

PACKAGE LEAFLET: Information for the patient

KIDAMOL

Suppositories – 100 mg, 125 mg or 250 mg

(Paracetamol)

Read all of this leaflet carefully before you start using this medicine.

- 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 your child. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Kidamol suppositories are and what they are used for
2. Before you use Kidamol suppositories
3. How to use Kidamol suppositories
4. Possible side effects
5. How to store Kidamol suppositories
6. Further information

1. WHAT KIDAMOL SUPPOSITORIES ARE AND WHAT THEY ARE USED FOR

These suppositories contain the active substance paracetamol. Paracetamol is an analgesic (painkiller) and an antipyretic (reduces fever) medicine. Paracetamol is indicated:

- in mild to moderate pain with different localizations (headache, toothache, neuralgia, myalgia, post-traumatic and post-surgical pain);
- for temperature lowering in fever conditions.

Suppositories are used in children who find it difficult to take paracetamol as a syrup or tablets.

2. BEFORE YOU USE KIDAMOL SUPPOSITORIES

Do not give Kidamol suppositories to your child if they:

- are hypersensitive to the active substance or to any of the other ingredients of this medicine;
- have a severe liver or kidney damage;
- have head and brain damage;
- have high intracranial pressure;
- have genetic glucose-6-phosphate dehydrogenase deficiency;
- have respiratory disorders.

Take special care with Kidamol

Ask your doctor or pharmacist before giving Kidamol suppositories to your child.

During treatment with paracetamol, before giving your child any other medicine, check to see if they contain the same active substance, considering that high doses of paracetamol may cause serious side effects.

Paracetamol should be used with caution by people who suffer from the following:

- anorexia (eating disorder characterized by lack or reduction of appetite);
- bulimia (eating disorder in which a person swallows an excessive amount of food and then uses various methods to eliminate it);
- cachexia (a condition characterized by extreme thinness, reduced muscle mass, and thinning of the skin due to chronic diseases);
- chronic malnutrition (if an incorrect diet has been followed for a long time);
- dehydration (severe loss of water / liquids from the organism);
- hypovolemia (reduced circulating blood volume);
- liver diseases that reduce its function (liver failure, hepatitis, Gilbert's syndrome);
- mild / moderate insufficiency of kidney function;
- hemolytic anemia (destruction of red blood cells);
- people who are being treated concomitantly with medicines that alter liver function (see "Taking other medicines").

The use of high or prolonged doses of this medicine may cause liver disease of a high risk and severe kidney and blood disorders.

In these cases, during Kidamol suppositories use, the doctor will monitor the functionality of the liver and kidneys, and blood composition.

If this medicine is used by adults, caution should be taken during pregnancy and breastfeeding, and in alcoholics.

Taking other medicines

Concomitant treatment with other drugs may affect or be affected by paracetamol.

Please contact your doctor or pharmacist if you are giving or you have recently given other drugs to your child, including those taken without a prescription. Do not forget to inform your doctor for the treatment with Kidamol suppositories if you have given your child another drug during treatment, especially the following:

- other medicines that contain paracetamol; during treatment with Kidamol suppositories, before giving any other medicine to your child, check that it does not contain paracetamol, as serious side effects may occur if paracetamol is taken in high doses;
- chloramphenicol (antibiotic); taking chloramphenicol concomitantly with Kidamol suppositories may increase the risk of side effects;
- anticoagulants (medicines used to make the blood thinner, e.g. warfarin);
- rifampicin (antibiotic);
- cimetidine (a medicine used to treat stomach ulcers);
- antiepileptics (drugs used to treat epilepsy, e.g. glutethimide, barbiturates, hydantoins, carbamazepine);
- zidovudine (medicine for the treatment of HIV).

Other substances that may interact with Kidamol suppositories are:

- isoniazide;
- sulfinpyrazone;
- ethyl alcohol;
- active carbon;
- intravenous busulfan;
- cholestyramine;
- metoclopramide.

Interference with blood tests

If your child is using Kidamol suppositories and need to have blood tests done, be aware that the administration of this medicine may interfere with the determination of uricemia and blood glucose.

Pregnancy and breastfeeding

If this medicine is used by adults, keep in mind that clinical experience with paracetamol use during pregnancy and breastfeeding is limited.

Pregnancy

Kidamol should be used according to your doctor's advice during pregnancy. You should use the lowest dose possible that relieves pain and / or reduces your fever, in the shortest period of time possible. Inform your doctor if your pain and / or fever are not reduced or if you need to take this medicine more often.

Breastfeeding

Use Kidamol according to your doctor's advice during breastfeeding. You should be aware that paracetamol passes through to breast milk.

Driving and using machines

Paracetamol does not affect driving and using machines.

3. HOW TO USE KIDAMOL SUPPOSITORIES

Always use Kidamol suppositories as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Suppositories are only for rectal administration. They must not be swallowed!

The rectal dose in adults and in children over 12 years old: 0.5 - 1 g every 6 to 8 hours without exceeding 4 g / daily.

In prolonged treatments not more than 2.6 g / daily.

In children: 60 mg as an antipyretic dose after vaccination in children aged 2 months. In other cases, in those aged younger than 3 months, only under medical advice.

