Package leaflet: Information for the user

AGOMOL SUSPENSION

Paracetamol 125mg/5ml Oral Suspension

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 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 or pharmacist. This includes any possible side effects not listed in this leaflet.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet?

- What Paracetamol Oral Suspension is and what it is used for
- What you need to know before you give Paracetamol Oral Suspension to a child.
- How to use Paracetamol Oral Suspension.
- Possible side effects.
- How to store Paracetamol Oral Suspension.
- Contents of the pack and other information.

1. What Paracetamol Oral Suspension is and what it is used for

For the treatment of mild to moderate pain and as an anti-pyretic. Used for the relief of pain and feverishness associated with teething, toothache, headache, colds, flu and post immunisation pyrexia.

2. What you need to know before you give

Paracetamol Oral Suspension to a child

Care is advised in the administration of Paracetamol to patients with severe renal or severe hepatic impairment. The hazards of overdose are greater in those with (non-cirrhotic) alcoholic liver disease.

Caution is advised if paracetamol is administered concomitantly with flucloxacillin due to increased risk of high anion gap metabolic acidosis (HAGMA), particularly in patients with severe renal impairment, sepsis, malnutrition and other sources of glutathione deficiency (e.g. chronic alcoholism), as well as those using maximum daily doses of paracetamol. Close monitoring, including measurement of urinary 5-oxoproline, is recommended.

3. How to use Paracetamol Oral Suspension

- Always give this medicine as your doctor or pharmacist has told you. Look on the label and ask your doctor or pharmacist if you are not sure.
- Using this medicine
- Refer the below table for dosage :

Child's Age	How Much	How Often (in 24 hours)
3 – 6 months	2.5 ml	4 times
6 – 24 months	5.0 ml	4 times
2 – 4 years	7.5 ml (5.0 ml + 2.05 ml)	4 times
4 – 8 years	10 .0 ml (5.0 ml + 5.0 ml)	4 times
8 – 10 years	15.0 ml (5.0 ml + 5.0 ml + 5.0 ml)	4 times
10 – 12 years	20.0 ml (5.0 ml + 5.0 ml + 5.0 ml + 5.0 ml)	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.

Babies over 2 months in age

For the relief of fever after vaccination at 2, 3 and 4 months 2.5 ml. This dose may be given up to 4 times a day at the time of vaccination. Do not give more than 4 doses in any 24 hour period. Leave at least 4 hours between doses. If your baby still needs this medicine two days after receiving the vaccine talk to your doctor or pharmacist.

It is important to shake the bottle for at least 10 seconds before use.

If you give more Paracetamol than you should (overdose):

Liver damage is possible in adults who have taken 10 g or more of Paracetamol. Ingestion of 5 g or more of Paracetamol may lead to liver damage if the patient has risk factors.

Risk Factors

If the patient:

a) Is on long term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St. John's Wort or other drugs that induce liver enzymes.
Or
b) Regularly consumes ethanol in excess of recommended amounts.
Or
c) Is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.

Symptoms

Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycaemia, cerebral oedema and death. Acute renal failure with acute tubular necrosis, strongly suggested by loin pain, haematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

Management

Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention. Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage. Management should be in accordance with established treatment guidelines, see BNF overdose section.

Treatment with activated charcoal should be considered if the overdose has been taken within one 1 hour. Plasma Paracetamol concentration should be measured at 4 hours or later after ingestion (earlier concentrations are unreliable). Treatment with N acetylcysteine may be used up to 24 hours after ingestion of Paracetamol, however, the maximum protective effect is obtained up to 8 hours post-ingestion. The effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous N-acetylcysteine, in line with the established dosage schedule. If vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside hospital. Management of patients who present with serious hepatic dysfunction beyond 24 h from ingestion should be discussed with the NPIS or a liver unit.

4. Possible side effects

Very rare cases of serious skin reactions have been reported. Adverse effects of Paracetamol are rare but hypersensitivity including skin rash may occur. There have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily causually related to Paracetamol. With prolonged use or overdosage, hepatic necrosis, acute pancreatitis and nephrotoxicity have been reported.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at ww.mhra.gov.uk/yellowcard.

5. How to store Paracetamol Oral Suspension

Do not store above 30°C. Protect from light. Keep medicines out of reach of children.

6. Contents of the pack and other information

What Paracetamol Suspension contains:

The active substance is paracetamol.

List of Excipients:

Lactose BP 60.0 mg, Micro Crystalline Cellulose Powder BP 20.0 mg, Pre Gelatinised Starch BP 8.63 mg, Methyl Paraben Sodium BP 0.1 mg, Propyl Paraben Sodium BP 0.05 mg, Maize Starch BP 10.0 mg.

7. What Paracetamol Oral Suspension look like and contents of the pack

Yellow coloured uniform suspension on shaking.

Shelf life: 36 months

Packing/pack size: 60 ml bottle pack & 100 ml bottle pack

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Marketing Authorisation Holder and Manufacturer

AGOG PHARMA LTD.

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140 mm

95 mm