

ESMOLOL NORIDEM

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 being given ESMOLOL NORIDEM

ESMOLOL NORIDEM contains the active ingredient Esmolol Hydrochloride. ESMOLOL NORIDEM is used as a short-term treatment for irregular heartbeat before, during or after surgery. It is also used in emergency situations.

For more information, see Section [1. Why am I being given ESMOLOL NORIDEM?](#) in the full CMI.

2. What should I know before I am given ESMOLOL NORIDEM?

Do not use if you have ever had an allergic reaction to Esmolol hydrochloride 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 am given ESMOLOL NORIDEM?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ESMOLOL NORIDEM 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 is ESMOLOL NORIDEM given?

- ESMOLOL NORIDEM must only be given by a doctor or nurse.

It is given as a slow injection into a vein. More instructions can be found in Section [4. How is ESMOLOL NORIDEM given?](#) in the full CMI.

5. What should I know while being given - ESMOLOL NORIDEM?

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| Things you should do | <ul style="list-style-type: none">• If you are about to be started on any new medicines, remind your doctor or pharmacist that you have recently been given ESMOLOL NORIDEM• Tell any other doctors or dentists, and pharmacists who treat you that you have been given this medicine• If you are going to have surgery, tell the surgeon or anaesthetist that you have been given this medicine.• If you plan to become pregnant, tell your doctor that you have been given this medicine• If you are being treated for diabetes, make sure you check your blood sugar level regularly and report any changes to your doctor. |
| Looking after your medicine | <ul style="list-style-type: none">• ESMOLOL NORIDEM will be stored in the pharmacy or on the ward of a hospital. The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C. Store in the original packaging. |

For more information, see Section [5. What should I know while being given ESMOLOL NORIDEM?](#) in the full CMI.

6. Are there any side effects?

Some common side effects that may occur are: tiredness, drowsiness, decreased alertness, You may also experience more serious side effects such as: dizziness or light-headedness (sometimes with fainting), especially on standing up, chest pain, swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing, which may be signs of a serious allergic reaction, These are only some side effects that may be experienced. 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.

ESMOLOL NORIDEM

Active ingredient(s): *Esmolol Hydrochloride*

Consumer Medicine Information (CMI)

This leaflet answers some common questions about ESMOLOL NORIDEM. It does not contain all the available information. It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given ESMOLOL NORIDEM against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor.

Keep this leaflet.

You may need to read it again.

Where to find information in this leaflet:

- [1. Why am I being given ESMOLOL NORIDEM?](#)
- [2. What should I know before I am given ESMOLOL NORIDEM?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is ESMOLOL NORIDEM given?](#)
- [5. What should I know while being given ESMOLOL NORIDEM](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given ESMOLOL NORIDEM?

ESMOLOL NORIDEM contains the active ingredient Esmolol Hydrochloride. ESMOLOL NORIDEM is used as a short term treatment for irregular heartbeat before, during or after surgery. It is also used in emergency situations.

Irregular heartbeat, also known as arrhythmia, means that there is a disturbance of the heart's normal rhythm or beat. Arrhythmia may be caused by a number of factors, including some heart diseases, an overactive thyroid gland, or chemical imbalances. ESMOLOL NORIDEM helps restore the heart's normal rhythm.

ESMOLOL NORIDEM belongs to a group of medicines called beta-blockers.

Ask your doctor if you have any questions about why ESMOLOL NORIDEM has been prescribed for you.

Your doctor may have prescribed it for another reason.

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There is not enough information to recommend the use of ESMOLOL NORIDEM in children.

2. What should I know before I am given ESMOLOL NORIDEM?

Warnings

You must not be given ESMOLOL NORIDEM if you have an allergy to:

- any medicine containing esmolol hydrochloride
- any of the ingredients listed at the end of this leaflet
- any other beta-blocker medicines.

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.
- Always check the ingredients to make sure you can use this medicine.

You should not be given ESMOLOL NORIDEM

- Have any other medical conditions like a very slow or irregular heartbeat, you have heart disease or you have certain other heart conditions
- You are taking certain heart medicines, called calcium channel blockers or calcium antagonists, such as verapamil
- You are receiving emergency treatment for shock or severely low blood pressure.

Tell your doctor if you have allergies to any other medicines, foods preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- low blood pressure
- any other heart problem
- history of severe life threatening allergic reactions
- asthma, wheezing, difficulty breathing or other lung problems
- diabetes
- low sugar levels in the blood
- Kidney problems.

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

Tell your doctor if you are pregnant or intend to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you are given ESMOLOL NORIDEM.

3. What if I am taking other medicines?

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

Some medicines and ESMOLOL NORIDEM may interfere with each other. These include:

- other beta-blocker medicines, including beta-blocker eye drops
- verapamil, a calcium channel blocker or calcium antagonist which is used to treat high blood pressure and chest pain
- reserpine, a medicine used to treat high blood pressure
- suxamethonium a muscle relaxant used during surgery
- warfarin, a medicine used to prevent blood clots
- digoxin, a medicine used to treat heart failure
- morphine, a medicine used for pain relief
- medicines commonly used during surgery or in emergency situations such as dopamine, adrenaline, noradrenaline and certain anaesthetics.

These medicines may be affected by ESMOLOL NORIDEM, or may affect how well it works. You may need to be given different amounts of your medicines, or you may need to be given different medicines.

4. How is ESMOLOL NORIDEM given?

How much will I be given?

ESMOLOL NORIDEM must only be given by a doctor or nurse.

It is given as a slow injection into a vein.

