

Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

Painotab Analgesic Caplet

2. Qualitative and quantitative composition

Each film coated caplet contains:

Paracetamol.....650 mg

Caffeine Anhydrous BP.....30 mg

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

Caplet

White, capsule shaped biconvex caplet embossed 'PAINOTAB' on one side and a break line on the other side.

4. Clinical particulars

4.1 Therapeutic indications

A mild analgesic and antipyretic formulated to give extra pain relief. The caplets 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

Oral use.

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

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

Children aged 12-15 years:

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

Not recommended for children under 12 years.

4.3 Contraindications

Hypersensitivity to paracetamol, caffeine 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. 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 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.

If symptoms persist, medical advice must be sought.

Keep out of the sight and reach of children.

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.

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 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

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. 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.
Metabolism and nutrition disorders	High anion gap metabolic acidosis (frequency not known – cannot be estimated from the available data) (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).
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

Reporting of suspected adverse reactions: Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via National Pharmacovigilance Electronic Reporting Systems to the respective National Regulatory Authorities.

4.9 Overdose

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 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 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, 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, vomiting, diuresis, tachycardia or cardiac 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

ATC code: N02B E51

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 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 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 pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SmPC.

6. Pharmaceutical Particulars

6.1 List of Excipients

Microcrystalline cellulose BP
Aerosil BP
Potassium sorbate BP
Povidone BP
Maize starch BP
Purified talc
Stearic acid BP

6.2 Incompatibilities

None

6.3 Shelf-Life

3 years

6.4 Special Precautions for storage

Do not store above 30°C. Protect from light.

6.5 Nature and Content of container

PVC blisters in unit cartons with literature insert
Available in pack sizes of 10 Caplets, 10 X 10 Caplets And 2 X 10 Caplets

6.6 Special precautions for disposal and other handling

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

7. Marketing Authorization Holder

Cosmos Limited
Rangwe Road; Off Lunga Lungu, Industrial Area
P.O Box 41433, GPO 00100-Nairobi, Kenya
Telephone: 020-2519603/4/5, 020-8042200/2/3/4/5
Telefax: +254-020-8096280/1
E-mail: admin@cosmos-pharm.com

8. Marketing Authorization Number

12235

9. Date of first authorization/renewal of the authorization

04/11/1999

10. Date of revision of the text

12/06/2026