PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed according to a physician's prescription only

Ventolin Injection

Solution for injection

Each 1 ml ampoule contains the active ingredient:

salbutamol (as sulfate) 0.5 mg

For the list of the inactive and allergenic ingredients in the medicine, see section 2 – "Important information about some of the ingredients in the medicine" and section 6 – "Additional information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Ventolin Injection is indicated in adults and is used for the relief of severe bronchospasm.

Ventolin Injection provides short-acting (4-6 hour) bronchodilation with a fast onset (within 5 minutes) in reversible airways obstruction.

Therapeutic group: selective beta-2 adrenoceptor agonist.

Ventolin Injection contains the active ingredient salbutamol, which belongs to a group of medicines called bronchodilators.

- Bronchodilators help the airways in your lungs to stay open. This makes it easier for air to get in and out.
- They help to relieve chest tightness, wheezing and cough.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

• you are sensitive (allergic) to salbutamol sulfate or to any of the additional ingredients contained in this medicine (listed in section 6).

Do not use Ventolin Injection if you think what is described above applies to you. If you are not sure, consult your physician or pharmacist before using Ventolin Injection.

Special warnings regarding use of the medicine

Before the treatment with Ventolin Injection, tell the physician if:

• you have high blood pressure.
• you are diabetic.
• you have an overactive thyroid gland.
• you have a history of heart problems such as an irregular or fast heartbeat or angina.
• you are taking xanthine derivatives (such as theophylline) or steroids to treat asthma.
• you are taking water tablets (diuretics), sometimes used to treat high blood pressure or a heart condition.
• you have taken other drugs used to relieve stuffy nose (such as ephedrine or pseudoephedrine) or other medicines used to treat asthma.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the physician or pharmacist. Especially tell your physician or pharmacist if you are taking:

• medicines for an irregular or fast heartbeat (especially from the beta blocker group such as propranolol).
• other medicines for your asthma.

Ventolin Injection should not be administered in the same syringe as any other medication.

Using this medicine and food

You can use Ventolin Injection at any time of day, with or without food.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your physician for advice before using this medicine.

Driving and using machines

Ventolin Injection is not likely to affect you being able to drive or use any tools or machines.

Important information about some of the ingredients in the medicine

This medicine contains less than 1 mmol sodium (23 mg) per 5 ml ampoule, that is to say essentially sodium-free.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the physician's instructions. Check with the physician or pharmacist if you are uncertain about the preparation dosage and treatment regimen.

The dosage and treatment regimen will be determined by the physician only.

How your injection is given

Ventolin Injection is usually given to you by a physician or nurse. It can be given under the skin (subcutaneously [S.C.]) or directly into a vein or muscle (intravenous [I.V.] or intramuscular route [I.M.]).

You will never be expected to inject yourself with this medicine. It will always be given to you by a person who is qualified to do so.

The ampoules are equipped with the OPC (One Point Cut) opening system and must be opened using the following instructions:

- hold with one hand the bottom part of the ampoule.

- put the other hand on the top of the ampoule positioning the thumb above the coloured point and press.

Subcutaneous (S.C.) or intramuscular (I.M.) route

- The usual dose is 8 mcg per kg body weight every 4 hours.

Slow intravenous (I.V.) injection

- The usual dose is 4 mcg per kg body weight.
- This will be injected slowly and may be repeated if necessary.
- Ventolin Injection may be diluted with 10 ml Water for Injection.
- 5 ml of the diluted preparation (250 mcg per 5 ml) may be administered by slow intravenous injection.

Do not exceed the recommended dose.

If you accidentally have taken a higher dosage

Ventolin Injection will always be given under carefully controlled conditions.
However, if you think that you have been given an overdose of Ventolin Injection, tell your physician or nurse as soon as possible. The following effects may happen:

- your heart beating faster than usual.
- you feel shaky.
- hyperactivity.
- acid build up in your body which may cause your breathing to become faster.

These effects usually wear off in a few hours.
If you have taken an overdose or if a child has accidentally swallowed some medicine, immediately see a physician or go to a hospital emergency room and bring the medicine package with you.

If you stop taking the medicine

Do not stop taking the medicine without consulting your physician.

Adhere to the treatment regimen recommended by your physician.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Ventolin Injection may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

The following side effects may happen with this medicine:

Allergic reactions (may affect **less than 1 in 10,000** people):
If you have an allergic reaction, stop using Ventolin Injection and contact a physician straight away.
Signs of an allergic reaction include: swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, itchy rash, feeling faint and light headed, and collapse.

Contact your physician as soon as possible if:

- you feel your heart is beating faster or stronger than usual (palpitations). This is usually harmless, and usually stops after you have used the medicine for a while.
- you may feel your heartbeat is uneven or it gives an extra beat.
- These may affect **less than 1 in 10** people.

If any of these happen to you, contact your physician as soon as possible. **Do not stop using this medicine unless told to do so.**

Tell your physician if you have any of the following side effects, which may also happen during use of this medicine:

Very common side effects
These may affect **more than 1 in 10** people:

- feeling shaky.

Common side effects

These may affect **up to 1 in 10** people:

- headache
- muscle cramps.

Rare side effects

These may affect **up to 1 in 1,000** people:

- a low level of potassium in your blood.
- increased blood flow to your extremities (peripheral dilatation).

Very rare side effects

These may affect **up to 1 in 10,000** people:

- changes in sleep patterns and changes in behaviour, such as restlessness and excitability.

The following side effects can also happen but the frequency of these are not known:

- stinging or pain when the injection is given directly into the muscle.
- feeling sick and being sick (nausea and vomiting).
- chest pain, due to heart problems such as angina. Tell your physician, nurse or pharmacist if this occurs. Do not stop using this medicine unless told to do so.
- a condition known as lactic acidosis which may cause stomach pain, hyperventilation, shortness of breath, cold feet and hands, irregular heartbeat or thirst.

If you think this medicine is not working well enough for you

If your medicine does not seem to be working as well as usual, contact your physician as soon as possible.

Your chest problem may be getting worse and you may need a different medicine. Do not take an additional dose of Ventolin Injection unless your physician instructs you to.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the physician.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il/

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store below 30˚C.
- Keep the ampoules in the outer carton to protect from light.
- Discard 24 hours after preparation.
- If you are told to stop using this medicine, return any unused Ventolin Injection to your pharmacist to be destroyed.
- Do not discard medicines in the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

- In addition to the active ingredients, the medicine also contains:
  Sodium chloride, sodium hydroxide, dilute sulfuric acid, water for injection, nitrogen.
- What the medicine looks like and the contents of the package:
  The carton includes 5 glass ampoules (each ampoule contains 1 ml) in a plastic tray. 5 ml contains 2.5 mg of salbutamol (as sulfate) in sterile normal saline adjusted to pH 3.5.

• License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
• Manufacturer: GlaxoSmithKline Manufacturing S.P.A, Parma, Italy.
• Registration number of the medicine in the National Drug Registry of the Ministry of Health: 027-64-21556-05.

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