

Package leaflet: Information for the patient

Hedelix cough syrup

Active substance: ivy leaves soft extract

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.

What is in this leaflet

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

1. What Hedelix cough syrup is and what it is used for

Hedelix cough syrup is a herbal medicinal product for use in common colds affecting the respiratory tract. You must talk to a doctor if you do not feel better after 7 days or if you feel worse.

Hedelix cough syrup is used to treat common colds affecting the airways, for alleviation of symptoms in chronic inflammatory bronchial diseases. If symptoms persist for prolonged periods or if laboured breathing, fever or expectoration of purulent or bloody sputum occur, please consult a doctor without delay.

2. What you need to know before you take Hedelix cough syrup

Do not take Hedelix cough syrup

- if you are allergic to the active substance or any of the other ingredients of this medicine (listed in section 6)
- if you have argininosuccinate synthetase deficiency (a metabolic disorder of the urea cycle)

Warnings and precautions

Talk to your doctor or pharmacist before taking Hedelix cough syrup.

Concomitant use with antitussives such as codeine or dextromethorphan is not recommended without medical advice.

Other medicines and Hedelix cough syrup

No known interactions.

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

Hedelix cough syrup with food, drink and alcohol

No special precautions are necessary.

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.

This medicinal product should not be used without medical advice as there are insufficient data available from studies.

Driving and using machines

No special precautions are necessary.

Hedelix cough syrup contains sorbitol.

Please take Hedelix cough syrup only after you have consulted your doctor if you know that you suffer from intolerance to certain types of sugar.

3. How to take Hedelix cough syrup

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:

Adolescents over the age of 10 year, adults and elderly:

5 ml syrup three times daily

Children aged 4 - 10 years:

2.5 ml syrup four times daily

Children aged 1 - 4 years:

2.5 ml syrup three times daily

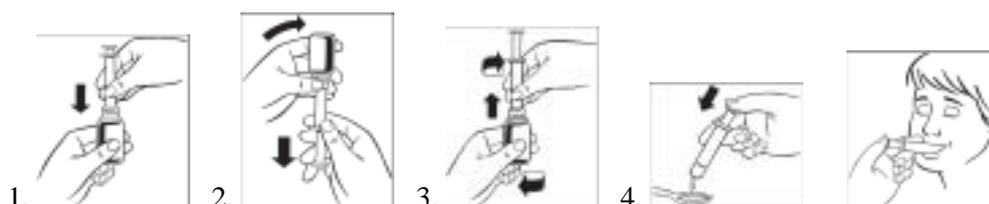
Infants aged 0 – 1 year:

2.5 ml syrup once daily

For exact dosing a dosing syringe is included to this medicinal product.

How to use the dosing syringe:

For the exact dosing a measuring scale is printed on the syringe.



1. Stick the dosing syringe together with the open bottle. Push it softly in the bottle until it is fixed. The plunger has to be in the syringe at that time.

2. Turn the bottle carefully upside down and draw up the liquid softly by drawing the plunger to the selected dosing mark.
3. Reverse the bottle and draw out the syringe by a soft rotation. Close the bottle after taking the dosage.
4. The syrup may be taken directly by emptying the syringe in the mouth towards the cheek or by using a spoon.
5. After taken the dosage clean the single parts of the syringe and dry them.

Method of administration

For oral use

Please take the syrup undiluted and ensure that you drink sufficient fluid (preferably drinking water) afterwards.

Duration of use

Do not take Hedelix cough syrup for more than a few days unless advised by a doctor. See also the section 1 “What Hedelix cough syrup is and what it is used for”.

If you have the impression that the effect of Hedelix cough syrup is too strong or too weak, please contact your doctor or pharmacist.

If you take more Hedelix cough syrup than you should

If you mistakenly take one or two individual doses more than you should, this is unlikely to result in any harmful effects. However, if you take much larger quantities than this, you may experience nausea, vomiting and diarrhoea. In this case, you should contact a doctor.

If you forget to take Hedelix cough syrup

Do not take a double dose to make up for a forgotten dose. Continue to take the medicine as instructed by your doctor or as described in this leaflet.

4. Possible side effects

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

Possible side effects:

Uncommon (may affect up to 1 of 100 people):

Gastric symptoms might occur (nausea, vomiting, diarrhoea) in sensitive persons.

Very rare (may affect 1 of 10,000 people):

Allergic reactions (breathlessness, tumescences, erythema, itches) might occur after the ingestion of ivy-containing drugs.

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

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. You can also report side effects directly via the Bundesinstitut für Arzneimittel und Medizinprodukte, Abt. Pharmakovigilanz, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, Website: www.bfarm.de. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Hedelix cough syrup

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and the label after “Exp”:
The expiry date refers to the last day of that month.

Storage conditions:

This medicinal product does not require any special storage conditions.

Information on shelf life after first opening of the container:

After first opening of the container Hedelix cough syrup can be used for 6 months.

6. Contents of the pack and other information

What Hedelix cough syrup contains

The active substance is ivy leaves soft extract

100 ml syrup contains 0.8 g soft extract of Hedera helix L., folium (ivy leaves) (2.2 – 2.9:1). The extraction solvents are ethanol 50 % V/V and propylene glycol (98:2 m/m).

The finished product contains no alcohol (ethanol).

The other ingredients are:

Macrogolglycerol hydroxystearate, star anise oil, hydroxyethylcellulose, sorbitol liquid (non crystallising), propylene glycol, glycerol, purified water.

What Hedelix cough syrup looks like and contents of the pack

Hedelix cough syrup is a clear, yellowish-brown solution.

Hedelix cough syrup is available in packs with 100 ml and 200 ml.

Marketing Authorisation Holder and Manufacturer

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This leaflet was last revised in August 2015.

Further information

Hedelix cough syrup contains no sugar or alcohol. It is therefore suitable for patients who must avoid alcohol and diabetics.

As Hedelix cough syrup contains plant extracts, the preparation may occasionally exhibit cloudiness, formation of a precipitate and/or slight variations in taste.