Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Panadol Actifast Tablets 500mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains paracetamol 500mg.
Excipients: Contains 176mg (7.5mmol) sodium per tablet. For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablets.
White to off-white film-coated capsule shaped tablets with flat edges, debossed with the letter 'P' on one side and '--' on the other side.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

A mild analgesic and antipyretic recommended in the short-term management of the symptoms of headaches, musculoskeletal disorders, menstrual pains, toothache and for relieving fever, aches and pains of common colds and flu.

4.2 Posology and method of administration

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 12-15 years:
One tablet up to four times daily as required.
Children should not be given Panadol ActiFast for more than 3 days without consulting a doctor.

Not recommended for children under 12 years of age.

Minimum dosing interval: 4 hours.
Not more than 4 doses should be taken in any 24-hour period.
Do not exceed the stated dose.
Should not be used with other paracetamol containing products.
The lowest dose necessary to achieve efficacy should be used.

4.3 Contraindications

Panadol Actifast is contraindicated in patients with a previous history of hypersensitivity to paracetamol or any of the other ingredients.

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.

Cases of high anion gap metabolic acidosis (HAGMA) due to pyroglutamic acidosis have been reported in patients with severe illness such as severe renal impairment and sepsis, or in patients with malnutrition and other sources of glutathione deficiency (e.g. chronic alcoholism) who were treated with paracetamol at therapeutic dose for a prolonged period or a combination of paracetamol and flucloxacillin. If HAGMA due to pyroglutamic acidosis is suspected, prompt discontinuation of paracetamol and close monitoring is recommended. The measurement of urinary 5-oxoproline may be useful to identify pyroglutamic acidosis as underlying cause of HAGMA in patients with multiple risk factors.

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 the 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 due to pyroglutamic 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

No significant effect.

4.8 Undesirable effects

Events reported from extensive post-marketing experience at therapeutic/labelled dose and considered attributable are tabulated below by System Organ Class and frequency.
Frequencies are defined as: very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1,000, <1/100), rare (≥1/10,000, <1/1000), very rare (<1/10,000), not known (cannot be estimated from available data).
Adverse event frequencies have been estimated from spontaneous reports received through post marketing data.

Body System	**Undesirable Effect**	**Frequency**
Paracetamol		
Blood and lymphatic system disorders	Thrombocytopaenia	Very rare
Metabolism and nutrition disorders	High anion gap metabolic acidosis*	Not known
Immune System disorders	Anaphylaxis, Cutaneous hypersensitivity reactions, including, among others, skin rashes, angiodema, Stevens Johnson syndrome and Toxic Epidermal Necrolysis. Very rare cases of serious skin reactions	Very rare

Respiratory, thoracic and mediastinal disorders	Bronchospasm in patients sensitive to aspirin and other NSAIDs	Very rare
Hepatobiliary disorders	Hepatic dysfunction	Very rare

* Cases of high anion gap metabolic acidosis due to pyroglutamic acidosis have been observed in patients with risk factors using paracetamol (see section 4.4). Pyroglutamic acidosis may occur as a consequence of low glutathione levels in these patients.

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 lead to 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.

High doses of sodium bicarbonate may be expected to induce gastrointestinal symptoms including belching and nausea. Gastric rupture has rarely been reported. In addition, high doses of sodium bicarbonate may cause hypernatraemia;

hyperosmolarity and metabolic alkalosis, particularly in patients with renal disease. Electrolytes should be monitored and if abnormalities occur, the patient should be managed appropriately after seeking expert advice.

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. The lack of peripheral prostaglandin inhibition confers important pharmacological properties such as the maintenance of the protective prostaglandins within the gastrointestinal tract. Paracetamol is, therefore, particularly suitable for patients with a history of disease or on concomitant medicaion where peripheral prostaglandin inhibition would be undesirable (such as, for example, those with a history of GI bleeding or the elderly).

Sodium bicarbonate has no known analgesic activity.

Clinical data showed PANADOL Actifast to provide faster onset of analgesia than standard paracetamol tablets.

Onset of pain relief for PANADOL Actifast showed no difference in both fasted and fed states in an acute pain study.

5.2 Pharmacokinetic properties

Paracetamol is metabolised in the liver and excreted in the urine mainly as glucuronide and sulphate conjugates – less than 5 % is excreted as unmodified paracetamol. Binding to the plasma proteins is minimal at therapeutic concentrations.

Sodium bicarbonate speeds up tablet dissolution in the stomach and enhances gastric emptying of paracetamol into the small intestine where it is absorbed.

In human volunteer pharmacokinetic studies, mean maximum plasma concentrations were reached at least twice as fast for PANADOL Actifast tablets compared to standard paracetamol tablets at both a one and two tablet dose and these were statistically significant.

The extent of absorption for PANADOL Actifast tablets is equivalent to that for standard paracetamol tablets as shown by AUC at both a one and two tablet dose.

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

Tablet core:

Sodium hydrogen carbonate Pregelatinised starch Povidone
Maize starch Microcrystalline cellulose Magnesium stearate Carnauba wax
Sodium starch glycolate Colloidal anhydrous silica
The tablets are coated with Opadry II Y-22-7719 White which contains: Titanium dioxide (E171)
Polydextrose Hypromellose Triacetin Macrogol

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Opaque PVD/Aluminium foil blister strips packed into cardboard cartons containing 4, 6, 8, 10, 12, 16, 20, 24 or 32 tablets or into cardboard wallets containing 10 or 12 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Haleon Ireland Limited
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X35 Y983
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8 MARKETING AUTHORISATION NUMBER

PA0678/039/012

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14 December 2001

Date of last renewal: 14 November 2006

10 DATE OF REVISION OF THE TEXT

July 2025