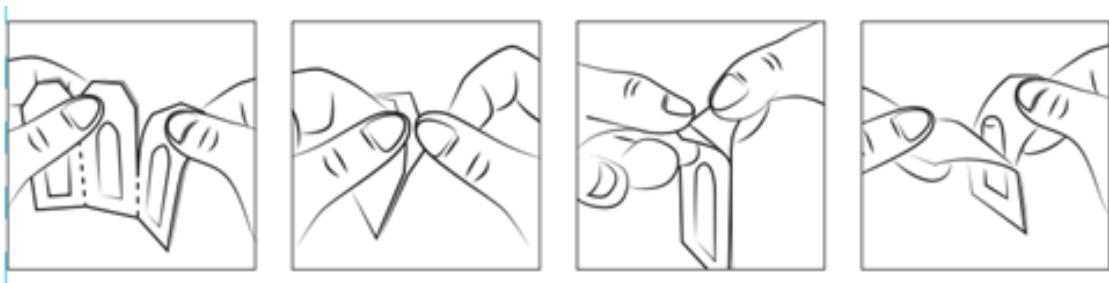
3 - 11 months: 60 - 125 mg every 4 - 6 hours as required; maximum 4 doses per day.

1 - 4 years old: 125 - 250 mg every 4 - 6 hours as required; maximum 4 doses per day.

5 - 11 years old: 250 - 500 mg every 4 - 6 hours as required; maximum 4 doses per day.

Method of administration

1. Your child must have defecated when you put the suppository in them, so that their bowels are emptied.
2. Giving your child the suppository may be easier if they are lying on their front or side.



3. Wash your hands. Open the alveoli to take out the suppository. Do not break the suppository before use.
4. Gently push the suppository into your child's back passage (rectum) with the pointed end first. Then wash your hands.
5. Try to keep your child still for a minute or two.

If you have given your child more Kidamol than you should

If you have given your child more Kidamol than you should, or if the children have taken this drug incorrectly, please contact your doctor, hospital, or call the emergency to take an opinion for the risk and advice for the actions to be taken.

Symptoms

If you accidentally take an overdose of paracetamol, tell your doctor immediately or go to the nearest hospital. Symptoms you may generally experience within the first 12-48 hours include:

- anorexia (lack of or reduced appetite), nausea and vomiting followed by a profound decline in general condition;

- alterations in blood laboratory values (increased blood bilirubin, lactic dehydrogenase, liver transaminase levels, decreased blood prothrombin levels);
- stomach pain;
- severe liver damage that can lead to coma or death.

Treatment

Based on the nature and severity of the symptoms, your doctor will carry out the appropriate therapy.

If you forget to give Kidamol to your child

If you forget to give your child a dose (or more doses), give them the following dose when it is time to usually give it to them.

Do not give them a double dose (or higher) to make up for the forgotten dose (doses).

If you have any other question on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all other drugs, Kidamol suppositories may cause side effects, although not everybody manifests them. Stop using them and immediately inform your doctor for the following side effects that may occur to your child:

- allergic reactions with:
 - redness of the skin accompanied by itching (hives);
 - swelling of the throat (laryngeal edema);
 - swelling of the hands, feet, ankles, face, lips, tongue and/or throat (angioedema);
 - severe manifestation (anaphylactic shock).

In addition, people who use this medicine may experience the following side effects, for which there are insufficient data available to determine the frequency.

Side effects that affect the blood:

- reduction in the number of platelets in the blood (thrombocytopenia);

- reduction in the number of white blood cells in the blood (leukopenia / agranulocytosis);
- reduced hemoglobin in the blood, the substance that carries oxygen in the blood (anemia);
- reduction in the number of neutrophils (neutropenia);
- reduction in the number of red blood cells, white blood cells and platelets in the blood (pancytopenia).

Side effects that affect the nervous system:

- dizziness.

Side effects that affect the gastrointestinal tract:

- reactions of the stomach and intestines.

Side effects that affect the liver:

- abnormal liver function;
- inflammation of the liver (hepatitis).

Side effects that affect the skin and subcutaneous tissues:

- red spots, bullous lesions with areas of skin breakdown, blisters, skin rashes (erythema multiforme, Stevens Johnson syndrome, toxic epidermal necrolysis).

These are serious skin reactions.

Side effects that affect the kidneys and the urinary tract:

- decreased kidney function (acute renal failure);
- inflammation of the kidneys (interstitial nephritis);
- blood in the urine (hematuria);
- cessation or reduction of urine production by the kidney (anuria).

Side effects that affect metabolism:

- hypoglycemia (reduction of blood glucose levels).

If any of the side effects worsens, or if you notice side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE KIDAMOL SUPPOSITORIES

Keep out of the sight and reach of children!

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

Do not store above 25°C!

Store in the original packaging to protect it from light and humidity!

6. FURTHER INFORMATION

What Kidamol suppositories contain

The active substance is paracetamol.

One suppository contains 100 mg, 125 mg or 250 mg paracetamol.

The excipients are: colloidal anhydrous silica and hard fat.

Content of the pack

Carton box with 10 suppositories.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

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