Your doctor will decide what dose and how long you will receive ESMOLOL NORIDEM. This depends on your condition and other factors, such as your weight.

If you use too much ESMOLOL NORIDEM

ESMOLOL NORIDEM must only be given by a doctor or nurse, so an overdose is not likely to occur.

Symptoms of an overdose may include:

- Dizziness, faintness or light-headedness
- Chest pain
- Drowsiness and loss of consciousness.

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

5. What should I know while being given ESMOLOL NORIDEM?

Things you should do

If you are going to have surgery, tell the surgeon or anaesthetist that you have been given this medicine.

It may affect other medicines used during surgery.

If you plan to become pregnant, tell your doctor that you have been given this medicine. Your doctor can discuss with you the risks and benefits involved.

If you have a severe allergic reaction to foods, medicines or insect stings, tell your doctor immediately.

If you have a history of allergies, there is a chance that ESMOLOL NORIDEM may cause allergic reactions to be worse and more difficult to treat.

If you are being treated for diabetes, make sure you check your blood sugar level regularly and report any changes to your doctor.

ESMOLOL NORIDEM may change how well your diabetes is controlled. It may also cover up some of the symptoms of low blood sugar, called hypoglycaemia, such as fast heartbeat. ESMOLOL NORIDEM may make low blood sugar last longer. Your doses of diabetic medicines, including insulin, may need to change.

Be sure to keep all of your doctor's appointment so that your progress can be checked.

Things to be careful of

If you feel light-headed, dizzy or faint when getting out of the bed or standing up, get up slowly.

You may feel light-headed or dizzy after you are given ESMOLOL NORIDEM. 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. If this problem gets worse or continues, talk to your doctor.

Looking after your medicine

ESMOLOL NORIDEM will be stored in the pharmacy or on the ward of a hospital. The injection is kept in a cool dry place, protected from light, where the temperature stays below 25°C.

ESMOLOL NORIDEM will be opened for use on you. It will be used only once and then it will be discarded. It will never be stored after it is opened nor used for more than one person.

6. Are there any side effects?

Tell your doctor or nurse as soon as possible if you do not feel well while you are being given ESMOLOL NORIDEM.

This medicine helps most people with irregular heartbeat, 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.

Do not be alarmed by the following list of side effects you may not experience any of them.

Ask your doctor to answer any questions you may have.

Less serious side effects

| Less serious side effects | What to do |
|---|---|
| <p>These side effects are usually mild.</p> <p>Whole body-related:</p> <ul style="list-style-type: none"> weakness, lack of energy shakiness, trembling, muscle stiffness aches and pains flushed or pale skin. <p>Nervous system(head)-related:</p> <ul style="list-style-type: none"> headache changes in mood such as anxiety, agitation, depression confusion dry mouth, change in taste sensation <p>Respiratory system-related:</p> <ul style="list-style-type: none"> runny or blocked nose <p>Gastrointestinal-related:</p> <ul style="list-style-type: none"> loss of appetite, feeling sick, vomiting stomach upset, diarrhoea or constipation | <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> |

Serious side effects

| Serious side effects | What to do |
|---|---|
| <p>Whole body-related:</p> <ul style="list-style-type: none"> dizziness or light-headedness (sometimes with fainting), especially on standing up fever and chills. <p>Nervous system(head)-related:</p> <ul style="list-style-type: none"> visual disturbances (e.g., blurred vision) difficulty in speaking <p>Injection site-related:</p> <ul style="list-style-type: none"> skin reactions at the injection site (e.g., swelling, redness or burning sensation, change in skin colour or hardness) | <p>Tell your doctor or nurse as soon as possible if you notice any of these serious side effects</p> |

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

Very Serious side effects

Nervous system(head)-related:

- abnormal thinking or hallucinations (seeing, feeling or hearing things that are not there)
- tingling or pins and needles in the hands and feet
- coldness, burning or numbness or pain and the arms and/or legs
- seizures, fits or convulsions.
- shortness of breath, sometimes with tiredness, weakness and reduced ability to exercise, swelling of the feet or legs due to fluid build up

Cardiovascular system-related:

- chest pain, changes in heart rate (fast, slow or irregular), palpitations

Allergy-related:

- swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing, which may be signs of a serious allergic reaction
- chest tightness, wheezing, rattly breathing

Urinary system-related:

- a change in the amount or frequency of urine passed

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare.

If any of these very serious side effects happen, tell your doctor or nurse immediately or go to the Emergency Department at your nearest hospital

Tell your doctor or nurse 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.

7. Product details

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

What ESMOLOL NORIDEM contains

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|---|--|
| Active ingredient (main ingredient) | ESMOLOL NORIDEM contains esmolol hydrochloride 100mg in 10mL as the active ingredient. |
| Other ingredients (inactive ingredients) | Sodium Chloride Sodium acetate trihydrate Acetic acid-glacial Hydrochloric acid Sodium hydroxide Water for injections |

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

ESMOLOL NORIDEM does not contain lactose, sucrose, gluten, tartrazine, alcohol, dyes or any preservatives.

What ESMOLOL NORIDEM looks like

ESMOLOL NORIDEM is a clear colourless to light yellow solution in a clear glass ampoule.

ESMOLOL NORIDEM is available in a 10mL ampoule.

ESMOLOL NORIDEM 100mg in 10mL in packs of 10 ampoules
AUST R 375799

Who distributes ESMOLOL NORIDEM

ESMOLOL NORIDEM is supplied in Australia by:

**InterPharma Pty Ltd Suite 103, 39 East Esplanade MANLY
NSW 2095 Australia.**

This leaflet was prepared in September 2022