

Package leaflet: Information for the patient

Hedelix s.a.
oral drops, solution
Extract of ivy leaves

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 a few days.

What is in this leaflet

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

1. What Hedelix s.a. is and what it is used for

Hedelix s.a. 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 s.a. is used to treat common colds affecting the airways, for alleviation of symptoms in chronic inflammatory bronchial diseases.

2. What you need to know before you take Hedelix s.a.

Do not take Hedelix s.a.:

- if you are allergic (hypersensitive) to ivy leaves, menthol or any of the other ingredients of Hedelix s.a.
- if you have argininosuccinate synthetase deficiency (a metabolic disorder of the urea cycle)

For infants and children of less than 2 years of age, other preparations are available.

Warnings and precautions

Talk to your doctor or pharmacist before taking Hedelix s.a..

With continuing discomfort or with apnoea, fever as well as with purulent or bloody sputum, a physician should be consulted immediately.

Other medicines and Hedelix s.a.

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

No known interactions.

Hedelix s.a. with food, drink and alcohol

No special precautions are necessary.

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.

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.

3. How to take Hedelix s.a.

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 10 years or older	31 drops, 3 times daily
Children aged 4 to 10 years	21 drops, 3 times daily
Children aged 2 to 4 years	16 drops, 3 times daily

Method of administration

For oral use

Hedelix s.a. is used with a sufficient amount of water.

Duration of use

If the symptoms persist longer than one week during the use of the medicinal product, a doctor or a pharmacist should be consulted.

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

If you take more Hedelix s.a. than you should

If you take a larger amount of this medicinal product as you should, please contact your doctor. He is able to decide about necessary measures. Below-mentioned side effects may accumulate.

If you forget to take Hedelix s.a.

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.

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 medicinal products.

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 s.a.

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 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 s.a. can be used for 6 months.

6. Contents of the pack and other information

What Hedelix s.a. contains

The active substance is extract of ivy leaves.

1 ml (= 31 drops) contains: 40 mg soft extract from *Hedera hedelix* 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 other ingredients are propylene glycol, glycerol, flavouring: star-anise oil, eucalyptus oil, menthol, peppermint oil (aroma).

The finished product contains no alcohol.

What Hedelix s.a. looks like and contents of the pack

Hedelix s.a. is a clear greenish-brown, viscous solution with an aromatic odour.
Hedelix s.a. is available in packs with 20 ml, 50 ml and 100 ml drops.

Marketing Authorisation Holder and Manufacturer

Krewel Meuselbach GmbH
Krewelstrasse 2
D-53783 Eitorf
Germany
Tel.: +49 (0) 2243 / 87-0
Fax: +49 (0) 2243 / 87-175
E-mail: info@krewelmeuselbach.de

This leaflet was last revised in August 2015.

Further information

Hedelix s.a. is free of sugar and alcohol and therefore suitable for diabetics and patients who have to avoid alcohol.

As Hedelix s.a. contains plant-extracted substances, sediment may form in the bottle, the sediment will cause turbidity of the fluid and the taste may change a little bit.