Package leaflet: Information for the user

KernaDol 1 g oral solution
Paracetamol

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

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- Talk to your doctor if symptoms worsen, or if the fever persists for more than 3 days or the pain for more than 5 days.

What is in this leaflet

1. What KernaDol is and what it is used for
2. What you need to know before you take KernaDol
3. How to take KernaDol
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1. What KernaDol is and what it is used for

KernaDol contains paracetamol. Paracetamol is effective in reducing pain and fever.

It is used for the short term relieve of mild to moderate pain, such as headache, toothache, muscle pain (spasms) or back pain (lumbago), and to reduce fever, in adults and adolescents over the age of 15 who weigh more than 50 kg.

2. What you need to know before you take KernaDol

Do not take KernaDol
- If you are allergic to paracetamol or to any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking the medicine.

- Do not take more medicine than what is recommended in section 3. How to take KernaDol.
- Do not use this medicine together with other medicines containing paracetamol, such as flu and cold medicines, because high doses may cause liver damage. Do not use more than one medicine containing paracetamol without talking to your doctor.
- Chronic alcoholics should not take more than 2 g of paracetamol in 24 hours.

– Patients with kidney, liver, heart or lung disease and patients with anaemia (decreased haemoglobin in the blood, whether due to a low red blood cell count or not), as well as patients suffering from chronic malnutrition or dehydration, should talk to their doctor before taking this medicine.
– If you are taking medicines used to treat epilepsy, you should talk to your doctor before taking this medicine, because when these medicines are used at the same time, their efficacy is decreased while the liver toxicity of paracetamol increases, especially treatments that use high doses of paracetamol.
– Asthma patients who are sensitive to acetylsalicylic acid should talk to their doctor before taking this medicine.

Children and adolescents
Because of the dose, this medicine is not indicated in children or adolescents under the age of 15 or those who weigh less than 50 kg.

Other medicines and KernaDol
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, in particular, if you are taking any of the following medicines, because it may be necessary to change the dose of some of them or discontinue the treatment:
- Medicines used to prevent blood clots: Oral anticoagulants (acenocoumarol, warfarin).
- Medicines used to treat epilepsy: Antiepileptic drugs (lamotrigine, phenytoin or other hydantoins, phenobarbital, methylphenobarbital, primidone, carbamazepine).
- Medicines used to treat tuberculosis: (isoniazid, rifampicin).
- Medicines used to treat depression and seizures: Barbiturates (used as hypnotics, sedatives and anticonvulsants).
- Medicines used to reduce blood cholesterol levels: (cholestyramine).
- Medicines used to increase urine output (loop diuretics such as those in the furosemide group).
- Medicines used to treat gout (probenecid and sulfinpyrazone).
- Medicines used to prevent nausea and vomiting: Metoclopramide and domperidone.
- Medicines used to treat high blood pressure (hypertension) and abnormal heart rhythm (cardiac arrhythmias): Propranolol.

Do not use with other painkillers (medicines that reduce pain) without talking to your doctor.

As a general rule for any medicine, always tell your doctor or pharmacist if you are on treatment with another medicine. In case of treatment with oral anticoagulants, it may be administered occasionally as a painkiller of choice.

Interference with laboratory tests
If you are going to have any laboratory tests (including blood, urine or other tests), tell your doctor that you are taking this medicine, as it may alter the results.

Paracetamol may cause changes in uric acid and glucose tests.

Use of KernaDol with food, drink and alcohol

The use of paracetamol in patients who regularly consume alcohol (three or more alcoholic beverages a day—beer, wine, spirits) may cause liver damage.

Taking this medicine with food does not affect its efficacy.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

The use of medicines during pregnancy can be dangerous to the embryo or the foetus, and should be monitored by your doctor.

If necessary, you can use KernaDol during pregnancy. You should use the lowest possible dose to reduce pain or fever and use it for as little time as possible. Contact your doctor if the pain or fever does not decrease or if you need to take the medication more frequently.

Paracetamol passes into breast milk, and women who are breast-feeding should therefore talk to their doctor or pharmacist before taking this medicine.

See also information concerning propyleneglicol below in this section

Driving and using machines

Paracetamol has no or negligible influence on the ability to drive and use machines.

KernaDol contains sorbitol (E-420), propylene glicol (E-1520), sulphites, glucose and ethanol

This medicine contains 2000 mg of sorbitol in each sachet.

Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to certain sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take this medicine.

This medicine may cause severe allergic reactions and bronchospasm (sudden choking sensation) because it contains sulphite ammonia caramel.

