METOPROLOL IV VIATRIS

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> 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 METOPROLOL IV VIATRIS?

METOPROLOL IV VIATRIS contains the active ingredient metoprolol tartrate. METOPROLOL IV VIATRIS is used to treat irregular heartbeat, also known as arrhythmia, which means there is a disturbance of the heart's normal rhythm or beat.

For more information, see Section <u>1. Why am I using METOPROLOL IV VIATRIS?</u> in the full CMI.

2. What should I know before I use METOPROLOL IV VIATRIS?

Do not use if you have ever had an allergic reaction to metoprolol tartrate or any of the ingredients listed at the end of the CMI, you have asthma, wheezing, difficulty breathing or other lung problems, or have had them in the past, you have a history of allergic problems, including hayfever, you have low blood pressure, you have a very slow heartbeat (less than 45-50 beats/minute), you have certain other heart conditions, you have phaeochromocytoma (a rare tumour of the adrenal gland) which is not being treated already with other medicines, you have a severe blood vessel disorder causing poor circulation in the arms and legs or if you are receiving/having emergency treatment for shock or severely low blood pressure.

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 METOPROLOL IV VIATRIS? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with METOPROLOL IV VIATRIS 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 METOPROLOL IV VIATRIS?

- METOPROLOL IV VIATRIS is given as a slow injection into the vein.
- METOPROLOL IV VIATRIS must only be given by a doctor or a nurse.

 Your doctor will decide what dose and for how long you will receive METOPROLOL IV VIATRIS. This depends on your condition and other factors, such as your weight.

More instructions can be found in Section <u>4. How do I</u> use METOPROLOL IV VIATRIS? in the full CMI.

5. What should I know while using METOPROLOL IV VIATRIS?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using METOPROLOL IV VIATRIS. Tell your doctor if you experience any side effects, including those not listed in this leaflet.
Driving or using machines	 Be careful before you drive or use any machines or tools until you know how METOPROLOL IV VIATRIS affects you.
Drinking alcohol	Tell your doctor if you drink alcohol.
Looking after your medicine	 METOPROLOL IV VIATRIS will be stored in the hospital pharmacy

or on the ward below
25°C.

For more information, see Section <u>5. What should I know while using METOPROLOL IV VIATRIS?</u> in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience side effects, most of them are minor and temporary. However some side effects may be serious and may need urgent medical attention or hospitalisation such as shortness of breath, being less able to exercise, swelling of the ankles, feet or legs, chest tightness, wheezing, noisy breathing, difficulty breathing, chest pain, changes in heart rate or palpitations, swelling of the face, lips, tongue or throat which may cause difficulty swallowing or breathing, yellowing of the skin or eyes (jaundice) and generally feeling unwell.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

METOPROLOL IV VIATRIS

Active ingredient: metoprolol tartrate

Consumer Medicine Information (CMI)

This leaflet provides important information about using METOPROLOL IV VIATRIS. 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 METOPROLOL IV VIATRIS.

Where to find information in this leaflet:

- 1. Why am I using METOPROLOL IV VIATRIS?
- 2. What should I know before I use METOPROLOL IV VIATRIS?
- 3. What if I am taking other medicines?
- 4. How is METOPROLOL IV VIATRIS given?
- 5. What should I know while using METOPROLOL IV VIATRIS?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using METOPROLOL IV VIATRIS?

METOPROLOL IV VIATRIS contains the active ingredient metoprolol tartrate. METOPROLOL IV VIATRIS belongs to a group of medicines called betablockers.

METOPROLOL IV VIATRIS is used to treat an irregular heartbeat, also known as arrhythmia, which means that there is a disturbance of the heart's normal rhythm or beat.

Arrhythmias may be caused by numerous factors, including some heart diseases, an overactive thyroid gland or chemical imbalances. After a heart attack there is also a chance of developing an arrhythmia.

Metoprolol tartrate helps to restore your heartbeat to a more normal rate, particularly if it is beating very fast.

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 not addictive.

2. What should I know before I use METOPROLOL IV VIATRIS?

Warnings

Do not use METOPROLOL IV VIATRIS if:

- you are allergic to metoprolol tartrate, any other betablocker medicine, or 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 or you may feel faint.
 Always check the ingredients to make sure you can use this medicine.
- you have asthma, wheezing, difficulty breathing or other lung problems, or have had them in the past
- you have a history of allergic problems, including hayfever
- you have low blood pressure
- you have a very slow heartbeat (less than 45-50 beats/minute)
- you have certain other heart conditions

- you have phaeochromocytoma (a rare tumour of the adrenal gland) which is not being treated already with other medicines
- you have a severe blood vessel disorder causing poor circulation in the arms and legs
- you are receiving/having emergency treatment for shock or severely low blood pressure.

If you are not sure whether any of these apply to you, check with your doctor.

Check with your doctor if you:

- have any other medical conditions, especially the following:
 - asthma, wheezing, difficulty breathing or other lung problems
 - diabetes
 - o an overactive thyroid gland
 - liver problems
 - kidney problems
 - o certain types of angina
 - any other heart problems
 - phaeochromocytoma, a rare tumour of the adrenal gland
 - any blood vessel disorders causing poor circulation in the arms and legs.
- take any medicines for any other condition
- have allergies to any other medicines, foods, preservatives or dyes.

If you have not told your doctor about any of the above, tell them before you are given METOPROLOL IV VIATRIS.

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

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

Like most beta-blocker medicines, METOPROLOL IV VIATRIS is not recommended for use during pregnancy.

