

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Panadol Original 500 mg film-coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 500 mg paracetamol.

For the full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet

White, film-coated capsule-shaped tablets, 14 mm, with flat edges, with a triangular logo debossed on one side and a break line on the other.

The tablet can be divided into equal doses.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Panadol Original is a mild analgesic and antipyretic. The tablets are recommended for use in the short-term management of headaches, musculoskeletal disorders, menstrual pain, toothache and for symptoms of common colds and flu. Panadol Original may also be used in the symptomatic relief of mild to moderate pain associated with osteoarthritis as diagnosed by a doctor.

4.2 Posology and method of administration

Panadol Original is for oral administration.

Adults (including the elderly) and children aged 16 years and over:

One or two tablets up to four times daily as required.

Children aged 10-15 years:

One tablet up to four times daily as required. Children should not be given Panadol Original Tablets for more than 3 days without consulting a doctor.

Panadol Original tablets are not recommended for children under 10 years of age.

These doses should not be repeated more frequently than every 4 hours and not more than 4 doses should be given in any 24 hour period.

The lowest dose necessary to achieve efficacy should be used.

4.3 Contraindications

Hypersensitivity to paracetamol or any of the other constituents.

4.4 Special warnings and precautions for use

Contains paracetamol. Do not use with any other paracetamol-containing products. The concomitant use with other products containing paracetamol may lead to an overdose. Paracetamol overdose may cause liver failure which can lead to liver transplant or death.

Underlying liver disease increases the risk of paracetamol related liver damage. Patients who have been diagnosed with liver or kidney impairment must seek medical advice before taking this medication.

Cases of hepatic dysfunction/failure have been reported in patients with depleted glutathione levels, such as those who are severely malnourished, anorexic, have a low body mass index or are chronic heavy users of alcohol.

Caution in patients with glutathione depleted states such as sepsis; the use of paracetamol may increase the risk of metabolic acidosis.

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.

Do not exceed the stated dose.

If symptoms persist, consult your doctor. Prolonged use except under medical supervision may be harmful.

This product should only be used when clearly necessary. Keep out of sight and reach of children.

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 daily use of paracetamol with increased risk of bleeding; occasional doses have no significant effect. Caution should be taken when paracetamol is used concomitantly with flucloxacillin as concurrent intake has been associated with high anion gap metabolic acidosis, especially in patients with risks factors (see section 4.4)

4.6 Fertility, pregnancy and lactation

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.

Lactation

Paracetamol is excreted in breast milk. However, the level of paracetamol present is not considered to be harmful. Available published data do not contraindicate breastfeeding.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

There have been rare reports of blood dyscrasias including thrombocytopenia and agranulocytosis but there were not necessarily casually related to paracetamol.

The frequency of adverse events associated with paracetamol are tabulated below:

Body System	Undesirable Effect	Frequency
Paracetamol		
Blood and lymphatic system disorders	Thrombocytopenia	Very rare
Immune system disorders	Anaphylaxis Cutaneous hypersensitivity reactions, Angiodema, Stevens Johnson syndrome	Very rare

	Very rare cases of serious skin reactions have been reported	
Respiratory, thoracic and mediastinal disorders	Bronchospasm in patients sensitive to aspirin and other NSAIDs	Very rare
Hepatobiliary disorders	Hepatic Dysfunction	Very rare

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 HPRA Pharmacovigilance website: www.hpra.ie.

4.9 Overdose

Paracetamol overdose may cause liver failure which can lead to liver transplant or death. Acute pancreatitis has been observed, usually with hepatic dysfunction and liver toxicity.

There is a risk of poisoning with paracetamol particularly in elderly subjects, young children, patients with liver disease, cases of chronic alcoholism and in patients with chronic malnutrition. Overdosing may be fatal in these cases.

Symptoms generally appear within the first 24 hours and may comprise: nausea, vomiting, anorexia, pallor, and abdominal pain, or patients may be asymptomatic.

Overdose of paracetamol in a single administration in adults or in children can cause liver cell necrosis likely to induce complete and irreversible necrosis, resulting in hepatocellular insufficiency, metabolic acidosis and encephalopathy which may cause coma and death. Simultaneously, increased levels of hepatic transaminases (AST, ALT), lactate dehydrogenase and bilirubin are observed together with increased prothrombin levels that may appear 12 to 48 hours after administration. Liver damage is likely in adults who have taken more than the recommended amounts of paracetamol. It is considered that excess quantities of toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are ingested), become irreversibly bound to liver tissue.

Some patients may be at increased risk of liver damage from paracetamol toxicity.

Risk Factors include: If the patient;

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

Emergency Procedure:

Immediate transfer to hospital.

Blood sampling to determine initial paracetamol plasma concentration. In the case of a single acute overdose, paracetamol plasma concentration should be measured 4 hours post ingestion.

Administration of activated charcoal should be considered if >150mg/kg paracetamol has been taken within 1 hour.

The antidote N-acetylcysteine, should be administered as soon as possible in accordance with National treatment guidelines.

Symptomatic treatment should be implemented.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Paracetamol has analgesic and antipyretic actions.

5.2 Pharmacokinetic properties

Paracetamol is rapidly and almost completely absorbed from the gastro-intestinal tract. Concentration in plasma reaches a peak in 30 - 60 minutes.

Plasma half-life is 1 - 4 hours.

Paracetamol is relatively uniformly distributed throughout most body fluids.

Plasma protein binding is variable.

Excretion is almost exclusively renal, in the form of conjugated metabolites.

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

Maize starch

Potassium sorbate

Talc

Stearic acid

Povidone

Starch, Pregelatinised

Hypromellose

Triacetin

Carnauba wax

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

4 years - HDPE Bottle.

5 years - blister pack.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Panadol Tablets are packed in:

- Blister packs packed either into cardboard cartons containing 12, 24, 48 or 96 tablets, or into cardboard wallets containing 12 tablets:
 - Blister packs comprising polyvinyl chloride (PVC) laminate heat-sealed with hard tempered aluminium foil.
 - Child resistant blister packs comprising PVC laminate heat sealed to bilayer of aluminium and polyethylene terephthalate.
 - Blister packs comprising polypropylene (PP) thermoforming foil heat sealed to PP push through lidding film.
- HDPE bottles fitted with screw closure or 'Clik Lok' caps containing 100 tablets

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Haleon Ireland Limited
12 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0678/039/005

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1978

Date of last renewal: 11 June 2008

10 DATE OF REVISION OF THE TEXT

28th April 2023