

Package leaflet: Information for the user

Vifex Syrup

Salbutamol sulphate, Bromhexine hydrochloride & Guaifenesin Syrup

Read this leaflet carefully before you start taking this medicine.

- 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 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, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

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

1. What Vifex Syrup is and what it is used for

Vifex Syrup is bronchodilator and mucolytic which is used to treat lung diseases associated with cough. The medicine has four active ingredients. Salbutamol that dilates bronchi; bromhexine that decreases viscosity of sputum; guaifenesin that helps loosen and clears bronchial passages of thickened mucus and aids expectoration; and menthol that gives a soothing relief to irritated and inflamed respiratory tissues.

2. What you need to know before you take Vifex Syrup

Do not take Vifex Syrup

- if you are allergic to salbutamol sulphate, bromhexine hydrochloride & guaifenesin or any of the other ingredients of this medicine (listed in Section 6)
- if you unexpectedly go into early labour (premature labour) or threatened abortion.

Warnings and precautions

Talk to your doctor, nurse or pharmacist before taking Ventolin Syrup 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.

Other medicines and Vifex syrup

Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines. Remember to take this medicine with you if you have to go to hospital. In particular, tell your doctor, nurse or pharmacist if you are taking:

- medicines for an irregular or fast heartbeat
- other medicines for your asthma.
- Paracetamol (Used treat fever)
- Anaesthetic agents such as chloroform, cyclopropane, halothane and other halogenated agents (used to control pain during surgery)

Pregnancy and breast-feeding

If you are pregnant, may be pregnant or are breast-feeding, then consult your physician before taking Vifex syrup. it is preferable to avoid the use of this syrup during pregnancy

Safety of Vifex Syrup in pregnancy and breast-feeding has not been established. You should inform your doctor if you are planning to become pregnant

Ask your doctor or pharmacist for advice before taking any medicine.

3. How to take Vifex Syrup

Always take Vifex Syrup exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- *Adults:*
10 ml (2 teaspoons) to be taken thrice daily
- *Children:*
6-12 years –5-10 ml (1-2 teaspoons) to be taken thrice daily
Below 6 years – 5 ml (1 teaspoon) to be taken thrice daily

4. Possible side effects

Like all medicines, Vifex Syrup can cause side effects, although not everybody gets them. VIFEX Syrup may cause:

Very common

- Tremor

Common

- Headache.
- Tachycardia
- Palpitations.
- Muscle cramps

Uncommon

- Abdominal pain upper
- Nausea
- Vomiting
- Diarrhoea

Rare

- Hypersensitivity reactions
- Hypokalaemia.
- Rash,
- Urticaria
- Cardiac arrhythmias including atrial fibrillation, supraventricular tachycardia and extrasystoles
- Peripheral vasodilatation

Very rare

- Hyperactivity.
- Feeling of muscle tension.

Not known (Frequency estimation is not possible as the adverse drug reaction did not occur in a clinical trial database)

- Anaphylactic reactions including anaphylactic shock, angioedema and pruritus
- Bronchospasm
- Severe cutaneous adverse reactions (including erythema multi-forme, Stevens-Johnson syndrome/toxic epidermal necrolysis and acute generalized exanthematous pustulosis)
- Myocardial ischaemia

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Vifex Syrup

Keep away from the reach of children.

Store in a dry place, below 30°C. Protect from light.

Do not use Vifex Syrup after the expiry date that is stated on the outer packaging.

6. Contents of the pack and other information

Each 5 ml contains:

Salbutamol sulphate BP equivalent to Salbutamol BP 1 mg
Bromhexine hydrochloride BP 2 mg

Guaifenesin BP50 mg

Flavoured Mentholated syrup base

- The other ingredients are: Citric acid monohydrate (BP), sodium citrate (BP), sodium benzoate (BP), propylene glycol (BP), glycerol (BP), liquid glucose (USP), sucrose (USP), aspartame (USP), sorbitol solution 70% (BP), Raspberry sweet flavor (In House), sunset yellow colour (In House), chloroform (BP) and Purified water (BP).

What Vifex Syrup looks like and contents of the pack:

100 ml syrup is filled in an amber colored Polyethylene Terephthalate (PET) bottle and the bottle is sealed with a cap. One measuring cup is placed on the bottle. Each bottle is packed in a printed carton along with a leaflet.

Marketing Authorization Holder

Emcure Pharmaceuticals Limited Bhosari, India

Manufacturer:

Emcure Pharmaceuticals Limited.