SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Paracetamol Effervescent 500mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Paracetamol 500 mg.

3 PHARMACEUTICAL FORM

Effervescent tablet.

White, circular tablet.

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

Adults, the elderly and children over 16 years: One or two tablets to be taken up to four times daily. Maximum dose of 8 tablets in 24 hours.

Children 12-15 years: One tablet,every 4-6 hours when necessary to a maximum of 4 doses in 24 hours.

Children under 12 years of age: Not recommended.

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 and/or other constituents.

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 recommended 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 everyday.

This medicinal product contains 438mg of sodium per dose, equivalent to 22% of the WHO recommended maximum daily intake for sodium. The maximum daily dose of this product is equivalent to 175% of the WHO recommended maximum daily intake for sodium.
Paracetamol Effervescent tablets are considered high in sodium. This should be particularly taken into account for those on a low salt diet.

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.

The tablets also contain aspartame (a source of phenylalanine) and so should not be taken by people with phenylketonuria. Neither nonclinical 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

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

Alcohol reduces liver capacity to deal with paracetamol.

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.

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

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 effects of paracetamol are rare but hypersensitivity including skin rash may occur. There have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily causally related to paracetamol.

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. Due to limited clinical trial data, the frequency of these adverse events is not known (cannot be estimated from available data), but post- marketing experience indicates that adverse reactions to paracetamol are rare and serious reactions are very rare.

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 effects**	**Frequency**
Skin and subcutaneous disorders	Very rare cases of serious skin reactions have been reported	Very Rare
Blood and lymphatic system disorders	Thrombocytopenia Agranulocytosis	Very Rare

Immune system disorders	Anaphylaxis Cutaneous hypersensitivity reactions including skin rashes, angiodema and Stevens Johnson syndrome/toxic epidermal necrolysis	Very Rare
Respiratory, thoracic and mediastinal	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 isimportant. 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, website 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 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 liverenzymes.

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.

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

ATC Code: NO2B EO1

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Anhydrous Citric Acid (E330)
Povidone
Sodium Hydrogen Carbonate (E500)
Saccharin Sodium
Anhydrous Sodium Carbonate
Simethicone
Polysorbate 80 (E433)
Aspartame (E951)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 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 24, 32, 60 and 100 tablets (not all packs may be marketed).

6.6 Special precautions for disposal

The tablets should be dissolved in water immediately before use. These tablets are effervescent tablets. Stir before use.

7. MARKETING AUTHORISATION HOLDER

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38, 1 Dover Place,
Ashford, Kent,
England,
TN23 1FB.

8 MARKETING AUTHORISATION NUMBER(S)

PL 51463/0031

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02/03/2009

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