

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Paracetamol and Caffeine 500 mg / 65 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 500mg paracetamol and 65mg caffeine.

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Film-coated tablet.

White capsule-shaped, film-coated tablets printed on one side.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Paracetamol and Caffeine 500 mg / 65 mg tablets are indicated for the symptomatic treatment of mild to moderate pain and relief of fever. The tablets are recommended for the treatment of most painful conditions including headache, migraine, backache, toothache, pain of osteoarthritis, and dysmenorrhoea, and for relieving the fever, aches and pains of colds and flu and sore throat.

4.2 Posology and method of administration

Adults (including the elderly) and children aged 16 years and over:

Two tablets up to four times daily. The dose should not be repeated more frequently than every 4 hours. Do not exceed 8 tablets in 24 hours.

Children aged 12-15 years:

One tablet up to four times daily. The dose should not be repeated more frequently than every 4 hours. Do not exceed 4 tablets in 24 hours.

Not recommended for children under 12 years.

For oral administration only.

4.3 Contraindications

Hypersensitivity to paracetamol, caffeine and/or any of the other constituents.

4.4 Special warnings and precautions for use

Do not exceed stated dose.

Contains paracetamol. Do not use with any other paracetamol containing products. Concomitant use with other products containing paracetamol may lead to an overdose.

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

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.

Caution should be exercised in patients with glutathione depleted states, as the use of paracetamol may increase the risk of metabolic acidosis (see section 4.9).

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.

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

This medicine contains less than 1 mmol sodium (23 mg) per tablets, that is to say essentially 'sodium-free'.

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 daily use of paracetamol with increased risk of bleeding; occasional doses have no significant effect. Caffeine may increase clearance of lithium. Concomitant use is therefore not recommended.

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 Pregnancy and lactation

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

Caffeine in breast milk may potentially have a stimulating effect in breast fed infants but significant toxicity has not been observed.

4.7 Effects on ability to drive and use machines

None.

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 MedDRA System Organ Class system class. Adverse reactions identified during post-marketing use are reported voluntarily from a population of uncertain size, the frequency of these reactions is unknown but likely to be very rare (<1/10,000).

Paracetamol

Body System	Undesirable effect
Blood and lymphatic system disorders	Thrombocytopenia Agranulocytosis
Immune system disorders	Very rare cases of serious skin reactions have been reported Anaphylaxis Cutaneous hypersensitivity reactions including (amongst others) skin rashes and angioedema
Metabolism and nutrition disorders	High anion gap metabolic acidosis*
Respiratory, thoracic and mediastinal disorders	Bronchospasm – more likely in patients sensitive to aspirin and other NSAIDs
Hepatobiliary disorders	Hepatic dysfunction

* 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

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.

Body System	Undesirable effect
Central nervous system	Dizziness Headache
Cardiac disorders	Palpitation
Psychiatric disorders	Insomnia Restlessness Anxiety and irritability
Gastrointestinal disorders	Gastrointestinal disturbances

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

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 National Poisons Information Service (NPIS) or a liver unit.

Caffeine

Symptoms

Overdose of caffeine may result in epigastric pain, vomiting, diuresis, tachycardia or cardiac arrhythmia, or 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 liver toxicity.

Management

Patients should receive general supportive care (e.g. hydration and maintenance of vital signs). The administration of activated charcoal may be beneficial when performed within one hour of the overdose, but can be considered for up to four hours after the overdose. The CNS effects of overdose may be treated with intravenous sedatives.

Summary

Treatment of overdose requires assessment of plasma paracetamol levels for antidote treatment, with signs and symptoms of caffeine toxicity being managed symptomatically.

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anilides ATC code: N02B E51

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

Paracetamol is an antipyretic and analgesic. Its mechanism of action is believed to include inhibition of prostaglandin synthesis, primarily within the central nervous system. The lack of peripheral prostaglandin inhibition confers important pharmacological properties such as the maintenance of the protective prostaglandins within the gastrointestinal tract. Paracetamol is, therefore, particularly suitable for patients with a history of disease or on concomitant medication where peripheral prostaglandin inhibition would be undesirable (such as, for example, those with a history of GI bleeding or the elderly).

Clinical data has demonstrated that the combination of paracetamol and caffeine gives better efficacy than paracetamol alone.

5.2 Pharmacokinetic properties

Paracetamol is rapidly and almost completely absorbed from the gastrointestinal 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 rapidly absorbed from the gastrointestinal tract and is widely distributed throughout the body. It is almost completely metabolized in the liver by oxidation and demethylation to various xanthine derivatives, which are excreted in the urine. The mean plasma half life is about 4.9 hours

5.3 Preclinical safety data

There are no pre-clinical 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

Starch pregelatinised
Maize starch
Purified Talc
Croscarmellose sodium
Stearic acid
Povidone
Potassium sorbate
Hypromellose
Triacetin

Printing Ink:
Propylene glycol
Shellac
Brilliant Blue FCF (E133)
Sodium Lactate
Dimethylpolysiloxane

6.2 Incompatibilities

None.

6.3 Shelf life

60 months.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

PVC 250 or 300µm / aluminium foil 20µm *or* Polypropylene (PP) 300µm / PP lidding film 90µm blister packs in an outer cardboard carton, containing 4, 6, 8, 10, 12, 16, 20, 24, 30, 32 tablets.
Not all pack sizes may be marketed

6.6 Special precautions for disposal

None.

7 MARKETING AUTHORISATION HOLDER

Haleon UK Trading Limited
The Heights
Weybridge
Surrey
KT13 0NY
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 44673/0085

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

First Authorisation: 19/05/2010

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10/02/2025