

APO-ISOSORBIDE MONONITRATE

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 APO-ISOSORBIDE MONONITRATE ?

APO-ISOSORBIDE MONONITRATE contains the active ingredient Isosorbide mononitrate. APO-ISOSORBIDE MONONITRATE is used to prevent angina pectoris (heart pain). It is not recommended and should not be taken for the treatment of acute attacks.

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

2. What should I know before I use APO-ISOSORBIDE MONONITRATE ?

Do not use if you have ever had an allergic reaction to APO-ISOSORBIDE MONONITRATE 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 APO-ISOSORBIDE MONONITRATE ?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-ISOSORBIDE MONONITRATE 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 APO-ISOSORBIDE MONONITRATE ?

- Your Doctor will advise you on how many tablets to take each day.

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

5. What should I know while using APO-ISOSORBIDE MONONITRATE ?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using APO-ISOSORBIDE MONONITRATE .• Tell your doctor if you continue to have angina attacks or if they become more frequent while you are using APO-ISOSORBIDE MONONITRATE
Things you should not do	<ul style="list-style-type: none">• Do not use it to treat any other complaints unless your doctor says to.• Do not give this medicine to anyone else, even if their symptoms seem similar to yours
Driving or using machines	<ul style="list-style-type: none">• Be careful driving or operating machinery until you know how APO-ISOSORBIDE MONONITRATE affects you. This medicine may cause tiredness, dizziness or light-headedness in some people.
Drinking alcohol	<ul style="list-style-type: none">• Be careful when drinking alcohol while using APO-ISOSORBIDE MONONITRATE• If you drink alcohol while using APO-ISOSORBIDE MONONITRATE , your blood pressure may drop, making you feel dizzy or faint.
Looking after your medicine	<ul style="list-style-type: none">• Store below 25°C.• Store in a cool, dry place away from young children.

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

6. Are there any side effects?

Possible side effects include headache (most common), dizziness ,nausea tiredness and disturbed sleep.

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.

APO-ISOSORBIDE MONONITRATE

Active ingredient(s): *Isosorbide mononitrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-ISOSORBIDE MONONITRATE. **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 APO-ISOSORBIDE MONONITRATE.**

Where to find information in this leaflet:

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

1. Why am I using APO-ISOSORBIDE MONONITRATE ?

APO-ISOSORBIDE MONONITRATE contains the active ingredient Isosorbide mononitrate. APO-ISOSORBIDE MONONITRATE belongs to a group of medicines called nitrates. It works by widening blood vessels to improve the blood flow around the heart which means there is more oxygen being carried by the blood. This reduces the pain associated with angina.

APO-ISOSORBIDE MONONITRATE is used to prevent angina pectoris (heart pain).

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.

2. What should I know before I use APO-ISOSORBIDE MONONITRATE ?

Warnings

Do not use APO-ISOSORBIDE MONONITRATE if:

- you are allergic to isosorbide mononitrate, or any of the ingredients listed at the end of this leaflet, or any medicine or food containing nitrates.
- Always check the ingredients to make sure you can use this medicine.
- You are pregnant or intend to become pregnant.

- You are breast feeding or intend to breast feed. Isosorbide passes into breast milk. The effect on the baby is unknown.
- If you are in a state of shock including shock caused by very low blood pressure due to a failing heart, have hypotension (low blood pressure), weakened muscle of the heart or pericarditis (swelling around the heart).
- You are having an acute angina attack. They should be taken once daily.
- you are not sure whether you should start taking APO-ISOSORBIDE MONONITRATE, contact your doctor.
- you are a child.**
The safety and effectiveness of Isosorbide has not been established in children.
- you are taking any of the following phosphodiesterase type 5 inhibitors,**
 - Sildenafil
 - Tadalafil
 - Vardenafil

Check with your doctor if you:

- have any other medical conditions, especially heart, liver or kidney failure
- take any medicines for any other condition.
- you suffer from low blood pressure or blood vessel disease such as hardening of the arteries.

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 take if pregnant or intend to become pregnant, or if you are breastfeeding or intend to breastfeed.

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

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

Isosorbide may affect your developing baby if you take it during pregnancy.

Isosorbide passes into breast milk. The effect on the baby is unknown.

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 APO-ISOSORBIDE MONONITRATE and affect how it works.. These medicines include:

- Sildenafil (Viagra®), Tadalafil and Vardenafil may cause fainting or heart attacks
- N-acetylcysteine or captopril with Isosorbide may result in a prolonged anti-angina effect.
- calcium channel blocker of the verapamil type may improve heart function. However, the combination of Isosorbide with any other calcium channel blocker may cause hypotension (low blood pressure) requiring dose adjustment of either medicine
- betablocker medicines such as propranolol may cause hypotension (low blood pressure).

