

Package Leaflet: INFORMATION FOR THE USER

PARACODIN® 10 mg/g oral drops, solution (dihydrocodeine hydrorhodanide)

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 Drops are and what they are used for
2. What you need to know before you take Paracodin Drops
3. How to take Paracodin Drops
4. Possible side effects
5. How to store Paracodin Drops
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 DROPS ARE AND WHAT THEY ARE USED FOR

Paracodin Drops are for oral administration.

The active substance in Paracodin Drops is dihydrocodeine hydrorhodanide.

Paracodin Drops belongs to a group of medicines called cough suppressants. Paracodin Drops are used to treat a dry (non-productive) cough.

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

Do not take Paracodin Drops if you:

- are allergic to dihydrocodeine hydrorhodanide 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 head injuries and 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 Drops if you:

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

Special Warnings

- This product contains dihydrocodeine hydrorhodanide.
- 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 duration 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 Drops

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 with hypotensive and sedative effects
- analgesics (medicines to relieve pain) as their effect is increased

Paracodin Drops 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 Drops 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 Drops contains Benzoic Acid

This medicine contains 2 mg benzoic acid in each 20-drop dose.

3. HOW TO TAKE PARACODIN DROPS

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): 6 to 12 drops taken up to three times daily.

Adults: 14 to 20 drops taken up to three times daily.

If you take more Paracodin Drops 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 Drops

If you forget to take a dose, miss it out altogether then take the next dose at the usual time. 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.

Side effects include:

- Stomach cramps
- Constipation
- Feeling 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 HPRÁ 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 DROPS

The drops 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 Drops above 30°C. 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. C ONTENTS OF THE PACK AND OTHER INFORMAT ION What Paracodin Drops

contain

The active substance in Paracodin Drops is dihydrocodeine hydrorhodanide. 1 g of drops (= 20 drops) contains 10 mg of dihydrocodeine hydrorhodanide (each drop contains 0.5 mg of dihydrocodeine hydrorhodanide). The other ingredients are purified water, glycerol, caramel (E150), sodium chloride, thyme flavour, saccharin sodium, benzoic acid (E210) and eucalyptus flavour.

What Paracodin Drops look like and contents of the pack

Paracodin Drops are oral drops, clear brown solution in an amber glass bottle. Each bottle of drops contains 15 g of medicine

Marketing 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.

This leaflet was last revised in

May 2020

Other sources of information

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

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