

PACKAGE LEAFLET: Information for the patient

KIDAMOL

Syrup – 120 mg / 5 ml

(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 you. 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 is and what it is used for
2. Before you give Kidamol to your child
3. How to give Kidamol to your child
4. Possible side effects
5. How to store Kidamol
6. Further information

1. WHAT KIDAMOL IS AND WHAT IT IS USED FOR

Kidamol contains the active substance paracetamol. It is an analgesic (relieves pain) and antipyretic (lowers the temperature) drug.

Kidamol 120 mg/5 ml syrup is indicated in:

- mild to moderate pain, including: headache, toothache, minor muscular sprains and strains;
- reduction of fever, including high fever caused from vaccines, cold and flu.

2. BEFORE YOU GIVE KIDAMOL TO YOUR CHILD

Do not give your child Kidamol syrup if they:

- are hypersensitive to the active substance or to any of the excipients of this drug;
- 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 before giving Kidamol to your child if they:

- have allergic reactions. In this case, you should stop giving your child Kidamol syrup and inform your doctor;
- suffer from with mild renal failure or hepatic impairment (mild to moderate hepatic insufficiency, Gilbert syndrome, acute hepatitis. Large doses or extended usage periods may cause high risk kidney diseases and severe kidney and blood disorders. Therefore, in children with mild to moderate kidney dysfunction, it should be administered only if necessary and under medical supervision);
- are taking concomitantly drugs that affect the liver function;
- suffer from hemolytic anemia;
- suffer from chronic dehydration, hypovolemia, chronic malnutrition, anorexia, bulimia or cachexia.

In cases of long-term treatment, tests on liver, kidney function and blood changes should be performed. Do not give your child Kidamol for longer than 3 days without consulting your doctor.

During treatment with Kidamol, before taking any other drug, make sure it does not contain the same active substance, as high doses of paracetamol may cause serious side effects.

If adults intend to take this medicine, caution is required during pregnancy, breastfeeding period and alcoholic dependence.

Taking other medicines

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

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

- barbiturates, rifampicin, some anti-epileptic drugs (carbamazepine, hydantoins) – have the same metabolic pathway as paracetamol;
- metoclopramide, domperidone – increase the speed of absorption of paracetamol;
- cholestyramine – reduces the speed of absorption of paracetamol;
- warfarin, other coumarins – the anticoagulant effect may be enhanced by prolonged daily use of paracetamol with increased risk of bleeding;
- zidovudine – neutropenia occurs;
- isoniazid – reduces paracetamol clearance;
- chloramphenicol – paracetamol increases its shelf-life.

Other drugs that can interact with Kidamol are:

- sulfinpyrazone;
- ethanol (alcohol);
- active charcoal;
- intravenous busulphan;

Important information about some of the excipients of Kidamol

Kidamol 120 mg/5 ml syrup contains:

- approximately 250 mg sorbitol per 5 ml syrup; sorbitol is a source of fructose; if you have been told by your doctor that your child has an intolerance to some sugars or if they have been diagnosed with hereditary fructose intolerance, a rare genetic disorder in which a person cannot break down fructose, contact your doctor before giving this medicine to your child; sorbitol may cause gastrointestinal discomfort and mild laxative effect;
- small amount of ethanol (alcohol), which will not have any noticeable effects.

- less than 1 mmol sodium (23 mg) per 5 ml syrup, that is to say essentially “sodium-free”;
- methyl hydroxybenzoate, that may cause allergic reactions (possibly delayed).

3. HOW TO GIVE KIDAMOL TO YOUR CHILD

Always give Kidamol to your child as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

The syrup is taken orally with a dosing cup or syringe.

Infants 2 - 3 months: 2.5 ml of syrup is suitable for babies who are vaccinated in the second month, in the other cases it is used under medical supervision.

Infants 3 - 12 months: 2.5 - 5 ml (60 - 120 mg paracetamol) every 4 - 6 hours, with a maximal administration of 4 times in 24 hours.

Children 1 - 6 years old: 5 - 10 ml (120 - 240 mg paracetamol), every 4 - 6 hours, with a maximal administration of 4 times in 24 hours.

If your child takes more Kidamol than they should

If your child takes more Kidamol than they should or if you have given 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 of overdose include nausea, vomiting, anorexia, abdominal pain and severe hepatic damage.

If you forget to give your child Kidamol

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

Do not give 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 may cause side effects, although not everybody manifests them.

Inform your doctor for the following side effects that may appear to your child. The frequency of the listed side effects cannot be estimated by the available data.

Effects on hematopoietic system	Thrombocytopenia, leucopenia, hemolytic anemia, agranulocytosis, neutropenia, pancytopenia
Effects on immune system	Allergic reactions (hives, swelling of larynx, angioedema, anaphylactic shock)
Effects on nervous system	Dizziness
Effects on gastrointestinal system	Gastrointestinal reactions
Effects on metabolism	Hypoglycemia
Effects on hepatobiliary system	Abnormal hepatic function (increased transaminases, jaundice), hepatitis
Effects on skin and subcutaneous tissue	Erythema multiforme, <i>Stevens-Johnson</i> syndrome, hemolytic necrosis, skin rash
Effects on kidneys and urinary system	Acute insufficiency of kidney function, interstitial nephritis, hematuria, anuria.

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

Keep out of the sight and reach of children!

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

Do not store above 25°C!

Store in the original packaging!

6. FURTHER INFORMATION

What Kidamol contains

The active substance is paracetamol. 5 ml syrup contain 120 mg paracetamol.

The excipients are: sorbitol, polyethylene glycol 6000, sodium cyclamate, sodium saccharin, sodium citrate, methyl hydroxybenzoate, povidone, glycerin, sodium chloride, ethanol 96%, strawberry flavor, caramel flavor and purified water.

Content of the pack

Carton box with one amber glass bottle of 120 ml.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

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This leaflet was last revised in November 2023.