

# **Esmolol Hydrochloride Medsurge**

### **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 Esmolol Hydrochloride Medsurge?

Esmolol Hydrochloride Medsurge contains the active ingredient esmolol hydrochloride. Esmolol Hydrochloride Injection 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 using Esmolol Hydrochloride Medsurge? in the full CMI.

### 2. What should I know before I use Esmolol Hydrochloride Medsurge?

Do not use if you have ever had an allergic reaction to esmolol hydrochloride or any of the ingredients listed at the end of this leaflet.

### Tell your doctor if you have or have had any other medical conditions, are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Esmolol Hydrochloride Medsurge? in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with Esmolol Hydrochloride Medsurge 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 Esmolol Hydrochloride Medsurge?

Esmolol Hydrochloride Medsurge is given as a slow injection into a vein by a doctor or nurse. Your doctor will decide what dose and how long you will receive Esmolol Hydrochloride Medsurge Injection. This depends on your condition and other factors, such as your weight.

More instructions can be found in Section 4. How do I use Esmolol Hydrochloride Medsurge? in the full CMI.

### 5. What should I know while using Esmolol Hydrochloride Medsurge?

Things you should do	<ul> <li>If you are about to be started on any new medicines, remind your doctor or pharmacist that you have recently been given Esmolol Hydrochloride Injection.</li> <li>If you are being treated for diabetes, make sure you check your blood sugar level regularly and report any changes to your doctor.</li> <li>Be sure to keep all of your doctor's appointments so that your progress can be checked.</li> <li>If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.</li> </ul>
Things you should not do	<ul> <li>You should not be given Esmolol Hydrochloride Medsurge Injection if the solution is discoloured, cloudy, turbid, or particles or a precipitate is present.</li> <li>You should not be given this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.</li> <li>If you are not sure whether you should be given this medicine, talk to your doctor.</li> </ul>
Looking after your medicine	• Esmolol hydrochloride Medsurge will be stored in the pharmacy or on the ward of a hospital. The injection is kept in a cool dry place, where the temperature stays below 25°C.

For more information, see Section 5. What should I know while using Esmolol Hydrochloride Medsurge? in the full CMI.

### 6. Are there any side effects?

Tell your doctor or nurse if you notice any of the following- tiredness, drowsiness, sweating, decreased alertness, dizziness or light-headedness (sometimes with fainting), especially on standing up, abnormal thinking or hallucinations (seeing, feeling or hearing things that are not there). Other side effects not listed above may also occur in some people. For more information, including what to do if you have any side effects, see Section <u>6. Are there any side effects</u>? in the full CMI.

# **Esmolol Hydrochloride Medsurge**

### Active ingredient(s): Esmolol Hydrochloride

### **Consumer Medicine Information (CMI)**

This leaflet provides important information about using Esmolol Hydrochloride Medsurge. You should also speak to your doctor or nurse if you would like further information or if you have any concerns or questions about using Esmolol Hydrochloride Medsurge.

#### Where to find information in this leaflet:

- 1. Why am I using Esmolol Hydrochloride Medsurge?
- 2. What should I know before I use Esmolol Hydrochloride Medsurge?
- 3. What if I am taking other medicines?
- 4. How do I use Esmolol Hydrochloride Medsurge?
- 5. What should I know while using Esmolol Hydrochloride Medsurge?
- 6. Are there any side effects?
- 7. Product details

# 1. Why am I using Esmolol Hydrochloride Medsurge?

**Esmolol Hydrochloride Medsurge contains the active ingredient** esmolol hydrochloride. Esmolol Hydrochloride Injection belongs to a group of medicines called beta-blockers.

Esmolol Hydrochloride Medsurge Injection 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 Hydrochloride Medsurge Injection helps restore the heart's normal rhythm.

#### Ask your doctor if you have any questions about why Esmolol Hydrochloride Medsurge has been prescribed for you.

Your doctor may have prescribed Esmolol Hydrochloride for another reason.

There is not enough information to recommend the use of Esmolol Hydrochloride Medsurge Injection in children.

### 2. `What should I know before I use Esmolol Hydrochloride Medsurge?

### Warnings

# You should not be given Esmolol Hydrochloride Medsurge 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.
- you have a very slow or irregular heart beat
- you have heart disease or 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:

- are not sure whether you should be given this medicine.
- have any allergies to any other medicines, foods, preservatives or dyes.
- 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 <u>6. Are there any side effects?</u>

### 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 Hydrochloride Medsurge injection.

### 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 or health food shop, naturopath or herbalist.

### Some medicines and Esmolol Hydrochloride Medsurge Injection 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 (epinephrine), noradrenaline (norepinephrine) and certain anaesthetics.

These medicines may be affected by Esmolol Hydrochloride Medsurge Injection 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.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while being given Esmolol Hydrochloride Medsurge Injection.

### 4. How do I use Esmolol Hydrochloride Medsurge?

### How much will I be given?

- Your doctor will decide what dose and how long you will receive Esmolol Hydrochloride Medsurge Injection. This depends on your condition and other factors, such as your weight.
- Esmolol Hydrochloride Medsurge is given as a slow injection into a vein.
- It must only be given by a doctor or nurse.

