

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Panadol Extra Film-Coated Tablets  
Paracetamol 500mg  
Caffeine 65mg

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film coated tablet contains 500mg paracetamol and 65mg caffeine

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Film coated tablet.

*Product imported from Greece:*

White, capsule shaped tablet, imprinted 'Panadol extra' on one side and a breakline on the other side.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

The tablets are recommended for use as an analgesic in the relief of mild to moderate pain such as is associated with rheumatism, neuralgia, musculoskeletal disorders, headache and of discomfort associated with influenza, feverishness and feverish colds, toothache and dysmenorrhoea.

### 4.2 Posology and method of administration

For oral administration.

Adults (including the elderly)

2 tablets up to four times daily. Do not exceed 8 tablets in 24 hours.

Children

Not recommended for children under 12 years of age.

Minimum dosing interval: 4 hours.

Should not be used with other paracetamol-containing products.

### 4.3 Contraindications

Known hypersensitivity to paracetamol or any of the other constituents.

### 4.4 Special warnings and precautions for use

Paracetamol should only be used with caution in patients with liver or kidney impairment.

Prolonged use except under medical supervision may be harmful.

Do not exceed the stated dose.

Take only when necessary.

If symptoms persist, consult your doctor.

## 4.5 Interaction with other medicinal products and other forms of interaction

Paracetamol may increase the elimination half-life of chloramphenicol. The absorption of paracetamol may be increased by metoclopramide and decreased by cholestyramine. 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 increased risk of bleeding; occasional doses have no significant effect.

## 4.6 Fertility, pregnancy and lactation

Epidemiological studies in human pregnancy have shown no ill effects due to caffeine or paracetamol used in the recommended dosage, but patients should follow the advice of their doctor regarding its use. Paracetamol is excreted in breast milk but not in a clinically significant amount.

## 4.7 Effects on ability to drive and use machines

None.

## 4.8 Undesirable effects

Adverse effects of paracetamol are rare but hypersensitivity including skin rashes may occur. The most common adverse events associated with caffeine are nausea due to gastrointestinal irritation, insomnia and restlessness as a result of stimulation of the central nervous system.

## 4.9 Overdose

Immediate medical attention (in-hospital, if possible) is required in the event of overdose, even if there are no significant early symptoms. There may be no early symptoms following a life-threatening overdose. Ingestion of more than 12 g paracetamol (24 standard 500 mg tablets) or more than 150 mg paracetamol per kg bodyweight (9 g paracetamol in a 60 kg individual), whichever is the smaller, can cause severe liver damage. Liver damage (as demonstrated by a rise in plasma transaminase levels) may be apparent between 8 and 36 hours following overdose. Biochemical evidence of maximal damage, however, may not be attained until 72-96 hours after ingestion of the overdose.

Intravenous N-acetylcysteine (NAC) is effective when initiated within 8 hours of the overdose. Efficacy declines progressively after this time, but NAC may provide some benefit up to and possibly beyond 24 hours.

Oral methionine is also effective provided that it is given within 10 to 12 hours of the overdose. Activated charcoal should be considered if the dose of paracetamol ingested exceeds 12 g or 150 mg/kg, whichever is the smaller, and the procedure can be undertaken within 1 hour of the overdose. There is little evidence that undertaking gastric lavage will be of benefit to a patient in whom paracetamol is known to have been the only substance ingested.

Symptoms of paracetamol overdose in the first 24 hours may include pallor, nausea, vomiting, anorexia, and abdominal pain. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, coma and death. Liver damage results when excess quantities of a toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are ingested) become irreversibly bound to liver tissue. Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.

High doses of caffeine may produce headache, tremor, nervousness and irritability.

# 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 well absorbed from the gastrointestinal tract, peak plasma concentrations occurring 0.5 – 2 hours after ingestion. It is metabolised in the liver and excreted in the urine mainly as glucuronide and sulphate conjugates – less than 5% is excreted as unmodified paracetamol. The half-life is 1 to 4 hours. Binding to the plasma proteins is minimal at therapeutic concentrations.

Caffeine is absorbed readily after oral administration, maximal plasma concentrations are achieved after approximately 20 – 60 minutes and the plasma half-life is about 4 hours. Over 48 hours, 45% of a dose 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 Summary.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Maize starch  
Povidone  
Potassium sorbate  
Talc  
Stearic acid  
Croscarmellose sodium  
Water

## 6.2 Incompatibilities

Not applicable.

## 6.3 Shelf Life

The shelf life expiry date of this product is the date shown on the container and outer packaging of the product on the market in the country of origin.

## 6.4 Special precautions for storage

Do not store above 25°C.

Store in the original package.

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

Blister packs of 12 tablets contained in an outer cardboard carton.

## **6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

No special requirements.

## **7 PARALLEL PRODUCT AUTHORISATION HOLDER**

PCO Manufacturing Limited  
Unit 10, Ashbourne Business Park  
Rath  
Ashbourne  
Co. Meath

## **8 PARALLEL PRODUCT AUTHORISATION NUMBER**

PPA 0465/157/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first Authorisation: 21 October 2005

Date of last renewal: 20 October 2010

## **10 DATE OF REVISION OF THE TEXT**

October 2010