

ILOMEDIN[®] (I-lom-ED-in)

iloprost (as trometamol)

What is in this leaflet

This leaflet answers some common questions about Ilomedin. It does not contain all the available information. It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Ilomedin against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor, nurse or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What is Ilomedin used for and how does it work?

Ilomedin contains the active substance iloprost (as trometamol), which mimics the action of a natural substance known as prostacyclin. Prostacyclin prevents inflammation, inhibits unwanted build up of platelets and widens blood vessels.

Ilomedin promotes the healing of ulcerations secondary to ischaemia (decreased blood supply) and lessens the pain in severe, long lasting disturbances of arterial circulation.

Ilomedin also widens narrow blood vessels in the lung, which in turn allows the heart to function more effectively.

It is used for the treatment of:

- Severe peripheral arterial occlusive disease (PAOD), where the blood vessels in the arms and legs either become blocked or narrowed.
- Advanced Buerger's disease - insufficient blood flow to the hands and feet causing swelling and clotting of the blood vessels.
- Severe disabling Raynaud's phenomenon - discolouration of the fingers, toes, and occasionally other areas - which is unresponsive to other therapies.
- Moderate or severe stages of pulmonary hypertension. Pulmonary hypertension is a condition where blood pressure is too high in the vessels which transport blood from the heart to the lungs.

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.

Before you are given Ilomedin

When you must not use it

You must not be given Ilomedin if:

- You are pregnant or you think you could be pregnant
- You are breast-feeding
- You have an allergy to iloprost or any of the ingredients listed at the end of this leaflet
- You have a condition where Ilomedin may increase the risk of bleeding (e.g. active stomach ulcers, injuries, haemorrhage or other bleeding)
- You have severe heart disease, including chest pain (unstable angina), a heart attack within the last 6 months, stroke within the last three months, heart failure, fast/irregular heartbeats (arrhythmia), valvular defects affecting the function of the heart
- You have suspected fluid build-up in the lungs (accompanied by difficulty breathing)
- You have a condition that is due to blocked or narrowed veins

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

If you are not sure whether you should start using this medicine, talk to your doctor.

Before you start to use it

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

If Ilomedin is used in the presence of any of the conditions listed below or they appear for the first time, recur or worsen during treatment, you may need to be kept under close observation. Your doctor can explain this to you.

Tell your doctor if:

- You suspect you might be pregnant
- You smoke
- You have low blood pressure
- You have a history of fainting and feeling dizziness when standing up
- You have liver or kidney disease
- You have an infection of the lungs or lung disease including severe asthma

Taking other medicines

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

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

- Medicines used to treat high blood pressure or heart disease
- Medicines used to prevent blood clots or treat the unwanted buildup of platelets e.g. aspirin, non-steroidal anti-inflammatory agents (NSAIDs)
- phosphodiesterase inhibitors and nitrovasodilators

These medicines may be affected by Ilomedin or may affect how well it works. Your doctor may need to adjust your other medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor, nurse or pharmacist before you use Ilomedin.

How Ilomedin is given

Follow all directions given to you by your doctor, nurse or pharmacist carefully. They may differ from the information contained in this leaflet.

How much is given

Your doctor will work out the right starting dose for you and the infusion rate will be altered accordingly at regular intervals.

How it is given

Ilomedin is given as a slow injection into a vein, usually as a drip, by a doctor or a nurse over six hours daily. The duration of infusion will be determined by your doctor.

Ilomedin should be used only under strict monitoring in hospitals or out-patient clinics with adequate facilities.

Ilomedin should be used only after dilution. Because of the possibility of interactions, no other medicine should be added to the ready-to-use infusion solution.

The infusion solution should be made up freshly each day to ensure sterility.

Caution: Ilomedin solution should not come in contact with your skin or eyes; oral ingestion of Ilomedin solution should be avoided. On contact with the skin, the active substance of Ilomedin may cause skin redness. In the event of such contact, the affected area should be washed immediately with running water or saline.

How long it is given

Your doctor will determine the length of treatment with Ilomedin, depending on your condition. Generally, the duration of treatment is up to 4 weeks.

While you are using Ilomedin

If you are about to be started on any new medicine, remind your doctor, nurse or pharmacist that you are using Ilomedin.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

If you have low blood pressure or heart disease, your doctor will monitor you while you are undergoing treatment with Ilomedin.

