SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Paracetamol 250mg/5ml Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml contains Paracetamol 250mg

Excipients with known effect:

Maltitol liquid (E965) – 1.0ml

Sodium methyl parahydroxybenzoate (E219) – 9.0ml

Sodium propyl parahydroxybenzoate (E217) – 1.0ml

For the full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral Suspension.

White uniform suspension.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Paracetamol 250mg/5ml Oral Suspension is indicated for the treatment of mild to moderate pain including headache, toothache, earache and sore throats. It is also used to treat colds and influenza, aches and pains and post-immunisation fever.

4.2 Posology and method of administration

Not recommended.

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

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 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.

The Elderly:

In the elderly, the rate and extent of paracetamol absorption is normal but plasma half-life is longer and paracetamol clearance is lower than in young adults.

4.3 Contraindications

Paracetamol suspension is contra-indicated in patients with known hypersensitivity to paracetamol, or any of the other constituents.

This product contains maltitol liquid, patients with rare hereditary problems of fructose intolerance should not take this medicine.

4.4 Special warnings and precautions for use

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help straight away. Quick medical attention is critical for adults as well as children even if signs or symptoms are not noticed.

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. Chronic alcohol abusers should consult a doctor before use.

Patients should be informed about the signs of serious skin reactions and use of the drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

This product contains Sodium methyl parahydroxybenzoate (E219) and Sodium propyl parahydroxybenzoate (E217). These may cause allergic reactions (possibly delayed).

It also contains maltitol liquid (E965). Patients with rare hereditary problems of fructose intolerance should not take this medicine.

The label will include:

- Contains paracetamol.
- Do not give anything else containing paracetamol while giving this medicine.
- For oral use only.
- Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor.
- Do not overfill the spoon.

- Always use the spoon supplied with the pack.
- 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
- As with all medicines, if your child is currently taking any medicine consult your doctor or pharmacist before taking this product.
- Do not store above 25°C. Store in the original package.
- Keep out of the sight and reach of children.
- Shake the bottle for at least 10 seconds before use.
- Talk to a doctor at once if you take too much of this medicine even if you seem well (label).

Talk to a doctor at once if you take too much of this medicine even if you seem well. This is because too much Paracetamol can cause delayed, serious liver damage (leaflet).

4.5 Interaction with other medicinal products and other forms of interaction

The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by cholestyramine.

The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular use of paracetamol with risk of bleeding; occasional doses have no significant effect.

Chronic alcohol intake can increase the hepatotoxicity of paracetamol overdose and may have contributed to the acute pancreatitis reported in one patient who had an overdose of paracetamol. Acute alcohol intake may diminish an individual's ability to metabolise large doses of paracetamol, the plasma half-life of which can be prolonged.

The use of drugs that induce hepatic microsomal enzymes, such as anticonvulsants and oral contraceptives, may increase the extent of metabolism of paracetamol, resulting in reduced plasma concentrations of the drug and a faster elimination rate.

4.6 Fertility, Pregnancy and lactation

Fertility

There is no information relating to the effects of paracetamol oral suspension on fertility (see section 5.3).

Pregnancy

A large amount of data on pregnant women indicate neither malformative, nor feto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

Breast-feeding

Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contraindicate breast feeding.

4.7 Effects on ability to drive and use machines

No adverse effects known

4.8 Undesirable effects

Adverse effects of paracetamol are rare. Very rare cases of serious skin reactions have been reported. Very rarely hypersensitivity and anaphylactic reactions including skin rash may occur.

There have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily causality related to paracetamol.

Most reports of adverse reactions to paracetamol relate to overdosage with the drug.

Chronic hepatic necrosis has been reported in a patient who took daily therapeutic doses of paracetamol for about a year and liver damage has been reported after daily ingestion of excessive amounts for shorter periods. A review of a group of patients with chronic active hepatitis failed to reveal differences in the abnormalities of liver function in those who were long-term users of paracetamol nor was the control of the disease improved after paracetamol withdrawal.

Nephrotoxic effects following therapeutic doses of paracetamol are uncommon. Papillary necrosis has been reported after prolonged administration.

Low level transaminase elevations may occur in some patients taking therapeutic doses of paracetamol; these are not accompanied with liver failure and usually resolve with continued therapy or discontinuation of paracetamol,

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: www.mhra.gov.uk/yellowcard.

4.9 Overdose

Children who have ingested 75mg/kg or more of paracetamol in less than 1 hour should be referred to hospital. Administration of activated charcoal should be considered if paracetamol in excess of 150mg/kg is thought to have been ingested within the previous hour.

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

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, hyperhidrosis, malaise, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion. This may include hepatomegaly, liver tenderness, jaundice, acute hepatic failure and hepatic necrosis. Abnormalities of glucose metabolism and metabolic acidosis may occur. Blood bilirubin, hepatic enzymes, INR, prothrombin time, blood phosphate and blood lactate may be increased. 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 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 24h from ingestion should be discussed with the NPIS or a liver unit.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Non-Opioid Analgesic

ATC CODE: N02B E01

Paracetamol has analgesic and antipyretic effects similar to those of aspirin and is useful in the treatment of mild to moderate pain. It has weak anti-inflammatory effects.

5.2 Pharmacokinetic properties

Approximatley 90-95% of a dose is metabolised in the liver, primarily by conjugation with glucuronic acid and cysteine. An intermediate metabolite, which may accumulate in overdosage after primary metabolic pathways become saturated, is hepatotoxic and possibly nephrotoxic.

Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract. Peak plasma concentrations are reached 30-90 minutes

post dose and the plasma half-life is in the range of 1 to 3 hours after therapeutic doses.It is widely distributed through the body. Metabolism is principally by the hepatic microsomal enzymes and urinary excretion accounts for over 90% of the dose within 1 day. Virtually no paracetamol is excreted unchanged, the bulk being conjugated with glucuronic acid (60%), sulphuric acid (35%) or cysteine (3%).

Small amounts of hydroxylated and deacetylated metabolites have also been detected. Children have less capacity for glucuronidation of the drug than do adults. In overdosage there is increased N-hydroxylation followed by glutathione conjugation. When the latter is exhausted, reaction with hepatic proteins is increased leading to necrosis.

5.3 Preclinical safety data

Conventional studies using the currently accepted standards for the evaluation of toxicity to reproduction and development are not available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol (E422)

Polysorbate 80 (E433)

Xanthan Gum (E415)

Maltitol liquid (E965)

Saccharin sodium (E954)

Citric acid monohydrate (E330)

Sodium methyl parahydroxybenzoate (E219)

Sodium propyl parahydroxybenzoate (E217)

Strawberry flavour (contains propylene glycol)

Purified water

6.2 Incompatibilities

None Known

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25ºC. Keep the container in the outer carton. Discard after 2 months of first opening.

6.5 Nature and contents of container

Amber Type III Glass

Child Resistant Tamper Evident Cap- High density polypropylene cap with a polyethylene lining

A spoon with a 2.5 ml and 5 ml measure is supplied with all packs of this product

Pack sizes available: 100ml, 200ml

6.6 Special precautions for disposal

No special requirements

7 MARKETING AUTHORISATION HOLDER

Crescent Pharma Limited
3&4 Quidhampton Business Units
Polhampton Lane
Overton
Hampshire
RG25 3ED
UK

8 MARKETING AUTHORISATION NUMBER(S)

PL 20416/0522

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28/02/2008

10 DATE OF REVISION OF THE TEXT

10/05/2021