

Package leaflet: Information for the user
Strepsils Herbal Chesty Cough syrup
ivy leaf dry extract

Read all of this leaflet carefully before you start using 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 has 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 Strepsils Herbal Chesty Cough syrup is and what it is used for
2. What you need to know before you take Strepsils Herbal Chesty Cough syrup
3. How to take Strepsils Herbal Chesty Cough syrup
4. Possible side effects
5. How to store Strepsils Herbal Chesty Cough syrup
6. Contents of the pack and other information

1. What Strepsils Herbal Chesty Cough syrup is and what it is used for

Strepsils Herbal Chesty Cough syrup is a traditional herbal medicine containing ivy leaf dry extract used as an expectorant in case of productive cough, exclusively based upon long-standing use.

Strepsils Herbal Chesty Cough syrup is indicated in adults and adolescents from 12 years of age.

You must talk to a doctor or pharmacist if you feel worse or if you do not feel better after 7 days.

2. What you need to know before you take Strepsils Herbal Chesty Cough syrup

Do not take Strepsils Herbal Chesty Cough syrup:

- if you are allergic to ivy leaf dry extract, to other plants of the *Araliaceae* (ivy) family or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Strepsils Herbal Chesty Cough syrup:

- if you suffer from gastritis (inflammation of stomach lining) or stomach ulcer.
- if you are taking other medicines to help stop you coughing such as codeine or dextromethorphan

If dyspnoea, fever or purulent or bloody sputum occurs before or while taking this medicine, please consult your doctor .

At the first signs of a severe allergic reaction you should immediately stop taking this medicine and contact a doctor (see section 4).

Use in patients with impaired renal and/or liver function

If you suffer from renal insufficiency or hepatic impairment, please talk to your doctor or pharmacist before taking Strepsils Herbal Chesty Cough syrup. Data for dose recommendations in these patients have not been established.

Children

Do not give this medicine to children under 12 years.

Other medicines and Strepsils Herbal Chesty Cough syrup

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

Strepsils Herbal Chesty Cough syrup has not been reported to influence the effects of other drugs.

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.

Pregnancy

Safety during pregnancy has not been established. In the absence of sufficient safety data, the use of Strepsils Herbal Chesty Cough syrup during pregnancy is not recommended.

Breast-feeding

It is unknown whether the active substance or its metabolites are excreted into human breast milk. A risk to the breastfed newborn/infant cannot be excluded. Strepsils Herbal Chesty Cough syrup should therefore not be used during breast-feeding.

Driving and using machines

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

Strepsils Herbal Chesty Cough syrup contains sorbitol

This medicine contains up to 2976 mg sorbitol in 6 mL syrup

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take this medicine.

Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

Strepsils Herbal Chesty Cough syrup contains propylene glycol

This medicine contains 50.4 mg propylene glycol in each 6 ml which is equivalent to 8.4 mg/ml.

Strepsils Herbal Chesty Cough syrup contains benzyl alcohol

This medicine contains 0.0114 mg benzyl alcohol in each 6 ml which is equivalent to 0.0019 mg/ml.

Benzyl alcohol may cause allergic reactions.

Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

Ask your doctor or pharmacist for advice if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).

3. How to take Strepsils Herbal Chesty Cough syrup

For oral short-term use only.

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

The recommended dose is:

Adolescents from 12 years of age, adults and elderly:

6 mL of syrup twice daily (corresponding to 99 mg of ivy leaf dry extract daily)

Use in children

Do not give this medicine to children under 12 years.

Use in patients with impaired renal and/or liver function

Please refer to section 2.

Method of administration

Oral use

Use the enclosed measuring spoon with graduations of 2 and 4 mL.

It is recommended that the dose of 6 mL is administered with a full measuring spoon (4 mL) + half a measuring spoon (2 mL).

Shake the bottle well before use.

Duration of use

You must talk to a doctor if you do not feel better, if you feel worse or if the symptoms don't resolve after 7 days.

If you take more Strepsils Herbal Chesty Cough syrup than you should

Intake of a larger dose than recommended can provoke nausea, vomiting, diarrhoea and agitation. If you take more Strepsils Herbal Chesty Cough syrup than you should, consult a doctor as soon as possible.

If you have taken more medicine than you should or if e.g. a child has taken medicine by accident, always contact a doctor, hospital or Poison Information Center for risk assessment and advice on action to be taken

If you forget to take Strepsils Herbal Chesty Cough syrup

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.

Undesirable effects that may occur during treatment with Strepsils Herbal Chesty Cough syrup:

- Common (may affect up to 1 in 10 people): Gastrointestinal reactions like nausea, vomiting and diarrhoea
- Uncommon (may affect up to 1 in 100 people): Allergic reactions like urticaria, skin rash, dyspnoea and anaphylactic reaction

At the first signs of a severe allergic reaction you should immediately stop taking this medicine and contact a doctor.

If other adverse reactions not mentioned above occur, a doctor or pharmacist should be consulted.

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 HPRA

Pharmacovigilance. Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Strepsils Herbal Chesty Cough syrup

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

This medicinal product does not require any storage conditions in the originally sealed package.

Do not store above 25°C after first opening.

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

The product can be used for 3 months after first opening.

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 Strepsils Herbal Chesty Cough syrup contains

- the active substance is ivy leaf dry extract. Each mL of the product contains 8.25 mg of extract (as dry extract) from *Hedera helix* L., folium (ivy leaf) (4-8:1). Extraction solvent: ethanol 30% m/m
- the excipients are: sorbitol liquid (non-crystallising) (E420), potassium sorbate (E202), xanthan gum (E415), citric acid (E330), natural honey thyme flavour (flavour contains propylene glycol (E1520), benzyl alcohol (E 1519)), purified water.

What Strepsils Herbal Chesty Cough syrup looks like and contents of the pack

Strepsils Herbal Chesty Cough syrup is a brown, opalescent liquid with a sweet taste and possible slight sediment.

The syrup is filled into a brown glass bottle with a white plastic (high density polyethylene) screw cap. The bottle is further packed in a carton together with a measuring spoon (made of polypropylene, with graduations of 2 mL and 4 mL).

Pack size: 100 mL.

Registration Holder and Manufacturer

Registration Holder

Reckitt Benckiser Ireland Ltd
7 Riverwalk, Citywest Business Campus, Dublin 24.

Manufacturer

Phytopharm Kłęka S.A
Kłęka 1, 63-040 Nowe Miasto nad Wartą, Poland

This medicinal product is authorized/registered in the Member States under the following names:

Finland: Strepmuco siirappi

This leaflet was last revised in MM/YYYY.
