Patient Information Leaflet

Iloprost Waymade, 100 micrograms/ml concentrate for solution for infusion
iloprost

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not give it to others.
- This - medicine may harm them, even if their signs of illness are the same as yours.
- If you have any side effects, including possible side effects not mentioned in this leaflet, talk to your doctor or pharmacist. See section 4.

What is in this leaflet:

1. What Iloprost Waymade is and what it is used for
2. What you need to know before using Iloprost Waymade
3. How to use Iloprost Waymade
4. Possible side effects
5. How to store Iloprost Waymade
6. Package contents and other information

1. What Iloprost Waymade is and what it is used for

Iloprost Waymade, 100 micrograms/ml concentrate for solution for infusion (called Iloprost Waymade in this information leaflet) contains an active substance called iloprost.

This medicine belongs to a group of medicines called platelet anti-aggregants.

Iloprost imitates a natural substance in the body called prostacyclin. Iloprost and prostacyclin inhibit undesired blocking or narrowing of blood vessels and allow more blood to circulate in your arteries.

Iloprost promotes the healing of ulcerations (superficial wounds on the skin or mucous membranes) that occur due to insufficient blood circulation, which thus fails to provide the right amount of oxygen (ischemia). Iloprost also alleviates pain in acute and chronic arterial circulation disorders.

What Iloprost Waymade is used for:
The treatment of advanced stage thromboangiitis obliterans (Buerger's disease), with severe circulation disorders, in cases where revascularisation (surgery intended to improve blood circulation in a given part of the body, is not indicated.

Thromboangiitis obliterans (Buerger's disease) is an inflammatory condition of the small and medium-size blood vessels in your extremities (hands and feet). Typical symptoms are pain in the feet and/or hands (claudication) caused by insufficient blood flow during physical activity, or pain in those areas when at rest.

2. What you need to know before using Iloprost Waymade

Do not use Iloprost Waymade:

- if you are allergic to iloprost or to any other ingredients of this medicine (listed in section 6).
- if you are at risk for haemorrhaging due, for example, to an active ulcer in your stomach or duodenum (the first section of your small intestine), trauma, intra-cranial haemorrhaging (inside your skull, the bone that protects your brain).
- if you have suspected accumulation of fluids in your lungs (pulmonary oedema). Some of the symptoms may be: shortness of breath, coughing up blood, and excessive sweating.

- if you have heart problems, such as:
    - a heart attack in the last six months;
    - serious arrhythmia;
    - poor blood circulation in the heart muscle (severe coronary disease or unstable angina). The symptoms may include chest pain;
    - heart weakness (de-compensated heart failure) and are not being closely monitored by your doctor.

Warnings and special precautions for use
Talk to your doctor or pharmacist before using Iloprost Waymade.

You should be especially cautious if any of the following conditions apply to you:
- if you urgently need an amputation
- if you smoke. It is strongly recommended that you stop smoking
- if you have serious kidney or liver problems
- if your blood pressure is low
- if you have significant heart disease, you should be carefully monitored (observed)
- if you have a significant heart disease and believe your disease is getting worse.

You should tell your doctor:
- if you suffer from dizziness when you stand up (orthostatic hypotension). You should stand up slowly in order to help your body become accustomed to its new position.
- if you are under 18 years of age. You should tell your doctor how old you are because very little is known about the use of this medicine in young people.

Do not let the Iloprost Waymade solution come into contact with your skin or eyes. When it comes into contact with your skin, Iloprost Waymade may cause persistent redness of the skin (erythema) but with no pain. If Iloprost Waymade comes into contact with your skin or eyes, you should immediately wash with copious amounts of water or saline solution. Do not drink Iloprost Waymade.

Other medicines and Iloprost Waymade

Tell your doctor or pharmacist if you are taking, or have recently taken, other medicines, including medicines obtained without a prescription and medicines containing plants.

You should especially tell your doctor if you are taking any of the following medicines:
- Medicines to treat high blood pressure or heart disease. Your blood pressure may decrease even further, in which case, your doctor will have to adjust your dose of Iloprost Waymade.

- Blood thinners or medicines that prevent blood coagulation, such as aspirin (or acetylsalicylic acid, frequently found in medicines to reduce fever or in pain relievers), heparin or anti-coagulants derived from coumarin. Your risk of haemorrhaging may increase. If you have haemorrhaging, treatment with Iloprost Waymade should be discontinued.

- Anti-inflammatory medicines, such as steroids (corticosteroids). The effect of Iloprost Waymade may be reduced.

Pregnancy and breast-feeding

Check with your doctor or pharmacist before taking any medicines.

Do not take this medicine:
- if you are pregnant, suspect that you are pregnant, or are planning to become pregnant. Talk to your doctor immediately.
- if you are breast-feeding or planning to breast-feed.

Effects on the ability to drive or use machines

There are no special precautions.

