

Package leaflet: Information for the user

Cinfahelix syrup

Dry extract of *Hedera helix L* (ivy)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See Section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

What is in this leaflet

1. What Cinfahelix is and what it is used for
2. What you need to know before you take Cinfahelix
3. How to take Cinfahelix
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1. What Cinfahelix is and what it is used for

Cinfahelix is a plant-based medicinal product used as an expectorant for a productive cough in adults, adolescents and children aged over 2 years.

2. What you need to know before you take Cinfahelix

Do not take Cinfahelix:

- If you are allergic to ivy (*Hedera helix L.*), to plants in the Araliaceae family or any of the other ingredients of this medicine (listed in section 6).

Do not administer this medicine to children aged under two years as there is a risk that respiratory symptoms may worsen.

Warnings and precautions

Talk to your doctor or pharmacist before taking Cinfahelix.

Consult your doctor or pharmacist in cases of dyspnoea (difficulty breathing), fever or purulent sputum.

Concomitant use with other antitussives such as codeine or dextromethorphan is not recommended without previous medical consultation.

Caution is recommended in patients with gastritis or gastric ulcer.

If symptoms worsen or there is no improvement 7 days after starting the treatment, stop the treatment and consult your doctor.

Children

In children aged between 2 and 4 years with persistent or recurrent cough, a medical diagnosis is required before starting treatment.

Use in patients with renal and/or hepatic impairment:

If you suffer from kidney or liver failure, consult your doctor or your pharmacist before taking Cinfahelix. There are no data for the recommendation of doses in these patients.

Other medicines and Cinfahelix

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

There have been no interactions reported of *Hedera helix* with other medicines or other forms of interaction.

Pregnancy, breast-feeding and fertility

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.

Pregnancy:

There are no adequate, well-controlled studies in pregnant women so its administration is not recommended.

Breast-feeding:

There is no information on whether the components of this medicinal product pass into maternal milk, so its administration to women during the lactation period is not recommended.

Driving and using machines

No studies have been performed on the effects on the ability to drive and use machines.

Cinfahelix contains sorbitol. If you have been told by your doctor that you are intolerant to certain sugars, please talk to your doctor before taking this medicine.

3. How to take Cinfahelix

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults and adolescents aged over 12 years: 4 ml of syrup, 2 or 3 times a day (equivalent to 66-99 mg daily of dry extract of ivy leaf).

Children aged 6 to 12 years: 4 ml of syrup, twice a day (equivalent to 66 mg daily of dry extract of ivy leaf).

Children aged 2 to 5 years: 2 ml of syrup, twice a day (equivalent to 33 mg daily of dry extract of ivy leaf).

In children aged between 2 and 4 years with persistent or recurrent cough, a medical diagnosis is required before starting treatment.

Children under 2 years of age: Cinfahelix must not be administered to children aged under 2 years as there is a risk that respiratory symptoms may worsen.

If you think the effects of Cinfahelix are too strong or too weak, tell your doctor or pharmacist.

Cinfahelix is taken orally. Shake the bottle well before using. To ensure you always take the recommended dose, use the dosing cup included, which has graduations of 1 ml, 2 ml, 2.5 ml, 4 ml and other measurements up to 20 ml.

You must talk to a doctor if you do not feel better or if you feel worse after a week of treatment.

If you take more Cinfahelix than you should

If you have taken more Cinfahelix than you should or in case of overdose or accidental ingestion, notify your doctor or pharmacist immediately, specifying the medicine and the amount ingested.

Taking amounts larger than those recommended can cause nausea, vomiting, diarrhoea and restlessness.

If you forget to take Cinfahelix

Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common (may affect between 1 and 10 people in every 100 patients): reactions of the gastrointestinal system have been reported such as nausea, vomiting or diarrhoea.

Uncommon (may affect between 1 and 10 people in every 1,000 patients): allergic reactions have been reported such as urticaria, skin rash, red cheeks (erythema), shortness of breath (dyspnoea).

If you notice any of the aforementioned adverse effects, stop taking the medicinal product and consult your physician.

If you notice symptoms of allergy (hypersensitivity), stop taking Cinfahelix.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cinfahelix

Keep this medicine out of the sight and reach of children.
Do not store above 30°C.

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

Once the bottle has been opened, it expires after 3 months. Remember to note the date of opening on the packaging of the medicinal product.

After the bottle is first opened, do not store above 25°C.

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. Contents of the pack and other information

What Cinfahelix contains

1 ml of Cinfahelix syrup (equivalent to 1.18 g) contains 8.25 mg of dry extract of *Hedera helix L.*, leaf (ivy leaves) (4-8:1), extraction solvent: ethanol 30% m/m.

- The active substance is: dry extract of *Hedera helix L.* leaf.
- The other ingredients are: Non-crystallisable liquid sorbitol, xanthan gum, potassium sorbate, anhydrous citric acid, purified water.

What Cinfahelix looks like and contents of the pack

Cinfahelix comes in 100-ml brown glass bottles with a high-density polyethylene screw cap.

The dosing device is a dosing cup with a graduation of 1 ml, 2 ml, 2.5 ml, 4 ml and other measurements up to 20 ml.

Marketing Authorisation Holder and Manufacturer

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This is a Medicament

- 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 the experts in medicines, their 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.
- Keep all medicaments out of reach of children.

**Council of Arab Health Ministers
Union of Arab Pharmacists**