Co-pan cough syrup

Ivy leaf 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. pharmacist or nurse. 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

What is in this leaflet

- 1. What Co-pan cough syrup is and what it is used for
- 2. What you need to know before you take Copan cough syrup
- 3. How to take Co-pan cough syrup

after seven days or if you feel worse.

- 4. Possible side effects
- 5. How to store Co-pan cough syrup
- 6. Further information

. What Co-pan cough syrup is and what it is used for

Co-pan cough syrup is a herbal medicinal Expectorant helps relieve symptoms of respiratory tract inflammation associated with cough. You must talk to a doctor if you do not feel better after 7 days or if you feel worse. 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 Co-pan cough syrup

Do not take Co-pan cough syrup

- if you are allergic to ivy leaves, to plants of the Araliaceae 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 Co-pan cough syrup.

When Dyspnea (shortness of breath), fever or purulent (pus containing) sputum occurs a doctor or pharmacist should be consulted. Caution is recommended if you have stomach problems such as gastritis or gastric ulcer.

Children

2 years of age

If your child aged from 2 to 4 years has persistent or recurrent cough, talk to your doctor. Your doctor will decide whether this medicine is appropriate for your child or not This product should not be used in children under

Other medicines and Co-pan cough syrup Tell your doctor or pharmacist if you are taking, have recently taken or might take any other

medicines. There are no known interactions between Co-pan cough syrup and other medicines

No interaction studies have been performed. Co-pan cough syrup with food, and drink 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.

Safety during pregnancy and lactation has not

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

No fertility data are available.

Driving and using machines No special precautions are necessary. No studies on the effect on the ability to drive and use machines have been performed.

Co-pan cough syrup contains sorbitol.

This medicine contains 1750 mg sorbitol per 5 ml. 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 or receive this medicine.

Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

Co-pan cough syrup contains propylene glycol.

If your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if they use other medicines that contain propylene glycol or alcohol. If you are pregnant or breast-feeding or if you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

Co-pan cough syrup contains

macrogolglycerol hydroxystearate. Macrogol glycerol hydroxy stearate may cause stomach upset and diarrhoea.

3. How to take Co-pan 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:

Dosage recommendation with dosing syringe] Children over the age of 10 years, adults and elderly:

5 ml syrup three times daily

Children aged 4 - 10 years:

2.5 ml syrup four times daily

Children aged 2 - 4 years:

2.5 ml syrup three times daily

This product should not be used in children under 2 years of age

For exact dosing, a dosing syringe or a measuring spoon is included to this medicinal

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
- 5. After taken the dosage clean the single parts of the syringe and dry them.

Dosage recommendation with measuring

Children over the age of 10 years, adults and

1 measuring spoon with 5 ml syrup three times

Children aged 4 - 10 years:

1/2 measuring spoon with 2.5 ml syrup four times

Children aged 2 - 4 years:

1/2 measuring spoon with 2.5 ml syrup three times daily

Method of administration

For oral use

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

If you take more Co-pan cough syrup than vou 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, diarrhoea and agitation. In this case, contact your doctor.

If you forget to take Co-pan 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.

Possible side effects:

-Gastrointestinal reactions (nausea, vomiting, diarrhoea)

-Allergic reactions such as urticaria, skin rash, dyspnoea (difficulty in breathing), anaphylactic

Reporting of side effects

If you get any side effects, talk to your doctor, nurse, or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Co-pan cough syrup

- · 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 bottle and carton after EXP.
- . The expiry date refers to the last day of that
- · After first opening of the container Co-pan cough syrup can be used for 6 months. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment

O Avalon Pharma

6. Further information

What Co-pan cough syrup contains

The active substance is: ivv leaf soft extract 100 ml syrup contains 0.8 g of extract (as soft extract) from 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:

Macrogol glycerol hydroxy stearate, star anise oil, hydroxyethyl cellulose, sorbitol, liquid (noncrystallising), propylene glycol, glycerol, purified

What Co-pan cough syrup looks like and contents of the pack

Co-pan cough syrup is a clear, yellowish-brown

Co-pan cough syrup is available in packs with 100 ml.

[Co-pan cough syrup contains no sugar or alcohol. It is therefore suitable for patients who must avoid alcohol and diabetics. As Co-pan cough syrup contains plant extracts, the preparation may occasionally exhibit cloudiness, formation of a precipitate and/or slight variations in tastel.

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 08\2022.

To report any side effect(s): Saudi Arabia:

- The National Pharmacovigilance and Drug Safety Centre (NPC)
- SFDA call center: 19999
- E-mail: npc.drug@sfda.gov.sa
 Website: https://ade.sfda.gov.sa

Other GCC States

Please contact the relevant competent authority

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumpti 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