Iloprost Waymade contains

This medicinal product contains 4.050 mg of alcohol (96% ethanol) in each 1 ml. The amount in 1 ml of this medicinal product is equivalent to less than 1 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.
This medicinal product contains less than 1 mmol sodium (23 mg) per 1 ml, that is to say essentially 'sodium free'.'

3. How to use Iloprost

Use this medicine exactly as recommended by your doctor or pharmacist. Check with your doctor or pharmacist if you are not sure.

Your doctor or nurse should administer Iloprost Waymade at the hospital, under strict monitoring and using proper equipment.

Iloprost Waymade is administered by infusion into a vein.

Iloprost Waymade is to be administered daily for 6 hours. Treatment may last up to 4 weeks.

During the first 2 or 3 days, the dose will be adjusted according to your tolerance (how your body reacts to the medicine) between the values of 0,5 – 2,0 ng of iloprost/kg/min.

Your blood pressure and pulse will be taken when administration starts, and after each dose increase.

Patients with renal impairment, hepatic cirrhosis or on dialysis:
These patients require dose adjustment (e.g. reducing the dose by half).

If you feel that the effect of Iloprost Waymade is too strong or too weak, talk to your doctor.

If you use more Iloprost Waymade than you should

Your doctor will carefully calculate the amount of Iloprost Waymade to be administered. It is therefore quite unlikely that your doctor or nurse will administer an overdose of this medicine.
In case of an overdose, your doctor will discontinue the administration of Iloprost Waymade, monitor you, and treat your symptoms. The symptoms you may experience are: a drop in your blood pressure (hypotensive reaction), headache, reddening of the face (flushing), nausea, vomiting and diarrhoea. Other possible reactions are: increased blood pressure (hypertensive reaction), a slower or faster heartbeat, and pain in the limbs and back.

If you stop using Iloprost Waymade

If your treatment with Iloprost Waymade is discontinued, your doctor will take into consideration the doses of other medicines you are taking.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

As all medicines, this medicine may cause side effects, although not everyone gets them.

The means of action of Iloprost Waymade in the body (pharmacological action) also causes very common side effects, such as headache or vasodilation (dilation of your blood vessels) that cause flushing (redness) or gastrointestinal symptoms. These effects may occur while your dose is being adjusted, at the start of treatment, in order to identify the dose that the patient tolerates best. However, these side effects usually disappear quickly after dose reduction.

The following side effects were found in clinical trials (studies of the medicine in humans) and are listed by their frequency of occurrence:

Very common (may affect more than 1 person in 10):
- Nervous system disorders: headache.
- Vascular disorders: flushing (reddening of the face).
- Gastrointestinal disorders: nausea, vomiting.
- Cutaneous and subcutaneous tissue disorders: sudation (abundant sweating).

Common (may affect 1 in 10 people):
- Metabolism and nutrition disorders: loss of appetite.
- Psychiatric disorders: apathy (lack of emotion, motivation or enthusiasm).
- Nervous system disorders: dizziness, loss of balance, vertigo, tingling and paraesthesia (a tingling feeling, pressure, cold, hot), palpitations, increased sense of touch (hyperaesthesia), a burning sensation, restlessness, agitation, sedation, sleepiness.
- Cardiac disorders: reduced heart rate.
- Vascular disorders: low blood pressure.
- Gastrointestinal disorders: diarrhoea, abdominal distress, abdominal pain.
- Musculoskeletal and connective tissue disorders: jaw pain, lower jaw spasm (lockjaw), muscle pain, joint pain.
- General disorders and alterations at the site of administration: localised or generalised pain, increased body temperature, an overall hot sensation, weakness, a general sensation of feeling ill, chills, thirst, reactions at the injection site such as redness (erythema), pain in or inflammation of the vein.

Uncommon (may affect 1 in 100 people):
- Psychiatric disorders: anxiety, depression, hallucinations.
- Nervous system disorders: tremors, migraine, fainting or loss of consciousness for a short period of time (syncope).
- Eye disorders: blurry vision, cloudy vision, eye irritation, pain in the eyes.
- Cardiac disorders: irregular heartbeat (arrhythmia, extra-systoles), heart attack (myocardial infarction).
- Vascular disorders: decreased brain blood circulation (stroke, cerebrovascular ischemia), pain in the legs due to blood clotting in the blood vessels (deep vein thrombosis), blood coagulation in the lungs (pulmonary embolism).
- Respiratory, thoracic and mediastinal disorders: asthma.
- Gastrointestinal disorders: dyspepsia (pain or discomfort in the upper abdomen or chest), pain due to constipation (tenesmus), constipation (obstipation), burping (eructation), difficulty swallowing (dysphagia), diarrhoea with bloody stools (haemorrhagic diarrhoea), haemorrhaging of the rectum, dry mouth, altered sense of taste (palate).
- Hepatobiliary disorders: yellowing of the skin and/or itching due to liver disorders (jaundice).
- Cutaneous and subcutaneous tissue disorders: itching (pruritus).
- Musculoskeletal and connective tissue disorders: muscle spasms, cramps, increased muscle tension.
- Renal and urinary disorders: pain in the kidneys, pain when urinating, changes in the urine, difficulty urinating, urinary tract problems (urinary tract disorders).