### If you are given too much Esmolol Hydrochloride Medsurge

Esmolol Hydrochloride Medsurge Injection 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 recognise and treat an overdose. Ask your doctor if you have any concerns.

### 5. What should I know while using Esmolol Hydrochloride Medsurge?

### Things you should do

Call your doctor straight away if:

• 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 the 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 or nurse immediately. If you have a history of allergies, there is a chance that Esmolol Hydrochloride Medsurge Injection 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 Hydrochloride Medsurge Injection 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 heart beat. Esmolol Hydrochloride Medsurge Injection may make low blood sugar last longer. Your doses of diabetic medicines, including insulin, may need to change.

Remind any doctor, dentist or pharmacist you visit that you have recently been given Esmolol Hydrochloride Medsurge if you are about to be started on any new medicines.

#### Things you should not do

- If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. You may feel light-headed or dizzy after you are given Esmolol Hydrochloride Medsurge Injection. 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.
- You should not be given Esmolol Hydrochloride Medsurge Injection if the solution is discoloured, cloudy, turbid, or particles or a precipitate is present. The solution is normally a clear, colourless to light yellow liquid.
- You should not be given this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If this medicine is used after the expiry date it may not work as well.

### Looking after your medicine

Esmolol Hydrochloride Medsurge will be stored in the pharmacy or on the ward of a hospital. The injection is kept in a cool dry place, where the temperature stays below  $25^{\circ}$ C..

Esmolol Hydrochloride Medsurge Injection 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 Hydrochloride Medsurge Injection.

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
<ul> <li>tiredness, drowsiness, sweating, decreased alertness</li> <li>weakness, lack of energy</li> <li>shakiness, trembling, muscle stiffness</li> <li>headache</li> <li>aches and pains</li> <li>changes in mood such as anxiety, agitation, depression</li> <li>confusion</li> </ul>	Tell your doctor or nurse if you have any of these less serious side effects and they worry you.
<ul> <li>stomach upset, diarrhoea or constipation</li> <li>loss of appetite, feeling sick, vomiting</li> <li>dry mouth, change in taste sensation</li> <li>runny or blocked nose</li> <li>flushed or pale skin.</li> </ul>	These side effects are usually mild.

### Serious side effects

Serious side effects	What to do
<ul> <li>dizziness or light-headedness (sometimes with fainting), especially on standing up</li> <li>skin reactions at the injection site (e.g., swelling, redness or burning sensation, change in skin colour or hardness)</li> <li>visual disturbances (e.g., blurred vision)</li> <li>difficulty in speaking</li> <li>fever and chills.</li> </ul>	Tell your doctor or nurse immediately if you have any of the following as you may need urgent medical attention Serious side effects are rare.

### Very Serious side effects

Very Serious side effects	What to do
<ul> <li>abnormal thinking or hallucinations (seeing, feeling or hearing things that are not there)</li> <li>shortness of breath, sometimes with tiredness, weakness and reduced ability to exercise, swelling of the feet or legs due to fluid build up</li> <li>chest pain, changes in heart rate (fast, slow or irregular), palpitations</li> <li>swelling of the face, lips, tongue or throat which may cause difficulty in swallowing or breathing, which may be signs of a serious allergic</li> </ul>	Call your doctor or nurse straight away, go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.
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<ul> <li>reaction</li> <li>chest tightness, wheezing, rattly breathing</li> <li>a change in the amount or frequency of urine passed</li> <li>tingling or pins and needles in the hands and feet</li> <li>coldness, burning or numbness or pain and the arms and/or legs</li> </ul>	rare.
<ul><li>pain and the arms and/or legs</li><li>seizures, fits or convulsions.</li></ul>	

### Tell your doctor or nurse if you notice anything that is making you feel unwell.

Other side effects not listed above 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 Medsafe online at https://nzphvc.otago.ac.nz/reporting/. 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 Esmolol Hydrochloride Medsurge contains

Active ingredient	Esmolol Hydrochloride
(main ingredient)	
Other ingredients	Sodium Chloride
(inactive	Sodium Acetate Trihydrate
ingredients)	Glacial Acetic Acid
	Sodium Hydroxide/
	Hydrochloric acid
	Water for Injections

Esmolol hydrochloride Injection does not contain lactose, sucrose, gluten, tartrazine, alcohol, dyes or any preservatives.

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

# What Esmolol Hydrochloride Medsurge looks like

Esmolol Hydrochloride Medsurge Injection is a clear, colourless to light yellow, sterile, nonpyrogenic solution of esmolol hydrochloride for intravenous injection.

Esmolol Hydrochloride Medsurge is available in strength 100mL/10 mL. Packs of 5, 20 or 25 vials (not all pack sizes may be available).

# Who distributes Esmolol Hydrochloride Medsurge

Medsurge Pharma Limited PO Box 331054 Takapuna Auckland 0622 Telephone: 0800 788 261 Website: <u>www.medsurgehc.com</u>

Marketed and distributed by Medsurge Healthcare.

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