After administration with Ilomedin, stand up slowly when moving from a lying to upright position as your blood pressure may fall, causing dizziness or fainting.

If you stop using Ilomedin suddenly, your condition may worsen or you may have unwanted side effects. If possible, your doctor will gradually reduce the amount you use each day before stopping the medicine completely.

Things to be careful of

Be careful driving or operating machinery until you know how Ilomedin affects you. Use of Ilomedin can occasionally lead to a sudden fall in blood pressure that may impair your ability to drive or to operate machinery. If you experience dizziness whilst under treatment with Ilomedin, do not drive or operate machinery or do anything else that could be harmful.

In case of overdose

Immediately tell your doctor, nurse or call the National Poisons Centre (telephone 0800 764 766) for advice, if you think that you or anyone else may have used too much Ilomedin. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Symptoms of an overdose may include headaches, flushing, nausea, vomiting, diarrhoea, limb or back pain, and changes to the heartbeat. Overdose may also lead to a decrease in blood pressure resulting in dizziness or fainting. If you notice these symptoms, tell your doctor or nurse straight away.

Side Effects

Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are taking Ilomedin.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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

Ask your doctor, nurse or pharmacist to answer any questions you may have.

The most common side effects of Ilomedin include flushing, headache, sweating, nausea, and vomiting. These side effects occur during the start of treatment but disappear when the dose is reduced.

The list below includes the common side effects of your medicine. Reddening, pain or a rash may also occur at or above the infusion site.

Ilomedin can increase or decrease your blood pressure. Your doctor or nurse will measure your blood pressure before the start of infusion or if the dose needs to be changed.

Tell your doctor, nurse or pharmacist if you notice any of the following:

- Loss of appetite

- Lack of emotion, indifference
- Feeling confused
- Dizziness, spinning sensation
- Burning, prickling sensation, tingling, throbbing
- Heightened senses
- Restlessness, agitated
- Slow or fast heartbeat
- Shortness of breath
- Diarrhoea
- Stomach discomfort or pain
- Jaw pain, difficulty in opening the mouth
- Muscle or joint pain, generalised pain
- Fever, feeling hot
- Weakness, feeling unwell, tiredness, drowsiness
- Chills
- Inflamed veins (usually in the legs) - pain, swelling, redness
- Feeling thirsty

If any of the following happen, stop using Ilomedin and tell your doctor immediately:

- Bruising or small red or purple spots on the skin, prolonged bleeding, bleeding gums
- Hallucinations, feeling depressed or anxious
- Fainting
- Signs of an allergy such as rash; itching or hives on the skin; swelling of the face; lips, tongue or other parts of the body; shortness of breath, wheezing or trouble breathing
- Problems with balance
- Blood or mucous in the stools, rectal pain
- Irregular heartbeat
- Chest pain and/or pain to your arms or jaw with/without sweating and nausea
- Problems with speech, blurred vision, numbness or weakness in the face, arms or legs
- Pain or swelling in the lower legs, ankles or feet
- Coughing blood
- Yellowing of the skin and eyes, also called jaundice
- Burning and/or prickling sensation, painful muscle spasms beginning in the jaw
- Back pain and/or changes to your urine, difficulty/pain while urinating or a frequent need to empty your bladder
- Convulsions

If you have these side effects, you may need urgent medical attention.

The risk of bleeding is increased in patients also taking medicines used to prevent blood clots or treat the unwanted buildup of platelets.

Tell your doctor, nurse or pharmacist if you notice anything that is making you feel unwell. Other side effects not listed above may occur in some people.

Storage

Store Ilomedin in a cool dry place where the temperature stays below 30°C.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Product Description

What it looks like

Ilomedin is a clear, colourless solution in a glass ampoule and is administered intravenously. A pack of Ilomedin contains 5 ampoules.

Ingredients

Active ingredient:

- Ilomedin – 50 µg iloprost (as trometamol) per 0.5 mL solution

Inactive ingredients:

- trometamol
- ethanol
- sodium chloride
- hydrochloric acid
- water for injection

Sponsor Details

Bayer New Zealand Limited
3 Argus Place, Hillcrest,
North Shore
Auckland 0627
Free phone call: 0800 233 988

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22 June 2012

See MEDSAFE website (www.medsafe.govt.nz) for latest New Zealand Consumer Medicine Information.

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