

PACKAGE LEAFLET: INFORMATION FOR THE USER

Paracodin® 0.20% w/w Syrup (dihydrocodeine hydrogen tartrate)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

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

The information in this leaflet applies to both adults and children who have been prescribed the medicine.

1. WHAT PARACODIN SYRUP IS AND WHAT IT IS USED FOR

Paracodin Syrup is for oral administration. The active ingredient in Paracodin Syrup is dihydrocodeine hydrogen tartrate. Paracodin Syrup belongs to a group of medicines called cough suppressants. Paracodin is used to treat a dry (non-productive) cough.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE PARACODIN SYRUP

Do not take Paracodin Syrup if you:

- are allergic to dihydrocodeine hydrogen tartrate or to any of the ingredients in this medicine (see section 6)
- suffer from breathing difficulties such as asthma
- have addiction problems
- suffer from confusion
- have any head injuries or are suffering from raised intracerebral pressure (an increase in the pressure of the fluid around the brain)
- are suffering from hypotension (low blood pressure)
- are suffering from a disorder of the blood called hypovolaemia (decrease in the volume of circulating blood in the body).
- are taking an antidepressant of the mono-amine oxidase inhibitor (MAOI) group, or have taken an MAOI during the last 14 days (MAOIs include phenelzine and tranylcypromine).

Paracodin should not be given to children under the age of 6 years.

Warnings and precautions

Talk to your doctor or pharmacist before taking Paracodin Syrup if you:

- have liver or kidney problems
- suffer from an underactive thyroid
- are elderly.

Special Warnings

- This product contains dihydrocodeine hydrogen tartrate.
- This medicine should only be taken when necessary.
- Do not exceed the dose prescribed by your doctor.
- Do not take more than the stated dose. This medicine should only be taken until relief of cough or for a maximum of 7 days for children (6 – 12 years).
- Prolonged regular use, except under medical supervision, may lead to physical and psychological dependence (addiction) and result in withdrawal symptoms such as restlessness and irritability, once the drug is stopped. If you find you need to use this product all the time, it is important to consult your doctor.
- Patients with pre-existing seizure disorders should be observed with caution when prescribed this product.

Other medicines and Paracodin Syrup

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

Please consult your doctor if you are taking

- antidepressants of the mono-amine oxidase inhibitor (MAOI) group or if you have been on treatment with these within the previous 14 days
- anxiolytics, hypnotics or tricyclic antidepressants (e.g. imipramine, amitriptyline) as they may enhance difficulties in breathing
- antipsychotic drugs as they may enhance low blood pressure (hypotensive) and sedative effects
- analgesics (medicines to relieve pain) as their effect is increased

Paracodin Syrup with food, drink and alcohol

Avoid alcohol whilst taking this medicine.

Pregnancy and breast-feeding

This medicine can cross the placenta and can be excreted in milk during breast feeding. Paracodin Syrup should not be used during pregnancy or breast feeding unless considered essential by a physician.

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.

Driving and Using Machines

Paracodin may cause drowsiness. If affected, do not drive or operate machinery.

Paracodin Syrup contains sucrose

Paracodin Syrup contains 2424.2 mg of sucrose (sugar) per dose. This should be taken into account in patients with diabetes mellitus.

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

Paracodin Syrup contains benzoic acid

This medicine contains 12.1 mg benzoic acid in each 5ml dose.

3. HOW TO TAKE PARACODIN SYRUP

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

Follow your doctor's directions about when and how to take your medicine or how to give it to your child. Check the label on the bottle or carton. Your pharmacist will also help if you are not sure.

The recommended dose is as follows:

Children (aged 6-12 years): 2.5 ml (½ teaspoon) to 5 ml (teaspoon) (half to one 5 ml teaspoon) taken up to three times each day.

Adults: One or two 5 ml teaspoon taken up to three times each day.

If you take more Paracodin Syrup than you should

If you or someone you know accidentally takes a lot more than the stated dose (an overdose), you should contact a doctor immediately or go to the nearest hospital casualty department.

If you forget to take Paracodin Syrup

If you forget to take a dose, miss it out altogether then take the next dose at the usual time. Never double-up on a dose to make up for the one you have missed.

4. POSSIBLE SIDE EFFECTS

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

Side effects include:

- Stomach cramps
- Constipation
- Feeling sick or getting sick
- Drowsiness
- Headache
- Dizziness
- Vertigo (a feeling of motion)
- Blurred vision
- Breathing problem
- Shortness of breath
- Spontaneous swelling of the throat (laryngeal oedema)
- Euphoria (feeling of extreme well-being and happiness)
- Confusion
- Slowing down of the heart
- Palpitations, abnormality of heartbeat
- Low blood pressure (possibly causing dizziness on standing)
- Facial flushing
- Skin rash, hives (urticaria) and itching
- Spontaneous swelling of the areas of skin or mucus membranes (Angioedema or Quincke's edema)
- Tiredness
- Difficulty in urinating

If you develop any problems with your breathing or vision, wheezing, a skin rash or itching, or if you feel faint whilst taking this medicine, stop taking it and contact your doctor.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE PARACODIN SYRUP

The syrup should be stored in a safe place (preferably in a locked cupboard). Keep this medicine out of the sight and reach of children.

Do not take this medicine after the expiry date which is stated on the bottle or carton after 'EXP'. The expiry date refers to the last day of that month.

Do not store Paracodin Syrup above 25 °C and do not refrigerate or freeze. Store in the original package in order to protect from light.

If your doctor decides to stop the treatment, return any left over to your pharmacist.

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 Paracodin Syrup contains

The active substance in Paracodin Syrup is dihydrocodeine hydrogen tartrate. 5 ml of syrup contains 12.1 mg dihydrocodeine hydrogen tartrate (0.20 % w/w) with purified water, sucrose (see section 2), glycerol, benzoic acid (E210) and cherry flavour.

What Paracodin Syrup looks like and contents of the pack

Paracodin Syrup is a clear, colourless or faintly yellow liquid with a cherry flavour. Each bottle of syrup contains 100 g of medicine.

Product authorisation holder:

Teofarma S.R.L., Via F.lli Cervi, 8, 27010 Valle Salimbene (PV), Italy
e-mail: servizioclienti@teofarma.it

Manufactured by: Teofarma S.R.L., Viale Certosa, 8/A, 27100 Pavia, Italy

Remember: This leaflet does not contain the complete information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist who have access to additional information.

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Other sources of information

This leaflet is available in formats suitable for the blind or the visually impaired.

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