

## **Summary Product Characteristics for Pharmaceutical Product**

### **1. Name of the medicinal product**

Caftamol

### **2. Qualitative and quantitative composition**

Each tablet contains Paracetamol 500.0 mg and Caffeine 65.0 mg.

#### Excipients with known effect

Contains Sodium Benzoate

For a full list of excipients, see section 6.1

### **3. Pharmaceutical form**

Tablet.

White caplet-shaped uncoated tablets having one side break-line and the other side plain

### **4. Clinical particulars**

#### **4.1 Therapeutic indications**

A mild analgesic and antipyretic formulated to give extra pain relief. The tablets are recommended for the treatment of most painful and febrile conditions, for example, headache, 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 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.

#### **4.3 Contraindications**

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

#### **4.4 Special warnings and precautions for use**

Do not exceed the 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 a 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).

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

#### **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. Oral contraceptives may increase the rate of clearance of paracetamol. The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with an increased risk of bleeding; occasional doses have no significant effect. Caffeine may increase the clearance of lithium. Concomitant use is therefore not recommended.

#### **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 breastfed infants.

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

#### **4.7 Effects on the 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).

## **PARACETAMOL**

<b>Body System</b>	<b>Undesirable effect</b>
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.

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

### **Reporting of suspected adverse reactions:**

Healthcare professionals are asked to report any suspected adverse reactions via the pharmacy and poisons board, Pharmacovigilance Electronic Reporting System (PvERS) <https://pv.pharmacyboardkenya.org>

## **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

- Is on long-term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes.

Or

- Regularly consumes ethanol in excess of recommended amounts.

Or

- Is likely to be glutathione depleted 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 the 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 the hospital. Management of patients who present with serious hepatic dysfunction beyond 24 hours 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, and 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**

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
- Croscarmellose Sodium
- Starch
- Pvpk 30
- Sodium Benzoate
- Magnesium Stearate
- Purified Talc

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

36 Months

### **6.4 Special precautions for storage**

Store below 30°C

### **6.5 Nature and contents of the container**

Alu-PVC blister pack  
Pack size: 3x10 tablets

### **6.6 Special precautions for disposal and other handling**

None

## **7. Marketing authorisation holder and manufacturing site addresses**

Simba Pharmaceuticals Ltd  
1<sup>st</sup> Floor, Almont Park, Westlands.  
P.O. Box 1541-00606 Nairobi  
KENYA  
E-Mail: [info@simbapharma.co.ke](mailto:info@simbapharma.co.ke)

### **Manufacturing site address:**

Aksharam Pharma Pvt. Ltd.  
Address: Plot No,1&2, Akshar Ind, Estate, Rajkot Highway  
Road, Opp. Tri-Mandir, Kherali, Surendranagar (363020),  
Gujarat, India  
E-Mail: [aksharampharma@gmail.com](mailto:aksharampharma@gmail.com)

## **8. Marketing authorisation number(s)**

CTD10403- Caftamol

## **9. Date of first authorisation/renewal of the authorisation**

Date of first authorization: 03-August-2023

## **10. Date of revision of the text**

15-Sep-2023

**11. Dosimetry:**

Not Applicable

**12. Instructions for preparation of radiopharmaceuticals:**

Not Applicable