

Package leaflet: Information for the patient

Asmalat Syrup 2 mg/5 ml

Salbutamol sulphate

Read all of this leaflet carefully before you start using 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, consult your doctor or pharmacist.

- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

- If you get any side effects, consult your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Asmalat syrup is and what it is used for.
2. What you need to know before you take Asmalat syrup.
3. How to take Asmalat syrup.
4. Possible side effects.
5. How to store Asmalat syrup.
6. Contents of the pack and other information.

1. What Asmalat syrup is and what it is used for

Asmalat syrup contains a medicine called salbutamol. This 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.

Asmalat syrup is used to treat breathing problems in people with asthma and similar conditions. The syrup is used when children and adults cannot use an inhaler device.

2. What you need to know before you take Asmalat syrup

Do not take Asmalat syrup:

- If you are allergic (hypersensitive) to salbutamol sulphate or any of the other ingredients of Asmalat syrup (listed in section 6)
- If the above applies to you, do not take Asmalat syrup and consult your doctor.

Warnings and precautions

Consult your doctor or pharmacist before taking this medicine.

Take special care with Asmalat syrup:

- if you have high blood pressure
- if you are diabetic
- if you have an overactive thyroid gland
- if you have a history of heart problems such as an irregular or fast heartbeat or angina

If any of the above applies to you, consult your doctor or pharmacist.

Other medicines and Asmalat syrup

Please consult your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular consult your doctor or pharmacist if you are taking:

- Medicines for irregular or fast heartbeat
- Other medicines for your asthma.

Asmalat syrup with food and drink

You can take Asmalat syrup with or without food at any time of day.

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 doctor or pharmacist for advice before taking this medicine.

Driving and using machines

This medicine is not likely to affect your ability to drive or use any tools or machines.

3. How to take Asmalat syrup

Always take this medicine exactly as your doctor has told you. You should check with your doctor if you are not sure.

Taking this medicine

- Use the 5 ml plastic spoon provided with the medicine to take the syrup.
- Shake well before use.
- 2.5 ml of undiluted syrup provides a dose of 1 mg and 5 ml provides a dose of 2 mg of salbutamol.

Children between 2 and 6 years

- The usual dose is 2.5 ml to 5 ml (1/2 to 1 teaspoonful), three or four times a day.

Children between 6 and 12 years

- The usual dose is 5 ml (1 teaspoonful), three to four times a day.

Children over 12 years

- The usual dose is 5 ml to 10 ml (1 to 2 teaspoonfuls), three or four times a day.

Adults (over 18 years)

- The usual dose is 5 ml to 20 ml (1 to 4 teaspoonfuls), up to four times a day.

Elderly (over 65 years)

- The usual dose is 5 ml (1 teaspoonful), up to three times a day.

If you take more Asmalat syrup than you should

If you take more than you should, consult your doctor immediately.

The following effects may happen:

- Your heart beating faster than usual
- You feel shaky

These effects usually wear off in a few hours.

If you forget to take Asmalat syrup

If you forget to take a dose of this medicine, take it as soon as you remember and then take the next dose at its usual time. If it is almost time for your next dose you should simply take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Asmalat syrup

Do not stop taking this medicine without consulting your doctor.

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

4. Possible side effects

Like all medicines this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Allergic reactions

If you have an allergic reaction, stop taking Asmalat syrup and see a doctor 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.

Consult your doctor 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.

If any of these happen to you, consult your doctor as soon as possible.

Do not stop taking this medicine without consulting your doctor.

Consult your doctor if you have any of the following side effects which may also happen with this medicine:

Very common

- feeling shaky.

Common

- headache, muscle cramps.

Rare

- changes in the salt balance of your body, a low level of potassium in your blood, increased blood flow to your extremities (peripheral dilatation).

Very rare

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

Unknown

- chest pain, due to heart problems such as angina.

If you get any side effects, consult your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Asmalat syrup

- Keep this medicine out of the sight and reach of children.
- Do not use Asmalat syrup after the expiry date which is stated on the blister and outer packaging. The expiry date refers to the last day of that month.
- Store below 30°C.
- Protect from light.
- Wipe the neck of the bottle after use.
- Do not use any Asmalat syrup pack that is damaged.
- Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Asmalat syrup contains

The active substances in Asmalat syrup is salbutamol sulphate.

- Asmalat syrup 2 mg/5 ml syrup: each 5 ml contains 2 mg of salbutamol.

The other ingredients are: water, propylene glycol, citric acid, sodium saccharine, sorbitol, sodium benzoate (E211) and caramel flavour.

Asmalat syrup is alcohol and sugar free.

What Asmalat syrup looks like and contents of the pack

Asmalat syrup comes in a glass bottle. Each bottle contains 150 ml of syrup.

Marketing Authorisation Holder and Manufacturer

Pharmaline s.a.l.- Lebanon.

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Registration N° Lebanon: 28556/93

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Council of Arab Health Ministers

Union of Arab Pharmacists

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