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

The active ingredient in METOPROLOL IV VIATRIS passes into breast milk and there is a possibility that your baby may be affected.

Use in children

Do not give this medicine to children.

Safety and effectiveness of this medicine in children have not been established.

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 and METOPROLOL IV VIATRIS may interfere with each other. These include:

- other beta-blocker medicines, including beta-blocker eye drops
- calcium channel blockers or calcium antagonists, medicines used to treat high blood pressure or angina, for example verapamil and diltiazem
- medicines used to treat blood pressure, for example clonidine, hydralazine, and prazosin
- medicines used to treat abnormal or irregular heartbeat, for example amiodarone, disopyramide and quinidine
- medicines used to treat arthritis, pain, or inflammation, for example indometacin and ibuprofen
- warfarin, a medicine used to prevent blood clots
- digoxin, a medicine used to treat heart failure
- medicines used to treat diabetes
- cimetidine, a medicine used to treat stomach ulcers
- medicines used to treat bacterial infections, for example rifampicin
- medicines used to treat depression
- monoamine oxidase inhibitors (MAOIs).

These medicines may be affected by METOPROLOL IV VIATRIS 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 will advise you.

Your doctor, nurse and pharmacist have more information on medicines to be careful with or avoid while using this medicine

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

4. How is METOPROLOL IV VIATRIS given?

How you are given METOPROLOL IV VIATRIS

METOPROLOL IV VIATRIS is given as a slow injection into a vein.

METOPROLOL IV VIATRIS should only be given by a doctor or nurse.

Your doctor will decide what dose and for how long you will receive METOPROLOL IV VIATRIS. This will depend on your condition and other factors, such as your weight.

To begin treatment, up to 5 mg of METOPROLOL IV VIATRIS is given at a rate of 1 to 2 mg per minute. This dose may be repeated at 5-minute intervals until a satisfactory effect is achieved.

Your blood pressure and heart will be monitored during treatment.

If you use too much METOPROLOL IV VIATRIS

The doctor or nurse giving you METOPROLOL IV VIATRIS will be experienced in its use, so it is unlikely that you will be given an overdose.

However, if you are accidentally given too much METOPROLOL IV VIATRIS you may experience nausea, vomiting, convulsions, an extreme slowing of the heartbeat, lowered blood pressure, possible heart failure and breathing difficulties.

In extreme cases, your skin may turn blue, and you may go into shock, unconsciousness or coma.

Your doctor has information on how to recognise and treat an overdose. Ask your doctor if you have any concerns.

If you believe that you have been given too much METOPROLOL IV VIATRIS, you should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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 METOPROLOL IV VIATRIS?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using METOPROLOL IV VIATRIS.
- Tell your doctor if you experience any side effects, including those not listed in the leaflet.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how METOPROLOL IV VIATRIS affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- METOPROLOL IV VIATRIS will be stored in the hospital pharmacy or on the ward.
- The medicine is kept in a cool, dry place, protected from light, where the temperature stays below 25°C.

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.

METOPROLOL IV VIATRIS should not be used if the expiry date printed on the pack has passed or if the packaging is torn or shows signs of tampering.

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.

If you are over 65 years of age you may have an increased chance of getting side effects.

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
 swelling, burning sensation, changes in skin colour or texture where you had the injection swelling or pain in a vein headache, tiredness, drowsiness aches and pains, painful joints 	Speak to your doctor or nurse if you have any of these less serious side effects and they worry you. These side effects are usually mild.

Less serious side effects	What to do
 nausea (feeling sick), vomiting 	
weakness, lack of energy	
 stomach upset, diarrhoea or constipation 	
 dry mouth, changes in taste sensation 	
difficulty sleeping, nightmares	
mood changesconfusion, short-term	
memory loss, inability to concentrate	
 increased sweating, runny or blocked nose 	
• hair loss	
weight gain	

Serious side effects

Serious side effects	What to do
 dizziness, lightheadedness or fainting especially on standing up, which may be due to low blood pressure 	Call your doctor or nurse straight away if you notice any of these serious side effects.

Serious side effects	What to do
tingling or "pins and needles"	Serious side effects are rare.
 coldness, burning, numbness or pain in the arms and/or legs 	
skin rash or worsening of psoriasis	
 symptoms of sunburn happening more quickly than before 	
 abnormal thinking or hallucinations 	
 buzzing or ringing in the ears, deafness 	
irritated eyes or blurred vision	
sexual problems	
unusual bleeding or bruising	
 constant "flu-like" symptoms with tiredness or lack of energy 	

Very serious side effects

Very serious side effects	What to do
 shortness of breath, being less able to exercise swelling of the ankles, feet or legs chest tightness, wheezing, noisy breathing, difficulty breathing chest pain, changes in heart rate or palpitations swelling of the face, lips, tongue or throat which may cause difficulty swallowing or breathing yellowing of the skin or eyes (jaundice), generally feeling unwell 	Call your doctor or nurse straight away if you notice any of these very serious side effects. You may need urgent medical attention or hospitalisation. Very serious side effects are rare.

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.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

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 METOPROLOL IV VIATRIS contains

Active ingredient (main ingredient)	metoprolol tartrate 5 mg per vial
Other ingredients (inactive ingredients)	sodium chloride, water for injections

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

What METOPROLOL IV VIATRIS looks like

METOPROLOL IV VIATRIS is a clear liquid packaged in 5 mL glass vials containing the active ingredient, metoprolol tartrate (AUST R 204665).

The medicine comes in packs of 5 vials.

Who distributes METOPROLOL IV VIATRIS

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

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