

COQUELUSEDAL PARACETAMOL 100mg, suppository

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

You must always use this medicine by following exactly the information given in this leaflet or by your doctor or your 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 100mg, suppository, is and what it is used for
- 2- What you need to know before you take COQUELUSEDAL PARACETAMOL 100mg, suppository
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- 6- Contents of the pack and other information

1- WHAT COQUELUSEDAL PARACETAMOL 100mg, suppository, IS AND WHAT IT IS USED FOR

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

This presentation is for infant weighing 5 to 8 kg only. Read the 'Dosage' section carefully. For infants of different weights, other paracetamol presentations are available: ask your doctor or pharmacist for advice.

2- WHAT YOU NEED TO KNOW BEFORE YOU TAKE COQUELUSEDAL PARACETAMOL 100mg, 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.

In the event of liver or kidney disease, it is necessary to consult your doctor before taking paracetamol.

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

Using other medicines:

Inform your doctor that your infant 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.

Excipient with a known effect: propylene glycol.

3- HOW TO TAKE COQUELUSEDAL PARACETAMOL 100mg, suppository

Dosage: The paracetamol dosage depends on the infant'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 infant'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 infant weighing 5 to 8 kg only (i.e. approximately 2 to 9 months).

The dosage is one 100mg suppository, to be repeated if necessary after 6 hours, without exceeding **4 suppositories per day**.

Administration route: rectal route.

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

- 1- Uncover your infant,
- 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 infant and child, 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 100 mg, suppository, is too strong or too weak, consult your doctor or pharmacist.

Duration of treatment:

If the pain persists for more than 4 or 5 days, do not continue the treatment without seeking your doctor's opinion.

If you use more COQUELUSEDAL PARACETAMOL 100 mg, suppository, than you should: in the event of overdose or erroneous intake of an excessive high dose, consult a doctor rapidly.

If you forget to use COQUELUSEDAL PARACETAMOL 100 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:

abnormally low levels of certain white blood cells or of other 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 100mg, suppository

Keep out of the reach and sight of children.

Do not use after the expiry date which is stated on the box. The expiry date refers to the last day of the month.

Store at a temperature not exceeding 25°C.

6- CONTENTS OF THE PACK AND OTHER INFORMATION

Active substances per suppository are:

Paracetamol 100mg

Soft hydro-alcoholic extract of Grindelia 10mg

Soft hydro-alcoholic extract of Gelsemium 5mg

Other ingredients: propylene glycol, hard fat.

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

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

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