SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Paracetamol 1000 mg effervescent tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each effervescent tablet contains 1000 mg of paracetamol.

Excipients with known effects:

Each effervescent tablet contains 586.11 mg of sodium

Each effervescent tablet contains 10 mg of aspartame.

For the full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Effervescent tablet.

White to off white coloured, circular, flat bevelled tablets, plain on both sides.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Paracetamol is a mild analgesic and antipyretic, and is recommended for the treatment of most painful and febrile conditions, for example, headache including migraine, tension headaches, toothache, backache, rheumatic and muscle pains, dysmenorrhoea, sore throat, and for relieving the fever, aches and pains of colds and flu.

4.2 Posology and method of administration

Posology

Adults,the elderly, and children aged 16 years and over

One tablet to be taken up to four times daily. Maximum dose of 4 tablets in 24 hours.

Paediatric population

Children and adolescents below 16 years of age

This product is not recommended in children aged less than 16 years.

Dosage of paracetamol should not be given more frequently than every 4 hours, and not more than 4 doses should be given in any 24 hour period.

Patients should not be given paracetamol for more than 3 days without consulting a doctor.

Method of administration

Oral administration only.

Dissolve the tablets in water (about 200 ml) before swallowing.

4.3 Contraindications

Hypersensitivity to paracetamol 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.

Patients should be advised to consult a doctor if they suffer from non-serious arthritis and need to take painkillers every day.

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.

This medicinal product contains 586.11 mg sodium per effervescent tablet, equivalent to 29.31% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

The effervescent tablet also contain aspartame (a source of phenylalanine) and so should not be taken by people with phenylketonuria.

Pack label

Immediate medical advice should be sought in the event of an overdose, even if you feel well.

Do not take with any other paracetamol containing products.

Patient information leaflet

Immediate medical advice should be sought in the event of an overdose even if you feel well, because of the risk of delayed serious liver damage.

Do not exceed the recommended dose.

Patients should be advised to consult their doctor if their headaches become persistent.

If symptoms persist consult your doctor.

Keep this medicine out of the sight and reach of children.

Patients should be advised not to take other paracetamol-containing medicines concurrently.

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 colestyramine.

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

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, as with any medicine it should be used at the lowest effective dose for the shortest possible time.

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

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Adverse events of paracetamol from historical clinical trial data are both infrequent and from small patient exposure. Accordingly, events reported from extensive post-marketing experience at therapeutic/labelled dose and considered attributable are tabulated below by system class and frequency.

The following convention has been utilised for the classification of the undesirable effects: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10,000 to <1/1000) and very rare (<1/10,000), not known (cannot be estimated from available data).

Post-marketing data

Body System	**Undesirable effect**	**Frequency**
Blood and lymphatic system disorders	Thrombocytopenia Agranulocytosis	Very rare
Immune system disorders	Anaphylaxis Cutaneous hypersensitivity reactions including, among others, skin rashes and angioedema.	Very rare
Metabolism and nutrition disorders	High anion gap metabolic acidosis	Not known
Respiratory, thoracic and	Bronchospasm*	Very rare

mediastinal disorders		
Hepatobiliary disorders	Hepatic dysfunction	Very rare
Skin and subcutaneous disorders	Very rare cases of serious skin reactions such as fixed drug eruption have been reported.	Very rare

* There have been cases of bronchospasm with paracetamol, but these are more likely in asthmatics sensitive to aspirin or other NSAIDs.

Description of selected adverse reactions

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.

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: https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

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 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 medicinal products 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 infective, 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, coma 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.

It is considered that excess quantities of a toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are employed), become irreversibly bound to liver tissue.

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 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 24 hours from ingestion should be discussed with the NPIS or a liver unit.

High doses of sodium bicarbonate may be expected to induce gastrointestinal symptoms including belching and nausea. In addition, high doses of sodium bicarbonate may cause hypernatraemia; electrolytes should be monitored and patients managed accordingly.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other Analgesics and Antipyretics – Anilides.

ATC Code – N02BE01

Paracetamol is an effective analgesic and antipyretic agent. The medicinal product has no effect on the cardiovascular and respiratory systems, and it does not cause gastric irritation or bleeding like salicylates.

5.2 Pharmacokinetic properties

Paracetamol is readily absorbed from the gastro-intestinal tract with peak plasma concentrations occurring 30 minutes to 2 hours after ingestion. It is distributed in most body tissues; it crosses the placenta and is present in breast milk. Plasma protein binding is negligible at usual therapeutic concentrations but increases with increasing concentration. The elimination half life varies from about 1 to 3 hours.

Paracetamol is metabolised in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates. Less than 5% is excreted unchanged as paracetamol. 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 overdosage and cause liver damage.

Paracetamol is relatively uniformly distributed throughout most body fluids and exhibits variable protein binding. 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.

No data of relevance which is additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid (anhydrous) (E330),
Povidone,
Sodium bicarbonate (E500),
Sodium saccharin,
Sodium carbonate (anhydrous),

Simeticone (E900),
Polysorbate 80 (E433),
Aspartame (E951).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package. Protect from moisture.

6.5 Nature and contents of container

Strip (4 layer - paper/LDPE/aluminium/LDPE), laminate on both sides of strip.

Pack sizes 8, 12 and 16 tablets.

Not all packs may be marketed

6.6 Special precautions for disposal

No special requirement for disposal.

7 MARKETING AUTHORISATION HOLDER

Cipla (EU) Limited,

Dixcart House, Addlestone Road,
Bourne Business Park, Addlestone,
Surrey, KT15 2LE, United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

PLGB 36390/0383

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

06/01/2025

10 DATE OF REVISION OF THE TEXT

06/03/2025