Package leaflet: Information for the user

Medinol Over 6 250 mg/5 ml oral suspension

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 or pharmacist has 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet

1. What this medicine is and what it is used for
2. What you need to know before you take this medicine
3. How to take this medicine
4. Possible side effects
5. How to store this medicine
6. Contents of the pack and other information

1. What this medicine is and what it is used for

This Medicine contains paracetamol. This medicine has been specifically formulated for children aged 6 and over and is used for the relief of mild to moderate pain, including headache, toothache and sore throat and can relieve the symptoms of colds, flu and fever.

2. What you need to know before you take this medicine

Do not take this medicine…

• If you or your child are allergic to any of the ingredients in this product. See 'What this medicine contains' for the full list of ingredients.

• At the same time as taking other medicines containing paracetamol.

Take special care with…

• Continual use of this medicine without a doctor's supervision may be harmful.
• Patients with poor liver or kidney function.
• Not to be used in patients with fructose intolerance.

Taking other medicines

Speak to your doctor or pharmacist
If an adult takes this medicine with alcohol, it may increase liver toxicity of paracetamol.

Take special care with this medicine. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines in particular the following:

• Blood clotting medicines e.g warfarin and other coumarins. There is an increased risk of bleeding.

• If you take alcohol, barbiturates, anti-depressants or anti-epileptic medicines with paracetamol, it may increase the liver toxicity of paracetamol.

The absorption of paracetamol may be affected by:
• Metoclopramide and domperidone (for nausea and vomiting).
• Cholestyramine (for lowering blood cholesterol).

The absorption of chloramphenicol (an antibiotic) may be affected by paracetamol

Driving and using machines

Medinol over 6 Suspension is unlikely to affect your ability to drive and use machines.

Pregnancy and breast-feeding

It is recommended not to give paracetamol products during the first three months of pregnancy. The product may be taken during breast-feeding.

Important information about some of the ingredients…

• This medicine contains Sodium Propyl Parahydroxybenzoate (E217) and Sodium Methyl Parahydroxy benzoate (E219) which may cause allergic reactions (possibly delayed).

• If you or your child has an inherited intolerance to fructose, speak to your doctor before giving this medicine. The body can make some fructose from the ingredient maltitol. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3 How to take this medicine

Check the tables below to see how much of the medicine to use

- For oral use only
- It is important to **shake the bottle** for at least 10 seconds before use
- Never give more medicine than shown in the table
- Do not overfill the spoon
- Always use the spoon supplied with the pack
- Do not give with any other paracetamol-containing products

Child's Age	How Much	How often (in 24 hours)
6 – 8 years	One 5 mL spoonful (large end)	4 times
8 – 10 years	One 5.0 mL spoonful (large end) and One 2.5 mL spoonful (small end)	4 times
10 – 12 years	Two 5 mL spoonfuls (large end)	4 times
• Do not give more than 4 doses in any 24 hour period • Leave at least 4 hours between doses • Do not give this medicine to your child for more than 3 days without speaking to your doctor or pharmacist • Do not give to children under the age of 6 years		

Children aged 12 – 16 years: Two – three 5mL spoonfuls (large end) up to 4 times a day

Adults and children over 16 years: Two – four 5mL spoonfuls (large end) up to 4 times a day

Children under 6 years:

• Not to be used in children under six years of age. If symptoms persist for more than 3 days consult a doctor.

If you take too much of this medicine…

Speak to your doctor immediately if you take or if you give your child more of this medicine than is stated on the pack and in this leaflet, even if you/the child seems well, because of the risk of delayed serious liver damage.

4 Possible side effects

As with all medicines, this suspension can have side effects in some people.
• Side effects of paracetamol are rare but allergic reactions, including skin rash, may occur.
• There have been rare reports of blood disorders.
If you feel you, or your child, are reacting badly to this medicine in any way, or you notice any other side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store this medicine

• Keep out of the reach and sight of children.
• Do not store above 25°C.
• Do not use this medicine after the expiry date which is stated on the carton and the bottle label after mm/yyyy (abbreviation used for expiry date). The expiry date refers to the last day of that month.

6. Contents of the pack and other information

What Medinol Over -6 Suspension contains

Each 5ml of Medinol Over -6 Suspension contains 250mg of the active Ingredient paracetamol. Paracetamol is used to treat high temperatures and provide pain relief.

It also contains sodium methylhydroxybenzoate (E219), sodium propylhydroxybenzoate (E217), sodium saccharin, sodium cyclamate, tragacanth, Maltitol Solution (E965), strawberry flavour PFW 50023E and water.

What this medicine looks like and contents of the pack

The oral suspension is yellowish-off white to light orange/brown in colour with a taste and smell characteristic of strawberries.

This medicine is available in 70ml, 100ml and 200ml bottles. Not all pack sizes may be marketed.

Marketing Authorisation Holder:
Cupal Limited, Tubiton House, Oldham, OL1 3HS, UK.

Manufacturer:

SSL International plc, Whitehouse Industrial Park, Traynor Way, Peterlee, SR8 2RU, UK.

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