

COQUELUSEDAL PARACETAMOL 250mg, suppository

Paracetamol, soft extract of Grindelia, soft extract of Gelsemium

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

If you have any further questions or if you are in doubt, ask your doctor or pharmacist.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist for more information or advice.
- If you get any side effects, even not listed in this leaflet, talk to your doctor or pharmacist (see section 4).
- You must contact your doctor if your symptoms do not improve or worsen after 3 days of fever or 5 days of pain.
- Keep out of the reach of children.

WHAT IS IN THIS LEAFLET

- 1- What COQUELUSEDAL PARACETAMOL 250mg, suppository, is and what it is used for
- 2- What you need to know before you take COQUELUSEDAL PARACETAMOL 250mg, suppository
- 3- How to take COQUELUSEDAL PARACETAMOL 250mg, suppository
- 4- Possible side effects
- 5- How to store COQUELUSEDAL PARACETAMOL 250mg, suppository
- 6- Contents of the pack and other information

1- WHAT COQUELUSEDAL PARACETAMOL 250mg, suppository, IS AND WHAT IT IS USED FOR

This medicine is an antipyretic, analgesic and antitussive. It contains paracetamol.

This medicine is indicated in the event of pain and/or fever such as headache, flu, toothache and stiffness.

This presentation is for children weighing 13 to 20 kg only. Read the 'Dosage' section carefully.

Other paracetamol presentations are available for children of different weights. Ask your doctor or pharmacist for advice.

2- WHAT YOU NEED TO KNOW BEFORE YOU TAKE COQUELUSEDAL PARACETAMOL 250mg, suppository

Never take this medicine in the following cases:

- 1- Known allergy to paracetamol or to the other constituents.

2- Serious liver disease.

3- Recent anal or rectal inflammation or recent bleeding from the rectum.

IF IN DOUBT, ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Special warnings:

In the event of overdose or erroneous intake of an excessive dose, consult your doctor immediately.

This medicine contains paracetamol. Other medicines also contain it. Do not combine medicines in order not to exceed the recommended daily dose (cf. Dosage section).

With suppositories, there is a risk of local irritation that is more frequent and intense, the longer the duration of the treatment, the higher the administration frequency and the higher the dosage.

Precautions for use:

If the pain persists for more than 5 days, or the fever for more than 3 days, or in the event of inadequate efficacy or emergence of any other sign, do not continue the treatment without seeking your doctor's opinion.

Before starting the treatment, check that you are not taking other medicines containing paracetamol.

Inform your doctor in the event of liver or kidney disease or if you are taking other medicines containing paracetamol.

In the event of nutrition disorders (malnutrition) or dehydration, COQUELUSEDAL PARACETAMOL 250 mg, suppository, must be used with caution.

IF IN DOUBT, ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE.

Using other medicines:

Inform your doctor that your child is taking this medicine if your doctor prescribes a test to determine the uric acid or sugar concentration in the blood.

Inform your doctor if your child is treated with Flucloxacillin due to a serious risk of blood and plasma abnormalities (high anion gap metabolic acidosis) which requires urgent treatment and which can occur particularly in the event of severe kidney disease, septicemia, malnutrition, chronic alcoholism and if the maximum daily doses of paracetamol are used. Symptoms of metabolic acidosis may include severe breathing difficulties with rapid, deep breathing, drowsiness, nausea and vomiting.

IN ORDER TO PREVENT POTENTIAL INTERACTIONS BETWEEN MEDICINES, ALWAYS INFORM YOUR DOCTOR OR PHARMACIST OF ANY OTHER ONGOING TREATMENT, including medicines obtained without a

prescription.

Pregnancy and breastfeeding:

This medicine is intended for children. However, in the event of use by a woman of reproductive age, the following points are to be noted: under normal conditions of use, paracetamol may be used during pregnancy and during breastfeeding.

