SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Paracetamol Plus 500mg/65mg Effervescent Tablets

Paracetamol & Caffeine 500mg/65mg Effervescent Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Paracetamol 500mg and Caffeine 65mg

Excipients with known effect:

- 24mmol (427mg) sodium per tablet
- 50mg sorbitol per tablet

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Effervescent Tablet

White bevel-edged scored tablets, one inch in diameter.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Paracetamol Plus 500mg/65mg Effervescent Tablets are a mild analgesic and antipyretic formulated to give extra pain relief. The soluble tablets are recommended for the treatment of most painful and febrile conditions, for example, headache including migraine, backache, toothache, colds and influenza, sore throat, rheumatic pain and dysmenorrhoea.

4.2 Posology and method of administration

Posology

Paracetamol Plus 500mg/65mg Effervescent Tablets should be dissolved in at least half a tumblerful of water.

Adults and children 16 years and over:

Two tablets every 4-6 hours up to four times daily. Do not exceed 8 tablets in 24 hours.

Elderly:

As for adults.

Children 12 to 15 years of age:

One tablet every 4-6 hours up to four times daily. Do not exceed 4 tablets in 24 hours.

Method of Administration

Paracetamol Plus 500mg/65mg Effervescent Tablets are for oral administration only

4.3 Contraindications

Hypersensitivity to the active substances (paracetamol, caffeine) or 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 renal or hepatic impairment. The hazard of overdose is greater in those with non- cirrhotic alcoholic liver disease.

Excessive intake of caffeine (e.g. coffee, tea and some canned drinks) should be avoided while taking this product.

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.

Do not exceed the stated dose.

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

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

Each 2 tablet dose contains 854 mg of sodium and should not be taken by patients on a low sodium diet. This medicinal product contains 427 mg sodium per effervescent tablet, equivalent to 21% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

This medicine contains 50 mg of sorbitol per effervescent tablet. Sorbitol is a source of fructose. Patients with an intolerance to some sugars or who have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, should talk to their doctor before taking or receiving this medicine.

If symptoms persist consult your doctor. Keep out of the reach and sight of children.

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.

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

Paracetamol-caffeine is not recommended for use during pregnancy due to the possible increased risk of lower birth weight and spontaneous abortion associated with caffeine consumption.

Caffeine in breast milk may potentially have a stimulating effect on breast fed infants.

Due to the caffeine content of this product it should not be used if you are pregnant or breast feeding.

4.7 Effects on ability to drive and use machines

Paracetamol Plus 500mg/65mg Effervescent Tablets have no or negligible influence on the ability to drive and use machines

4.8 Undesirable effects

Adverse events 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.

Post marketing data

Body System	**Undesirable effect**
Blood and lymphatic system disorders	Thrombocytopenia Agranulocytosis
Immune system disorders	Anaphylaxis Cutaneous hypersensitivity reactions including skin rashes, angioedema and Stevens Johnson syndrome/toxic epidermal necrolysis Very rare cases of serious skin reactions have been reported.
Respiratory, thoracic and mediastinal disorders	Bronchospasm*
Hepatobiliary disorders	Hepatic dysfunction

Metabolism and nutrition disorders	High anion gap metabolic acidosis* have been reported frequency is Not known

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

*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.

Caffeine	
Central Nervous system	Nervousness Dizziness
When the recommended paracetamol-caffeine dosing regimen is combined with dietary caffeine intake, the resulting higher dose of caffeine may increase the potential for caffeine-related adverse effects such as insomnia, restlessness, anxiety, irritability, headaches, gastrointestinal disturbances and palpitations.	

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 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

Symptoms of paracetamol overdose 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, coma and death. Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported. Liver damage is possible in adults who have taken 10g or more of paracetamol. It is considered that excess quantities of a toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are ingested), become irreversibly bound to liver tissue.

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 and any patient who has ingested around 7.5g or more of paracetamol in the preceding 4 hours should undergo gastric lavage.

Administration of oral methionine or intravenous N-acetylcysteine which may have a beneficial effect up to at least 48 hours after the overdose, may be required. General supportive measures must be available.

Overdose of caffeine may result in epigastric pain, vomiting, diuresis, tachycardia or cardia arrhythmia, CNS stimulation (insomnia, restlessness, excitement, agitation, jitteriness, tremors and convulsions).

It must be noted that for clinically significant symptoms of caffeine overdose to occur with this product, the amount ingested would be associated with serious paracetamol-related toxicity.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The combination of paracetamol and caffeine is a well established analgesic combination.

5.2 Pharmacokinetic properties

Paracetamol is rapidly and almost completely absorbed from the gastro- intestinal tract. It is relatively uniformly distributed throughout most body fluids and exhibits variable protein binding. Excretion is almost exclusively renal, in the form of conjugated metabolites.

Caffeine is absorbed readily after oral administration, maximal plasma concentrations are achieved within one hour and the plasma half-life is about 3.5 hours. 65 - 80% of administered caffeine is excreted in the urine as 1- methyluric acid and 1-methylxanthine.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium hydrogen carbonate
Sorbitol
Saccharin sodium
Sodium laurilsulfate
Citric acid anhydrous
Sodium carbonate anhydrous
Povidone
Dimeticone

6.2 Incompatibilities

None applicable

6.3 Shelf life

48 months

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Paper/PE/aluminium/PE laminate strips in cardboard carton outers containing 4, 6, 12, 16, 18, 24 or 30 tablets.

Not all pack sizes may be marketed

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Galpharm Healthcare Limited
Wrafton
Braunton
Devon
EX33 2DL

8 MARKETING AUTHORISATION NUMBER(S)

PL 16028/0183

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01/03/2023

10 DATE OF REVISION OF THE TEXT

27/02/2025