

Co-pan Effervescent Tablet

Ivy leaf dry extract



Read all of this leaflet carefully before you start taking this product.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider, or presents pharmacist.
- Do not pass the product on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider, or pharmacist.

In this leaflet?

1. What Co-pan Cough Effervescent Tablet is and what it is used for?
2. Before you take Co-pan Cough Effervescent Tablet
3. How to take Co-pan Cough Effervescent Tablet
4. Possible side effects
5. How to store Co-pan Cough Effervescent Tablet
6. Further information

1. What Co-pan Cough Effervescent Tablet is and what it is used for?

Co-pan Cough Effervescent Tablets are Expectorant, helps relieve symptoms of respiratory tract inflammation associated with cough.

2. Before you take Co-pan Cough Effervescent Tablet

Do not take Co-pan Cough Effervescent Tablets

- if you are allergic to ivy, plants belonging to the aralia family, such as Schefflera, Panax ginseng or Eleutherococcus senticosus or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Co-pan Cough Effervescent Tablets. When dyspnoea, fever, bloody or purulent sputum occurs, a doctor or a pharmacist should be consulted.

Caution is recommended in patients with gastritis or gastric ulcer.

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

Children

Co-pan Cough Effervescent Tablets are not intended for use in children under 6 years of age.

Other medicines and Co-pan Cough Effervescent Tablets

No interaction studies have been performed.

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

Co-pan Cough Effervescent Tablets with food and drink

The product should be used after a meal.

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.

Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

No fertility data are available.

Driving and using machines

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

Co-pan Cough Effervescent Tablets contain sodium.

This medicine contains 316 mg sodium (main component of cooking / table salt) in each effervescent tablet. This is equivalent to 15.8 % of the recommended maximum daily dietary intake of sodium for an adult.

The maximum daily dose of this medicinal product contains 632 mg sodium (main component of cooking / table salt). This is equivalent to 31.6 % of the recommended maximum daily dietary intake of sodium for an adult.

Talk to your doctor or pharmacist if you need 2 effervescent tablets daily for a prolonged period, especially if you have been advised to follow a low salt (sodium) diet.

Co-pan Cough Effervescent Tablets contain macroglycerol hydroxystearate.

Macroglycerol hydroxystearate may cause stomach upset and diarrhoea.

Co-pan Cough Effervescent Tablets contain glucose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Co-pan Cough Effervescent Tablets

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.

Unless prescribed otherwise by your doctor, the recommended dose is:

Adolescents aged 12 years and above, adults and elderly

should take one effervescent tablet (corresponding to 50 mg of ivy leaves dry extract) twice daily (in the morning and evening).

Children from 6 to 11 years of age

should take half an effervescent tablet (corresponding to 25 mg of ivy leaves dry extract) twice daily (in the morning and evening).

This product is not intended for use in children under 6 years of age.

Sachet:

Store the second half of the effervescent tablet in the closed sachet until the next application (max. 24 hours).

The open edge area of the sachet is closed by folding over twice.

The tablet can be divided into equal doses.

Insufficient data are available to permit specific dose recommendations in the case of impaired kidney/liver function.

Method of administration:

Oral use.

Dissolve the effervescent tablet in half a glass of water and drink after eating.

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 take more Co-pan Cough Effervescent Tablets than you should

There are normally no adverse effects if one effervescent tablet more than recommended is taken.

Nausea, vomiting, diarrhoea and restlessness can develop if considerably more tablets are taken.

One case of a 4-year-old child who developed aggressivity and diarrhoea after accidental intake of an ivy extract corresponding to six effervescent tablets has been reported. You should consult your doctor in such a case.

If you forget to take Co-pan Cough Effervescent Tablets

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.

The following list covers all the known side effects from treatment with extract of ivy leaves, including those from higher doses and long-term treatment.

Possible side effects:

Gastrointestinal reactions (nausea, vomiting, diarrhoea) have been reported. The frequency is not known.

Allergic reactions (urticaria, skin rash, dyspnoea, anaphylactic reaction) have been reported. The frequency is not known.

If other adverse reactions not mentioned above occur, a doctor or a 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.

5. How to store Co-pan Cough Effervescent Tablets

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

- Store below 25 °C.

- Do not use this medicine after the expiry date which is stated on the carton and container after "EXP". The expiry date refers to the last day of that month.

- Store in the original package in order to protect from moisture.

- Shelf life after first opening is 24 hours.

- 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. Further information

What Co-pan Cough Effervescent Tablets contain

The active substance is ivy leaf dry extract.

Each effervescent tablet contains 50 mg of dry extract from Hedera helix L., folium (ivy leaves) (4-8:1), extraction solvent: ethanol 30% (m/m).

The other ingredients are:

Anhydrous citric acid (Ph. Eur.), sodium hydrogen carbonate (Ph. Eur.), mannitol (Ph. Eur.), anhydrous sodium carbonate (Ph. Eur.), saccharin sodium (Ph. Eur.), sodium cyclamate (Ph. Eur.), simeticone (Ph. Eur.), medium-chain triglycerides (Ph. Eur.), sodium citrate (Ph. Eur.), macroglycerol hydroxystearate (Ph. Eur.), beetroot powder (beetroot sap concentrate (E 162), maltodextrin (Ph. Eur.), citric acid monohydrate (Ph. Eur.), encianin powder (anthocyanin extract from grape skin (E 163), glucose syrup), blackcurrant flavour (ethyl butyrate, raspberry ketone, linalool, hexenyl acetate c-3, menthyl, L-, maltodextrin, propylene glycol (E 1520), modified starch (E 1450)).

What Co-pan Cough Effervescent Tablets look like and contents of the pack

Co-pan Cough Effervescent Tablets are round, flat tablets with purple speckles and a break-mark on one side.

Packages:

Sachet of laminated aluminium-paper-foil, paper carton, package leaflet

Pack sizes: 12, 20 and 24 effervescent tablets

Not all pack sizes may be marketed.

Manufacturer:

Krewel Meuselbach GmbH

Krewelstr. 2, 53783 Eitorf, Germany

Telephone: +49 (0)2243/ 87-0

Fax: +49 (0)2243/ 87-175

E-mail: info@krewelmeuselbach.de

Marketing Authorization Holder:

Middle East Distribution Co.Ltd. (MEDICO)

8146 King Muhammad V, Sulimaniyah, RIYADH 12223 - 3904 P.O. Box 4180, Riyadh

11491, Kingdom of Saudi Arabia

Tel.: 920010564

Fax:+966 (11) 4000225

This leaflet was last approved in 05/2022.

To report any side effect(s):

Saudi Arabia:

The National Pharmacovigilance and Drug Safety Centre (NPC)

- SFDA call center: 19999
- E-mail: npc.druginfo@sda.gov.sa
- Website: <https://ade.sda.gov.sa>

• Other GCC States:

Please contact the relevant competent authority.

THIS IS A MEDICATION

- 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