Rare (may affect 1 in 1,000 people):
- Ear and labyrinth disorders: loss of balance due to vestibular disorders (in the part of the ear responsible for balance).
- Respiratory, thoracic and mediastinal disorders: cough.
- Gastrointestinal disorders: inflammation of the rectum (proctitis).

In addition to the above-mentioned side effects, the following have been reported: allergic reactions, states of confusion, accelerated heartbeat, and elevated blood pressure. Isolated cases of shortness of breath (dyspnoea) and individual cases of pulmonary oedema and heart failure in elderly patients with advanced-stage arteriosclerosis (thickening and hardening of the artery walls). Iloprost may cause chest pain due to angina, especially in patients with insufficient blood flow to the heart muscle (coronary disease).

Reporting side effects

If you get any side effects, talk to your doctor or, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Iloprost Waymade

This medicine does not require any special storage conditions.

Keep this medicine out of the sight and reach of children.

After opening and dilution
The physical and chemical stability of the solution prepared for infusion (diluted in saline solution or glucose solution) has been demonstrated in an assay of 6 hours at 25°C. From a microbiological point of view, this medicine should be used immediately. If not used immediately, the user will be responsible for period of time and conditions of use, which should normally not exceed 24 hours at a temperature of 2°C - 8°C, unless the dilution was prepared under controlled and validated aseptic conditions.

Do not use this medicine after the expiry date which is stated on the carton and ampoule label after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Package contents and other information

What Iloprost Waymade contains

The active substance is iloprost.
Each ampoule of 0.5 ml of solution contains 50 micrograms of active substance.
Each 1 ml of concentrate contains 100 micrograms of active substance.
The other ingredients are: trometamol, ethanol 96% (v/v), sodium chloride, hydrochloric acid and water for injection.

What Iloprost Waymade looks like and contents of the pack

Iloprost Waymade is a clear colourless solution, free of visible particles.

Iloprost Waymade is available in cartons containing 1, 5 or 20 glass ampoules, each with 0.5 ml concentrate for solution for infusion

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Waymade B.V.
Herikerbergweg 88,
1101CM Amsterdam,
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Manufacturer

Vianex S.A.
MetamorfosiTo Athina - Lamia N.r. (lamia)
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The following information is intended for medical and healthcare professionals only:

Instructions for use and handling
Iloprost Waymade must be administered only after dilution.
Only clear solutions free of particles should be used.
Given possible drug interactions, no other medicines should be added to the solution for infusion. The solution for infusion must be prepared daily in order to ensure it is sterile.

Instructions for dilution
The contents of the ampoule and the solvent must be thoroughly mixed. Depending on the method of infusion, there are two different dilutions for the ampoule. One of them is 10 times less concentrated than the other (0.2 µl/ml versus 2 µl/ml) and can only be used with an infusion pump (Infusomat, for example). In contrast, the solution with the higher concentration is to be administered using a bypass system (Perfusor, for example).

Dilution of Iloprost Waymade for use with an infusion pump:
The contents of one ampoule of 0.5 ml (50 µg) of Iloprost Waymade must be diluted in 250 ml of 5% saline solution or glucose solution. The infusion rate for a solution with a concentration of 0.2 µl/ml must be calculated according to the following table, so as to obtain a dose of between 0.5 and 2.0 ng/kg/min. Please be sure to check the patient's body weight and determine the infusion rate for the desired dose.

Body weight (kg)	Dose (ng/kg/min)			
	0.5	1.0	1.5	2.0
	Infusion rate (ml/h)			
40	6.0	12	18.0	24
50	7.5	15	22.5	30
60	9.0	18	27.0	36
70	10.5	21	31.5	42
80	12.0	24	36.0	48
90	13.5	27	40.5	54
100	15.0	30	45.0	60
110	16.5	33	49.5	66

Dilution of Iloprost Waymade for use with a bypass system:
The contents of one ampoule of 0.5 ml (50 µg) of Iloprost Waymade must be diluted in 25 ml of 5% saline solution or glucose solution. The infusion rate for a solution with a concentration of 0.2 µl/ml must be calculated according to the following table, so as to obtain a dose of between 0.5 and 2.0 ng/kg/min.

Please be sure to check the patient's body weight and determine the infusion rate for the desired dose.

Body weight (kg)	Dose (ng/kg/min)			
	0.5	1.0	1.5	2.0
	Infusion rate (ml/h)			
40	0.60	1.2	1.80	2.4
50	0.75	1.5	2.25	3.0
60	0.90	1.8	2.70	3.6
70	1.05	2.1	3.15	4.2
80	1.20	2.4	3.60	4.8
90	1.35	2.7	4.05	5.4
100	1.50	3.0	4.50	6.0
110	1.65	3.3	4.95	6.6