SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Paracetamol and Caffeine 500 mg/65 mg capsules, soft

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each soft capsule contains 500 mg of paracetamol and 65 mg of caffeine.

Excipient with known effect:

Each soft capsule contains 126 mg sorbitol.

Each soft capsule contains 0.600 mg of Sunset yellow (E110)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, soft.

Opaque orange coloured oval shaped soft gelatin capsules containing off white to orange colored suspension, imprinted with “PCF” in black colored edible ink (19.0 ± 1.0 mm long x 10.5 ± 1.0 mm width).

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Posology

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

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

Children aged 12-15 years:

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

Paediatric population

This medicine is not recommended for children under 12 years.

Method of administration

For oral administration.

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1;

4.4 Special warnings and precautions for use

Do not exceed stated dose.

Keep out of the sight and reach of children.

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

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 andclose 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.

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).

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

If symptoms persist, medical advice must be sought.

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

This medicine contains sorbitol.
The additive effect of concomitantly administered products containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account.

The content of sorbitol in medicinal products for oral use may affect the bioavailability of other medicinal products for oral use administered concomitantly.

Patients with hereditary fructose intolerance (HFI) should not take/be given this medicinal product.

This medicine contains the Azo colouring agent Sunset yellow FCF (E110) which may cause allergic reactions.

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)’.

Caffeine may increase clearance of lithium. Concomitant use is therefore not recommended.

4.6 Fertility, pregnancy and lactation

Pregnancy

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

Breastfeeding

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

This medicine has 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 MedDRA System Organ 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).

Post marketing data

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.
Respiratory, thoracic and mediastinal disorders	Bronchospasm – more likely in patients sensitive to aspirin and other NSAIDs
Hepatobiliary disorders	Hepatic dysfunction

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

Metabolism and nutrition disorders
High anion gap metabolic acidosis with frequency “Not known” (cannot be estimated from the available data)

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

4.9 Overdose

Paracetamol

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 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 alcohol in excess of recommended amounts.

Or

c) Is likely to be glutathione depleted 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.

Caffeine

Symptoms

Overdose of caffeine may result in epigastric pain, vomitting, 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.

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 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other analgesics and antipyretics. Anilides, ATC code: N02BE51

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

Preclinical safety data on paracetamol in the literature have not revealed any pertinent and conclusive findings which are of relevance to the recommended dosage and use of the product, and which have not been mentioned elsewhere in this SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule content

Macrogol 400

Povidone K-30

Purified water

Capsule shell

Gelatin 160 bloom (E441)

Sorbitol, liquid, partially dehydrated

Titanium dioxide (E171)

Sunset Yelow FCF (E110)

Purified water

Ink imprint (Opacode Black-S-1-17823):

Shellac glaze 45% (20% esterified) in ethanol, isopropyl alcohol, ferrosoferric oxide/black oxide, N-butyl alcohol, propylene glycol, ammonium hydroxide 28 %.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

The soft capsules are packed in child-resistant white opaque PVC/PVDC/Aluminium/PET blisters.

Pack sizes: 4, 8, 10 or 16 capsules, soft.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

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

7 MARKETING AUTHORISATION HOLDER

Socium Pharma B.V.
Amsterdamsestraatweg 5,
1411AW Naarden,
The Netherlands.

8 MARKETING AUTHORISATION NUMBER(S)

PL 54536/0002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18/12/2024

10 DATE OF REVISION OF THE TEXT

05/05/2026