This medicine contains glucose (potato maltodextrin). If your doctor has told you that you have an intolerance to certain sugars, talk to him or her before taking this medicine.

This medicine contains 2.500 mg propyleneglicol in each sachet.
If you are pregnant or breast-feeding, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.
If you suffer from a liver or kidney disease, do not take this medicine unless recommended by your doctor. Your doctor may carry out extra checks while you are taking this medicine.

This medicine contains up to 18,2 mg of alcohol (ethanol) in each sachet. The amount in ml of this medicine is equivalent to less than 0,5 ml beer or 0,2 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

3. How to take KernaDol

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor, pharmacist or nurse if you are not sure.

The recommended dose is:

Adults and adolescents over the age of 15 who weigh more than 50 kg: Take 1 g of paracetamol (1 sachet) every 6–8 hours, 3 times daily.

Do not take more than 3 g of paracetamol (3 sachets) in 24 hours. Always take the lowest effective dose.

The use of this medicine is dependent on the onset of pain or fever. Treatment should be discontinued as symptoms disappear.

Avoid taking high daily doses of paracetamol for extended periods of time, because this increases the risk of adverse effects, such as liver damage.

If the pain lasts for more than 5 days, or the fever for more than 3 days, or if they get worse or other symptoms appear, stop taking the medicine and talk to your doctor.
For sore throat, do not take the medicine for more than 2 days without talking to your doctor.

Renal impairment: :
This medicine does not match the dosage recommendations for these patients.

Hepatic impairment:
These patients should ask their doctor for advice before taking this medicine.
Should take the amount of medicine prescribed by their doctor with a minimum interval of 8 hours between doses.
Should not take more than 2 g of paracetamol (2 sachets) in 24 hours, spread out over several doses.

Method of administration
This medicine is taken orally.
The contents of the sachet may be taken diluted in liquid, preferably water, or directly. Use the full content of the sachet after opening.

If you take more KernaDol than you should
You must tell your doctor or pharmacist immediately. In the event of overdose or accidental intake, go to hospital immediately, indicating the medicine and the amount taken.

Symptoms of overdose may include dizziness, vomiting, loss of appetite, yellowing of the skin and eyes (jaundice) and abdominal pain.

If you have taken an overdose, you should go to hospital immediately even if you do not notice any symptoms, as they often do not occur until 3 days after the overdose, even in cases of severe poisoning.

Treatment for an overdose is most effective if it is started within 4 hours of ingesting the medicine.

Patients on treatment with barbiturates or chronic alcoholics may be more susceptible to the toxicity of a paracetamol overdose.

If you forget to take KernaDol
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, although not everybody gets them.

Rare side effects, affecting up to 1 in 1,000 people, include malaise, low blood pressure (hypotension) and elevated levels of blood transaminases.

Very rare side effects, affecting up to 1 in every 10,000 people, include: Kidney diseases, cloudy urine, allergic dermatitis (skin rash), jaundice (yellowing of the skin), blood disorders (agranulocytosis, leukopenia, neutropenia, haemolytic anaemia) and hypoglycaemia (low blood sugar), and severe skin reactions.

Paracetamol may cause liver damage if taken in high doses or in prolonged treatments.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system. By reporting side effects, you can help to provide more information on the safety of this medicine.

Comentado [MDF1]: Please insert the national sentence for reporting the side effects

5. How to store KernaDol

Keep this medicine out of the sight and reach of children.

Store below 30°C.

Do not use this medicine after the expiry date which is stated on the pack after "EXP". The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

Comentado [MDF2]: Confirm if there is other sentence to include in this part

6. Contents of the pack and other information

Composition of KernaDol 1 g

- The active substance is paracetamol. Each sachet contains 1 g of paracetamol.
- The other ingredients are: propylene glycol (E1520), macrogol 400, povidone K12, sorbitol (E420), sulphite ammonia caramel (E150-d) (containing corn maltodextrin), masking SC274292 (containing sucralose (E955), maltodextrin (potato) and mono-ammonium glycyrrhizinate), neohesperidin dihydrochalcone (E959), orange essence (containing ethanol), citric acid monohydrate (for pH adjustment) and purified water.

What KernaDol looks like and contents of the pack
Brown-coloured oral solution, packed in single-dose sachets.

Each pack contains 10 sachets, packed in heat-sealed aluminium sachets (polyester/aluminium/polyethylene, polyester and polyethylene).

Not all pack sizes are marketed.

Marketing authorisation holder and manufacturer
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