

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Panadol

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Paracetamol 500.0 mg

3. PHARMACEUTICAL FORM

Film-coated tablets

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the short-term relief of pain and antipyretic including:

- Headache
- Musculoskeletal pain.
- Dysmenorrhoea
- Toothache.
- Cold and flu symptoms

It can also be used for symptomatic relief of pain from mild to moderate intensity in osteoarthritis diagnosed by a doctor.

4.2 Posology and method of administration

For oral administration only.

Adults (including the elderly) and children aged 16 years and over: 1-2 tablets up to 4 times daily as required.

Children 10 - 15 years: 1 tablet up to 4 times daily as required. Maximum duration of continued use without medical advice: 3 days.

Minimum dosing interval: 4 hours. No more than four doses in any 24 hour period.

Children: Not recommended for children under the age of 10 years.

Patients with renal / hepatic impairment: Patients with severe hepatic or severe renal insufficiency are not recommended to use the drug. Patients who have been diagnosed with kidney/liver impairment must seek medical advice before taking this medication.

Do not exceed the stated dose.

The lowest dose necessary to achieve efficacy should be used.

4.3 Contraindications

Previous history of hypersensitivity to paracetamol or any of the excipients.

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

In patients with glutathione depleted states such as sepsis, the use of paracetamol may increase the risk of metabolic acidosis.

Do not exceed the stated dose.

If symptoms persist consult your doctor. Long-term use of the drug, except when it happens under medical supervision, can lead to serious consequences.

This medicine should be used only in case of obvious need.

Keep out of the sight and reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

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. Paracetamol absorption rate can be increased when combined with metoclopramide and domperidone. Absorption of paracetamol may be reduced when used with cholestyramine.

4.6 Pregnancy and lactation

Pregnancy: A large amount of data on pregnant women indicate neither malformative, nor fetoneonatal 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.

However, as in case of taking any other drug, it is necessary to follow the doctor's instructions and take the medicine with caution during the first trimester.

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:

Very rare (< 1/10,000):

Blood and lymphatic system disorders	Thrombocytopaenia
Immune System disorders	Anaphylaxis Cutaneous hypersensitivity reactions including skin rashes, Angiodema, Stevens Johnson syndrome and Toxic Epidermal Necrolysis.
Respiratory, thoracic and mediastinal disorders	Bronchospasm in patients sensitive to aspirin and other NSAIDs.
Hepatobiliary disorders	Hepatic dysfunction

Reporting suspected adverse reactions:

If you experience any adverse reactions, please consult your doctor. This recommendation applies to any possible adverse reactions, including those not listed in the instruction for use. You can also report adverse reactions to the information database, including reports of drug's being not effective. Reporting suspected adverse reactions of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

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. The risk of intoxication with paracetamol is higher in elderly people, small children, patients with liver diseases, chronic malnutrition, people with chronic alcoholism. In these cases overdose may be fatal. After a single use of high dose of paracetamol, complete and irreversible liver necrosis leading to hepatocellular insufficiency, metabolic acidosis, encephalopathy, coma, and death may be developed in adults and children. 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, such as:

- the patient has long term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes;
- patient regularly consumes ethanol in excess of recommended amount;
- patient with the risk of glutathione deplete (eating disorders, cystic fibrosis, HIV infection, starvation, cachexia).

Symptoms of paracetamol overdosage in the first 24 hours are nausea, vomiting, anorexia, skin pallor, abdominal pain. In some cases there can be no symptoms.

Within 12 to 48 hours after an overdose, elevated levels of hepatic transaminases (AST, ALT), lactate dehydrogenase, and bilirubin may occur. 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.

Treatment: 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.

Immediate medical management is required in the event of overdose, even if symptoms of overdose are not present.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Paracetamol is an analgesic and antipyretic (.

Its mechanism of action is believed to include inhibition of prostaglandin synthesis, primarily within the central nervous system.

5.2 Pharmacokinetic properties

Absorption

Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract. The maximum plasma concentration is reached within 30-60 minutes. The half-life ($t_{1/2}$) - 1-4 hours.

Distribution

Binding to the plasma proteins is minimal at therapeutic concentrations. Paracetamol is relatively evenly distributed in most body fluids. Plasma protein binding is low and may vary.

Metabolism

Paracetamol is metabolised in the liver and excreted in the urine mainly as glucuronide and sulphate conjugates.

Elimination

Less than 5% is excreted as unmodified paracetamol.

5.3 Preclinical safety data

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pregelatinised starch, Corn starch, Povidone, Talc, Potassium sorbate, Stearic Acid, Hypromellose, Triacetin, Carnauba wax.

6.2 Incompatibilities

None

6.3 Shelf life

5 years. Should not be used after expiry date stated on a pack.

6.4 Special precautions for storage

Store below 25°C. Keep out of the sight and reach of children.

6.5 Nature and contents of container

1 blister in a cardboard carton with patient information leaflet, containing 12 tablets with function child resistant blister packs comprising PVC laminate heat sealed to bilayer of aluminium and polyethylene terephthalate.

6.6 Special precautions for disposal

None

7. MANUFACTURER

GlaxoSmithKline Dungarvan Limited, Knockbrack, Dungarvan, Co. Waterford, Ireland.

8. MARKETING AUTHORIZATION HOLDER

GlaxoSmithKline Consumer Healthcare (UK) Trading Limited, 980 Great West Road, Brentford, Middlesex, TW8 9GS, UK.

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION

29.05.84/01.11.89

10. DATE OF REVISION OF THE TEXT

21/02/2022