VEBULIS
Iloprost (as trometamol)

CONSUMER MEDICINE INFORMATION

WHAT IS IN THIS LEAFLET

Please read this leaflet carefully before you start using VEBULIS.

This leaflet answers some common questions about VEBULIS.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

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

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

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

WHAT VEBULIS IS USED FOR

VEBULIS is used to treat:
- Moderate or severe stages of pulmonary hypertension, caused by some defect of the vessel walls, connective tissue disease or other medications
- Moderate and severe cases of secondary pulmonary hypertension that may have been caused by blood clots in the lungs, where surgery is not possible

Pulmonary hypertension is a condition where blood pressure is too high in the vessels which transport blood from the heart to the lungs.
VEBULIS widens blood vessels, allowing more blood to reach the lungs and receive oxygen. This widening results in a decreased work load on the heart, which in turn allows the heart to function more effectively, leading to an improved supply of oxygen to the body and reduced strain on the heart.

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 USE VEBULIS

When you must not take it

Do not take VEBULIS if you have an allergy to:
- Iloprost, the active ingredient of VEBULIS
- 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

Do not take VEBULIS if you have any of the following conditions:
- Increased risk of bleeding (for example active stomach ulcers, injuries, haemorrhaging or other bleeding)
- Severe coronary heart disease or unstable angina (chest pain), heart attack within the last six months
- Heart failure, severe irregular heart rate, suspected fluid build-up in the lungs
- Stroke or other interruption of blood supply to the brain within the last 3 months
- Pulmonary hypertension due to the blockage of the veins
- Congenital or acquired valvular defects with heart function which are not related to your disease

If you suffer from pulmonary hypertension, avoid getting pregnant as pregnancy may lead to a worsening of your condition and may even endanger your life.

If there is the possibility that you may become pregnant, use reliable contraception from the time you start treatment and during treatment.

Tell your doctor straight away if you are pregnant, or think you might be.

The medicine should only be used during pregnancy if you doctor decides that the potential benefit outweighs the potential risk to the foetus.

Do not breast-feed if you are taking this medicine.

It is not known whether the medicine passes into human milk.

Do not use this medicine after the expiry date printed on the pack and blister.
The expiry date is printed on the carton and on each ampoule after "Expiry Date" (e.g. 1118 refers to November 2018). The expiry date refers to the last day of that month.
If it has expired return it to your pharmacist for disposal.

Do not use this medicine if the packaging is torn or shows signs of tampering.
If the packaging is damaged, return it to your pharmacist for disposal.

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.

Tell your doctor if you have or have had any of the following medical conditions:
- Heart failure
- Low blood pressure
- Lung infections or other lung disease including Chronic Obstructive Pulmonary Disease (COPD) and severe asthma
- Liver function problems, or problems with your kidneys that require dialysis

If you have a history of fainting in association with pulmonary hypertension; you should avoid any unusual straining, for example during exercise; if fainting occur when you get out of bed, it may be helpful to take the first dose of the day while you are still in bed; if fainting gets worse, tell your doctor.

If you have not told your doctor about any of the above, tell him/her before you start using VEBULIS.

VEBULIS is not recommended for use in children under 18 years of age.

Taking other medicines

Tell your doctor 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 VEBULIS may interfere with each other. These include:

- Medicines used to treat high blood pressure or heart disease
- Medicines which inhibit blood clotting or platelet aggregation [this includes Aspirin® or acetylsalicylic acid, warfarin, heparin, clopidogrel, NSAIDs, e.g. ibuprofen (Nurofen®), diclofenac (Voltaren®), as well as others]

These medicines may be affected by VEBULIS 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 and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

HOW TO USE VEBULIS

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

If you do not understand the instructions printed on the pharmacist label, ask your doctor or pharmacist for help.

Caution: VEBULIS solution should not come in contact with your skin or eyes; oral ingestion of VEBULIS solution should be avoided. During nebulisation sessions a facial mask must not be used. Only a mouthpiece should be used.

How much to use

The usual dose per inhalation that is right for you depends on your individual condition and will be worked out by your doctor.

How to use it

VEBULIS is taken as inhalation therapy using a special device (a nebuliser).

At the beginning of each inhalation session, a new ampoule of VEBULIS should be used. Break the ampoule and transfer the contents of one ampoule of VEBULIS completely into the nebuliser immediately before use.

VEBULIS is administered with a suitable inhalation device (nebuliser). Each inhalation session will usually last about 4 to 10 minutes.. Do not let VEBULIS solution come into contact with your skin or eyes. Do not drink or swallow VEBULIS solution. For the inhalation you should avoid facial mask and use a mouthpiece.

In patients with liver problems, severe kidney problems and require dialysis, your doctor may consider different initial doses and dosing intervals depending on how you tolerate the treatment.

How long to use it

Depending on your individual condition, you will have **6 to 9 inhalation sessions per day**. The duration of one inhalation session is about **4 to 10 minutes**.

The pulmonary vessel widening effect of VEBULIS is of short duration (one or two hours).

To minimise accidental exposure, it is recommended to use VEBULIS with nebulisers with a filter or inhalation-triggered systems, and to keep the room well ventilated. Your doctor will advise you on the

appropriate nebuliser to be used. Any additional instructions from the manufacturer of the nebulising device should also be followed carefully.

