

PACKAGE LEAFLET: Information for the patient

KIDAMOL

Oral suspension – 160 mg / 5 ml

(Paracetamol)

Read all of this leaflet carefully before you start taking 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 they have the same symptoms.
- 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 take Kidamol
3. How to take Kidamol
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, which is a para-aminophenol derivative. It has analgesic and antipyretic properties.

Kidamol 160 mg/5 ml oral suspension is indicated in:

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

2. BEFORE YOU TAKE KIDAMOL

Kidamol is contraindicated:

- in hypersensitivity to paracetamol or to the other excipients of the oral suspension;
- if you are treating your child with another drug that contains paracetamol;
- in severe liver and kidney impairment;
- in children under 2 years old.

Take special care with Kidamol

Ask your doctor before giving Kidamol to your child if they have:

- glucose-6-phosphate dehydrogenase deficiency;
- liver and kidney impairment;

Check with your doctor if the symptoms last more than 5 days, fever lasts more than 3 days or if your child develops allergic reactions like: wheezing, rash or itching.

Taking other medicines

Kidamol should not be used with other drugs that contain paracetamol.

Ask your doctor before taking Kidamol if your child takes other products, like: natural products, salicylates, other drugs for the treatment of pain and fever, warfarin, barbiturates, hydantoins, isoniazid, carbamazepine, rifampicin, sulfinpyrazone, active charcoal, intravenous busulphan, cholestyramine, metoclopramide, zidovudine; chloramphenicol.

Important information on some of the excipients of Kidamol

Kidamol oral suspension contains:

- approximately 875 mg sorbitol in 5 ml suspension; 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, talk to your doctor before giving this medicine to your child; sorbitol may cause gastrointestinal discomfort and mild laxative effect;
- 250 mg propylene glycol in 5 ml suspension; if your child is less than 5 years old, talk to your doctor or pharmacist before giving them this medicine, in particular if you are giving them

concomitantly other medicines that contain propylene glycol or alcohol; if the need arises for this medicine to be taken by a pregnant or breast-feeding adult, it should not be taken without a doctor's recommendation; your doctor may carry out extra checks while you are taking this medicine; if your child (or you) suffer from a liver or kidney disease, do not take this medicine without a doctor's recommendation; your doctor may carry out extra checks while you are taking this medicine.

- methylhydroxybenzoate and propylhydroxybenzoate, that may cause allergic reactions (possibly delayed).

3. HOW TO TAKE KIDAMOL

Always take Kidamol as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure. If you feel that the effects of Kidamol are too strong or too weak, talk to your doctor or pharmacist.

Shake well the bottle before use.

Kidamol should not be used in children under 2 years old.

DOSAGE	
Age (Weight):	Single dose
2 - 3 years old (11 - 15.9 kg)	5 ml
4 - 5 years old (16 - 21.9 kg)	7.5 ml
6 - 8 years old (22 - 26.9 kg)	10 ml
9 - 10 years old (27 - 31.9 kg)	12.5 ml
11 years old (32 - 43.9 kg)	15 ml

The single dose may be repeated every 4 - 6 hours as needed.
Kidamol should not be given more than 4 times daily.
This drug should not be given for more than 3 consecutive days without medical advice.

If your child takes more Kidamol than they should

If your child takes more Kidamol than they should, even if they do not manifest serious symptoms, please contact your doctor or call the hospital or emergency to get an opinion for the risk and an advice for the actions to be taken.

Overdose may cause severe to fatal liver impairment.

Symptoms of overdose are: sweating, nausea, vomiting, stomach pain, and loss of appetite.

If you forget to give your child Kidamol

If you forget a dose, give your child the next dose when it is time to take it usually.

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

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

4. POSSIBLE SIDE EFFECTS

All drugs may cause side effects. Sometimes they get serious, most of the time not.

Paracetamol, generally, is well tolerated by the organism.

Very rare cases of serious skin reactions have been reported.

Hemolytic anemia, neutropenia, leucopenia, pancytopenia, thrombocytopenia agranulocytosis, and hepatic function abnormal, are also reported.

If you notice side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE KIDAMOL

Keep out of the sight and reach of children!

Store below 25°C!

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

Store in the original packaging to protect from light!

6. FURTHER INFORMATION

What Kidamol oral suspension contains

The active substance is paracetamol.

5 ml of the oral suspension contain 160 mg paracetamol.

The excipients are: sorbitol, propylene glycol, glycerol, dispersible cellulose, polysorbate, sodium citrate, citric acid monohydrate, sodium saccharin, methylhydroxybenzoate, propylhydroxybenzoate, banana flavor, strawberry flavor, purified water.

Content of the pack

Carton box with one glass bottle of 120 ml.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

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