.You may need to take different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

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

4. How do I use APO-ISOSORBIDE MONONITRATE ?

How much to take / use

- Your doctor will advise you on how many tablets you should take
- Follow the instructions provided and use APO-ISOSORBIDE MONONITRATE until your doctor tells you to stop.

When to take / use APO-ISOSORBIDE MONONITRATE

- Food does not affect the absorption of isosorbide so the tablets may be taken with or without food.
- Follow all directions given to you by your doctor and pharmacist carefully.
- These directions may differ from the information contained in this leaflet.
- If you do not understand the instructions on the packaging, ask your doctor or pharmacist for help.

If you forget to use APO-ISOSORBIDE MONONITRATE

APO-ISOSORBIDE MONONITRATE should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember unless more than eight hours have passed.

If more than eight hours have passed since the time the dose should have been taken, do not take the missed dose but take the next dose at the normal time.

A missed dose may lead to an angina attack that in turn may need medication, prescribed by your doctor, capable

of treating an acute attack such as use of immediate release tablets or spray administered under the tongue.

APO-ISOSORBIDE MONONITRATE is not recommended and should not be taken for the treatment of acute angina attacks.

Do not take a double dose to make up for the dose you missed.

If you use too much APO-ISOSORBIDE MONONITRATE

If you think that you have used too much APO-ISOSORBIDE MONONITRATE , you may need urgent medical attention.

If you take too much APO-Isosorbide mononitrate , the most common symptom is a pulsing headache. More serious symptoms are excitation, flushing, cold sweats, nausea, vomiting, vertigo, increased heart beat and a fall in blood pressure.

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 APO-ISOSORBIDE MONONITRATE ?

Things you should do

Use APO-ISOSORBIDE MONONITRATE exactly as your doctor has prescribed.

If you do not follow your doctor's instructions, you may not get relief from your attacks of angina.

Call your doctor straight away if you:

- continue to have angina attacks or if they become more frequent while you are using APO-ISOSORBIDE MONONITRATE

Remind any doctor, dentist or pharmacist you visit that you are using APO-ISOSORBIDE MONONITRATE .

Things you should not do

- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
- Do not use it to treat any other complaints unless your doctor says to.

Things you should be careful of

Be careful not to overdo physical activities when you first start using APO-ISOSORBIDE MONONITRATE .

You may feel better when you start taking it, but you will need time to improve your physical fitness.

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

You may feel light-headed or dizzy when you begin to take Isosorbide or if the dose is increased. This is because your blood pressure is falling suddenly. 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. The problem usually goes away after the first few days.

If this problem gets worse or continues, talk to your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how APO-ISOSORBIDE MONONITRATE affects you.

APO-ISOSORBIDE MONONITRATE may cause dizziness, tiredness or light headedness in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

Alcohol may cause your blood pressure to drop making you feel dizzy or faint.

Looking after your medicine

- **Keep your tablets in a cool dry place.** APO-ISOSORBIDE MONONITRATE should be stored below 25 °C

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.

Keep it where young children cannot reach it.

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.

Less serious side effects

Less serious side effects	What to do
Neurological or brain related:	Speak to your doctor if you

<ul style="list-style-type: none">• Headache• Dizziness• Nausea• Tiredness• Disturbed sleep	have any of these less serious side effects and they worry you.
---	---

Serious side effects

Serious side effects	What to do
Gastrointestinal <ul style="list-style-type: none">• Poor appetite• Vomiting• Diarrhoea• heartburn	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

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 APO-ISOSORBIDE MONONITRATE contains

Active ingredient (main ingredient)	Isosorbide mononitrate 60 mg
Other ingredients (inactive ingredients)	stearic acid, carnauba wax, hypromellose, lactose monohydrate, magnesium stearate, purified talc, titanium dioxide, colloidal anhydrous silica, macrogol 4000, iron oxide yellow.

Potential allergens	Lactose monohydrate
---------------------	---------------------

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

What APO-ISOSORBIDE MONONITRATE looks like

APO-ISOSORBIDE MONONITRATE are oval tablets with a cream coloured film coating and half scored on both sides.

APO-ISOSORBIDE MONONITRATE is available in blisters (AUST R 75240) packs of 30 tablets.

Who distributes APO-ISOSORBIDE MONONITRATE

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel St
Cremorne 3121 VIC
Australia

www.arrotex.com.au

This leaflet was prepared in January 2024.