SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Paracetamol 1000mg Soluble Tablets.

Parasolve Max 1000mg Soluble Tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 1000mg of the active ingredient paracetamol.

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Effervescent tablet.

Paracetamol 1000mg Soluble Tablets are white to off white coloured, circular, flat bevelled tablets, plain on both sides.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the relief of headache including migraine, neuralgia, toothache, period pain, and rheumatic aches and pains.

Symptomatic relief of colds and influenza, and sore throats.

4.2 Posology and method of administration

For oral administration only.

Adults and the elderly: One tablet to be taken up to four times daily. Maximum dose of 4 tablets in 24 hours.

Not recommended for children under 16 years of age.

The dose should not be repeated more frequently than every 4 hours, and not more than 4 doses should be taken in any 24 hour period.

Dosage should not be continued for more than 3 days without consulting a doctor.

4.3 Contraindications

Hypersensitivity to paracetamol to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Contains paracetamol. Do not use with any other paracetamol-containing products.

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

Do not exceed the stated dose

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

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 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.

This medicinal product contains 587mg sodium per dose, equivalent to 29.4% of the WHO recommended maximum daily intake for sodium. The maximum daily dose of this product is equivalent to 120% of the WHO recommended maximum daily intake for sodium. Paracetamol Soluble Tablets are considered high in sodium. This should be particularly taken into account for those on a low salt diet.
The tablets also contain aspartame (a source of phenylalanine) and so should not be taken by people with phenylketonuria. Neither non-clinical nor clinical data are available to assess aspartame use in infants below 12 weeks of age.

If symptoms persist, medical advice must be sought.

Keep out of the sight and reach of children.

Pack Label:

Talk to a doctor at once if you take too much of this medicine even if you feel well.

Do not take anything else containing paracetamol while taking this medicine.

Patient Information Leaflet:

Talk to a 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

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 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 it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

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 known.

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).

Adverse event frequencies have been estimated from spontaneous reports received through post-marketing 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 angiodema. Very rare cases of serious skin reactions have been reported	Very rare

Respiratory, thoracic and mediastinal disorders	Bronchospasm*	Very rare
Hepatobiliary disorders	Hepatic dysfunction	Very rare
Metabolism and nutrition disorders	High anion gap metabolic acidosis**	Not Known

Description of selected adverse reactions

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

** 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 www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App store

4.9 Overdose

Paracetamol overdose may cause liver failure which may require liver transplant or lead to death.
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 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 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

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

Paracetamol is an effective analgesic and antipyretic agent. The drug 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.

5.3 Preclinical safety data

Conventional studies using the currently accepted standards for the evaluation of toxicity to reproduction and development are not available for paracetamol.

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, 16 and tablets.

Not all packs may be marketed

6.6 Special precautions for disposal

Not applicable.

7. MARKETING AUTHORISATION HOLDER

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1 Dover Place,
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8 MARKETING AUTHORISATION NUMBER(S)

PL 51463/0022

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

17/01/2025

10 DATE OF REVISION OF THE TEXT

24/02/2025