doctor if you have any of these side effects and they worry you.

Side effects	What to do
<ul style="list-style-type: none"> ● Muscle tenderness or weakness, not caused by exercise. <p>Stomach related</p> <ul style="list-style-type: none"> ● Poor appetite ● Nausea ● Vomiting ● Diarrhoea ● Heartburn <p>Skin related</p> <ul style="list-style-type: none"> ● Rash ● Pruritus 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What MONODUR contains

Active ingredient (main ingredient)	Isosorbide mononitrate 60mg or 120mg
Other ingredients (inactive ingredients)	Aluminium sodium silicate Synthetic paraffin Magnesium stearate Hyprolose Hypromellose Colloidal anhydrous silica Macrogol 6000 Titanium dioxide Iron oxide yellow (60 mg only)

Do not take this medicine if you are allergic to any of these ingredients.

What MONODUR looks like

MONODUR 60mg modified release tablets (AUST-R 59600) are yellow, oval tablets, scored on both sides, marked A/ID.

MONODUR 120mg modified release tablets (AUST-R 64284) are whitish, oval tablets marked A/IF

Who distributes MONODUR

Clinect Pty Ltd,
120-132 Atlantic Drive,
Keysborough, VIC 3173,
Australia

Free Call Australia: 1800 899 005

This leaflet was prepared 10 June 2022