VEBULIS solution that is not used in one inhalation session has to be discarded.

If the effect of VEBULIS seems too strong or too weak, talk to your doctor or pharmacist.

How long to take it for
The duration of your treatment will be determined by your specialist.

IN CASE OF OVERDOSE

If you take too much (overdose)
This may lead to dizziness, headache, flushing (reddening of the face), nausea (feeling sick), jaw pain or back pain. You may also experience an increase or decrease in blood pressure, slow heartbeat, fast heartbeat, vomiting, diarrhoea or limb pain.

Have someone contact a doctor immediately in these cases and mention that you are taking iloprost. Please be sure to tell your doctor if you have problems with these side effects. The doctor will need to monitor your condition and possibly administer appropriate therapy.

Interruption of inhalation is recommended in this case.

Immediately telephone your doctor, or the Poisons Information Centre (New Zealand: 0800 POISON or 0800 764 766), or go to the Accident and Emergency department at your nearest hospital. Do this even if there are no signs of discomfort or poisoning. Urgent medical attention may be needed.

WHILE YOU ARE USING VEBULIS

Things you must do
Tell any other doctors, dentists or pharmacists who are treating you that you are taking VEBULIS.

If you are about to be started on any new medicine tell your doctor, dentist or pharmacist that you are taking VEBULIS.
If you become pregnant while taking this medicine, tell your doctor immediately.

Things you must not do
Do not take VEBULIS to treat any other complaints unless your doctor tells you to.
Do not give VEBULIS to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.
If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

Things to be careful of
Do not drive or operate any tools or machines if you sense low blood pressure or dizziness occurring; the ability to properly drive or operate machines might be seriously affected.

SIDE EFFECTS

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

This medicine helps most people, 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 attention if you get some of the side effects.

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

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

Tell your doctor or pharmacist if you notice any of the following and they worry you.

The list below includes the most common side effects of your medicine seen.

- widening of blood vessels (this may cause flushing, that is, a reddening of the face)
- bleeding (mostly nosebleed or coughing up of blood); some serious cases of bleeding have been reported
- chest pain
- headache
- increased cough
- nausea and vomiting
- pain in jaw or spasm of the jaw muscles (difficulty in opening the mouth)
- pain when swallowing
- fast or irregular heartbeat
- low blood pressure
- dizziness
- diarrhoea
- rash
- back pain
- swelling, usually in the legs
- mouth and tongue irritation (including pain)
- throat irritation
- breathlessness
- nasal congestion (stuffy nose)
- fainting is a common symptom of the illness itself, but can also occur under therapy

You should tell your doctor immediately if you have any of the following:
Hypersensitivity, shortness of breath, wheezing.

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

AFTER USING VEBULIS

Storage
Keep VEBULIS in a cool dry place where the temperature stays at or 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.

Disposal
If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.
Return any unused medicine to your pharmacist.

PRODUCT DESCRIPTION

What it looks like

VEBULIS comes as a colourless, clear, visible particle free solution in 3 mL, colourless, Type I glass ampoules with two coded rings coloured pink and white and is administered as an aerosol by using a special inhalation device.

Each VEBULIS ampoule contains 2 mL of solution for 1 inhalation session. A pack of VEBULIS contains 30 ampoules.

Ingredients

Active ingredient:

Each 2 mL VEBULIS ampoule solution contains 20 microgram iloprost (as trometamol).

It also contains:

- Trometamol
- Ethanol
- Sodium chloride
- Hydrochloric acid
- Water for injections

Sponsor

DEVATIS LIMITED
Findex, 173 Spey Street,
Invercargill 9810,
New Zealand
Toll Free Number: 0800 887750
www.devatis.nz

Date of preparation

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THE FOLLOWING INFORMATION IS INTENDED FOR HEALTHCARE PROFESSIONALS ONLY

Incompatibilities
In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

Special precautions for disposal and other handling
Any unused material should be disposed according to local disposal regulations.

For each inhalation session the content of 1 opened ampoule of VEBULIS has to be transferred completely into the medication chamber immediately before use.

After each inhalation session, any solution remaining in the nebuliser should be discarded. In addition, instructions for hygiene and cleaning of the nebulisers provided by the device manufacturers should be followed carefully.

Use with nebulisers:
In general suitable nebulisers to be used for the inhalation therapy with VEBULIS are registered according to the regional medical device regulations and work with compressed air technology.

Nebulisers suitable for inhalation of VEBULIS fulfil the following requirements:
The nebulising devices deliver 2.5 mcg or 5 mcg iloprost at the mouthpiece in a time period of approximately 4 to 10 minutes. The Mass Median Aerodynamic Diameter (MMAD) of the aerosol is between 1 and 5 micrometer.

Following nebulisers have been tested and found appropriate for the application of VEBULIS:
- HaloLite AAD (Philips Respironics)

To minimize accidental exposure, it is recommended to use VEBULIS with nebulisers with inhalation-triggered systems and to keep the room well ventilated. Patients stabilized on one nebuliser should not switch to another nebuliser without supervision by the treating physician.