

PACKAGE LEAFLET: INFORMATION FOR THE USER

PARACODIN® 10 mg TABLETS (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 Tablets are and what they are used for
2. What you need to know before you take Paracodin Tablets
3. How to take Paracodin Tablets
4. Possible side effects
5. How to store Paracodin Tablets
6. Contents of the pack and other information

1. WHAT PARACODIN TABLETS ARE AND WHAT THEY ARE USED FOR

Paracodin Tablets are for oral administration.

The active ingredient in Paracodin 10mg tablets is dihydrocodeine hydrogen tartrate. Paracodin Tablets belongs to a group of medicines called cough suppressants. Paracodin 10 mg tablets are used to treat a dry (non-productive) cough.

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

Do not take Paracodin Tablets if you:

- are allergic to dihydrocodeine hydrogen tartrate or to any of the ingredients in the tablets (see section 6)
- suffer from breathing difficulties such as asthma
- have addiction problems
- 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 12 year.

Warnings and precautions

Talk to your doctor or pharmacist before taking paracodin tablets 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 take more than the stated dose.
- Do not exceed the dose prescribed by your doctor.
- 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 Tablets

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 may enhance low blood pressure with hypotensive and sedative effects
- analgesics (medicines to relieve pain) as their effect is increased

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

Paracodin Tablets contains lactose monohydrate

Paracodin Tablets contains lactose monohydrate, if you have been told by your doctor that you have an intolerance to some sugars (lactose see section 6), contact your doctor before taking this medicinal product.

3. HOW TO TAKE PARACODIN TABLETS

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 tablets and check the label on the carton. Your pharmacist will also help if you are not sure.

The usual dose is as follows:

Adults and children over 12 years: one, two or three tablets taken up to three times each day.

Children under 12 years: not recommended.

If you take more Paracodin Tablets 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 Tablets

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 Paracodin Tablets 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.

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 PARACODIN TABLETS

The tablets 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.

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

Keep blister in the outer carton.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Paracodin Tablets contain

The active ingredient in Paracodin 10 mg tablets is dihydrocodeine hydrogen tartrate. Each tablet contains 10 mg dihydrocodeine hydrogen tartrate with lactose monohydrate (see section 2), microcrystalline cellulose (E460), sodium starch glycolate and magnesium stearate (E572). The tablets are available in blister packs containing 20 tablets.

What Paracodin Tablets look like and contents of the pack

Paracodin tablets are round, off white biplane tablets, with a score line on one side and a star with three rays on the other side.

The tablets are available in blister packs containing 20 tablets.

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

Other information

Remember: This medicine is for you and has been prescribed for you by a doctor.

Never give it to anybody else, even if their symptoms are the same as yours.

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

Other sources of information

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

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