SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Paracetamol 500mg Tablets BP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Paracetamol 500mg

Excipients with known effect:
Each tablet contains 6.7mg of Lactose
For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablet

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Taken orally for relief from:

1. Headache
2. Toothache
3. Rheumatic Pains
4. Neuralgia
5. The symptoms of colds and influenza

4.2. Posology and Method of Administration

Adults, the elderly and children 16 years and over:
Dose to be taken every four hours (not more than 4 times in 24 hours).
Adults, including the elderly, and children over 15 years: 1 to 2 tablets

Maximum dose of 8 tablets in 24 hours

Paediatric population
Children aged 10 to 15 years:
1 tablet every 4-6 hours when necessary to a maximum of 4 doses in 24 hours

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

Under no circumstances must the daily dose of paracetamol exceed four grams in 24 hours.

Do not take these tablets for more than three days except on medical advice.

Use with care in patients with liver or kidney problems, and in patients taking other drugs that affect the liver.

Do not exceed the stated dose. An overdose is dangerous: medical attention should be sought immediately.

4.3. Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

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.

Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor.
Contains Paracetamol.
Do not take anything else containing paracetamol while taking this medicine.
Talk to your doctor at once if you take too much of this medicine, even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage.
Patients should be advised that paracetamol may cause severe skin reactions. If a skin reaction such as skin reddening, blisters, or rash occurs, they should stop use and seek medical assistance right away.

Each tablet contains approximately 6.7mg of lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

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 or 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.

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, dehydrated, are chronic heavy users of alcohol or have sepsis. In patients with glutathione depleted states the use of paracetamol may increase the risk of metabolic acidosis.
If symptoms persist, medical advice must be sought.
Keep out of sight and reach of children.

4.5 Interaction with other medicinal products and other forms of interaction

Cholestyramine: The speed of absorption of paracetamol is reduced by cholestyramine. Therefore, the cholestyramine should not be taken within one hour if maximal analgesia is required.

Metoclopramide and Domperidone: The absorption of Paracetamol is increased by metoclopramide and domperidone. However, concurrent use need not be avoided.
Warfarin: The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

Chloramphenicol: Increased plasma concentration of chloramphenicol.

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.

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

None

4.8 Undesirable effects

The following convention has been utilised for the classification of the frequency of adverse reactions: 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 effects of Paracetamol are rare. Very rare cases of serious skin reactions have been reported There have been reports of blood dyscrasias including thrombocytopenia purpura, methaemoglobenaemia and agranulocytosis, but these were not necessarily causally related to Paracetamol.

System organ class	Frequency	Undesirable effects
Metabolism and nutrition disorders	‘’Not known’’ (cannot be estimated from the available data)	High anion gap metabolic acidosis 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.
Blood and lymphatic system disorders	Very rare	Thrombocytopaenia
Immune system disorders	Very rare	Anaphylaxis, Cutaneous hypersensitivity reactions including, among others, skin rashes, angioedema, Stevens Johnson syndrome and Toxic Epidermal Necrolysis
Respiratory, thoracic and mediastinal disorders	Very rare	Bronchospasm in patients sensitive to aspirin and other NSAIDs
Hepatobiliary disorders	Very rare	Hepatic dysfunction

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

Symptoms and Signs

Experience following overdose with paracetamol indicates that the clinical signs of liver injury occur usually after 24 to 48 hours and peak after 4 to 6 days.

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

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, 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 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: Analides, Other Analgesics and Antipyretics.
ATC Code: N02B E01

Mechanism of action

Analgesic – the mechanism of analgesic action has not been fully determined. Paracetamol may act predominantly by inhibiting prostaglandin synthesis in the central nervous system (CNS) and to a lesser extent, through a peripheral action by blocking pain-impulse generation.
The peripheral action may also be due to inhibition of prostaglandin synthesis or to inhibition of the synthesis or actions of other substances that sensitise pain receptors to mechanical or chemical stimulation.

Antipyretic – paracetamol probably produces antipyresis by acting centrally on the hypothalamic heat-regulation centre to produce peripheral vasodilation resulting in increased blood flow through the skin, sweating and heat loss. The central action probably involves inhibition of prostaglandin synthesis in the hypothalamus

5.2. Pharmacokinetic Properties

Absorption and Fate
Paracetamol is readily absorbed from the gastro-intestinal tract with peak plasma concentrations occurring about 30 minutes to 2 hours after ingestion. It is metabolised in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates. Less than 5% is excreted as unchanged Paracetamol. The elimination half-life varies from about 1 to 4 hours. Plasma protein binding is negligible at usual therapeutic concentrations but increases with increasing concentrations.
A minor hydroxylated metabolite which is usually produced in very small amounts by mixed function oxidases in the liver and which is usually

detoxified by conjugation with liver glutathione, may accumulate following Paracetamol overdose and cause liver damage.

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

Povidone (Kollidone K30) Ph. Eur.
Lactose 200# Ph. Eur.
Starch (Maize) Ph. Eur.
Magnesium Stearate Ph. Eur.
Sodium Starch Glycollate Ph. Eur.

6.2 Incompatibilities

None Known

6.3 Shelf life

3 Years

6.4 Special precautions for storage

None Stated

6.5 Nature and contents of container

NATURE	CONTENTS
Foil backed plastic blister in card carton	16
Foil backed plastic blister in card carton	24
Foil backed plastic blister in card carton	32

Foil backed plastic blister in card carton	48
Foil Backed plastic blister in card carton	96
Foil Backed plastic blister in card carton	100
Plastic snap-safe tub	50
Plastic snap-safe tub	100
Plastic snap-safe tub	1000

Not all pack sizes may be marketed

6.6 Special precautions for disposal

None Stated

7 MARKETING AUTHORISATION HOLDER

Medley Pharma Limited

Unit 2A

Olympic Way

Sefton Business Park

Bootle

Merseyside

L30 1RD

United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 43870/0006

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10/07/2025

10 DATE OF REVISION OF THE TEXT

19/08/2025