GENERALLY SPEAKING, DURING PREGNANCY AND BREASTFEEDING, ASK YOUR DOCTOR OR PHARMACIST FOR ADVICE BEFORE TAKING ANY MEDICINE.

Excipient with a known effect: propylene glycol.

3- HOW TO TAKE COQUELUSEDAL PARACETAMOL 250mg, suppository

Dosage: The paracetamol dosage depends on the child's weight; ages are only indicated for information. If you do not know your child's weight, you should weigh him/her in order to administer the most appropriate dose.

Paracetamol is available in numerous strengths enabling adjustment of treatment to the infant's body weight.

The recommended daily dose of paracetamol depends on the child's weight: the dose is approximately 60 mg/kg/day divided into 4 to 6 intakes, i.e. approximately 15 mg/kg every 6 hours.

Due to the risk of rectal irritation, suppository administration should be as short a time as possible, should not exceed 4 doses per day and should be replaced as soon as possible by oral treatment.

In the event of diarrhea, the suppository form is not appropriate.

This presentation is for children weighing 13 to 20 kg only (i.e. approximately 2 to 7 years).

The dosage is one 250mg suppository, to be repeated if necessary after 6 hours, without exceeding **4 suppositories per day**.

Administration route: rectal route.

In addition, if your child has a fever greater than 38.5°C, you can improve the efficacy of the medicinal treatment by the following measures:

- 1- Uncover your child,
- 2- Have your infant drink,
- 3- Do not leave your infant in an excessively hot place.

Administration frequency: regular administrations enable prevention of oscillations in pain or fever.

In children, administration is to be at regular intervals, including at night, of 6 hours preferably and 4 hours minimum.

In the event of serious kidney disease (severe kidney failure), the interval between administrations is to be at least 8 hours.

If you have the impression that the effect of COQUELUSEDAL PARACETAMOL 250mg, suppository, is too strong or too weak, consult your doctor or pharmacist.

Duration of treatment:

If the pain persists for more than 5 days or the fever for more than 3 days, or in the event of inadequate efficacy or emergence of any other sign, do

not continue the treatment without seeking your doctor's opinion.

If you use more COQUELUSEDAL PARACETAMOL 250 mg, suppository, than you should: the suppository form makes excessive use unlikely.

If you forget to use COQUELUSEDAL PARACETAMOL 250 mg, suppository: do not take a double dose to make up for a forgotten dose.

4- POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects but not everyone gets them.

- In certain rare cases, skin rash, skin redness may occur, or an allergic reaction with possible signs including sudden swelling of the face and neck, or a sudden malaise and a drop in blood pressure. You must immediately discontinue the treatment, contact your doctor, and never take any medicines containing paracetamol again.

- Exceptionally, biological changes requiring blood tests have been observed: disorders of liver function, abnormally low levels of certain white blood cells such as platelets, which may result in nose or gum bleeding. In that case, consult a doctor.

- Risk of rectal or anal irritation (see Special warnings section).

- Frequency not known: a serious condition which can make the blood more acidic (called metabolic acidosis), in patients with serious illness who are using paracetamol (see section 2).

If you feel any side effects, talk to your doctor or pharmacist. This also applies to any possible side effects not listed in this leaflet. You can also report side effects directly through the national reporting system. By reporting side effects, you are helping to provide more information on drug safety.

5- HOW TO STORE COQUELUSEDAL PARACETAMOL 250mg, suppository

Keep out of the reach and sight of children.

Do not use after the expiry date which is stated on the box.

Store at a temperature not exceeding 25°C.

6- CONTENTS OF THE PACK AND OTHER INFORMATION

Active substances per suppository are:

Paracetamol 250mg

Soft hydro-alcoholic extract of Grindelia 20mg

Soft hydro-alcoholic extract of Gelsemium 10mg

Other ingredients: propylene glycol, hard fat.

This medicine is in the form of suppositories, box of 10.

Chaeul Pharmaceuticals (CHA- PHA) S.A.L. - Lebanon (packing)
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