

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Paracetamol 500 mg Capsules, Hard

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each capsule contains paracetamol 500mg.

For the full list of excipients, see section 6.1.

### **3 PHARMACEUTICAL FORM**

Capsule, hard. (Capsule)

Size 0 hard gelatin capsule, with red cap and white base containing a white powder.

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

Paracetamol is a mild analgesic and antipyretic, and is recommended for the treatment of most painful and febrile conditions, for example, headache including migraine and tension headaches, toothache, backache, rheumatic and muscle pains, dysmenorrhoea, sore throat, and for relieving the fever, aches and pains of colds and flu. Also recommended for the symptomatic relief of pain due to non-serious arthritis.

#### **4.2 Posology and method of administration**

Adults, including the elderly:

One or two capsules up to four times daily as required.

These doses should not be repeated more frequently than every four hours nor should more than four doses be given in any 24-hour period.

#### **Method of administration**

For oral use.

### **4.3 Contraindications**

Hypersensitivity to paracetamol or any of the excipients listed in section 6.1.

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

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

Underlying liver disease increases the risk of paracetamol related liver damage. Patients who have been diagnosed with liver or kidney impairment must seek medical advice before taking this medication.

Do not exceed the stated dose.

Patients should be advised to consult their doctor if their headaches become persistent.

Patients should be advised to consult a doctor if they suffer from non-serious arthritis and need to take painkillers every day.

Caution is advised if paracetamol is administered concomitantly with flucloxacillin due to increased risk of high anion gap metabolic acidosis (HAGMA), particularly in patients with severe renal impairment, sepsis, malnutrition and other sources of glutathione deficiency (e.g. chronic alcoholism), as well as those using maximum daily doses of paracetamol. Close monitoring, including measurement of urinary 5-oxoproline, is recommended.

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

Use with caution in patients with glutathione depletion due to metabolic deficiencies.

If symptoms, medical advice must be sought.

Keep out of the sight and reach of children.

#### **Pack Label:**

Do not take more medicine than the label tells you to. If you do not get better, talk to your doctor.

Do not take anything else containing paracetamol while taking this medicine.

Talk to a doctor at once if you take too much of this medicine, even if you feel well.

#### 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. If your symptoms continue or your headache becomes persistent, **see your doctor**.

### **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, especially in patients with risks factors (see section 4.4)

### **4.6 Fertility, Pregnancy and lactation**

#### Pregnancy

A large amount of data on pregnant women indicate neither malformative, nor fetoneonatal toxicity.

Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. If clinically needed, paracetamol can be used during pregnancy, however, as with any medicine it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

#### Breastfeeding

Paracetamol is excreted in breast milk but not in a clinically significant amount in recommended dosages. Available published data do not contraindicate breastfeeding.

### **4.7 Effects on ability to drive and use machines**

Paracetamol has no influence on the ability to drive and use machines.

## 4.8 Undesirable effects

Adverse events of paracetamol 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 system class and frequency.

The following convention has been utilised for the classification of the undesirable effects: very common ( $\geq 1/10$ ), common ( $\geq 1/100$  to  $< 1/10$ ), uncommon ( $\geq 1/1000$  to  $< 1/100$ ), rare ( $\geq 1/10,000$  to  $< 1/1000$ ) and very rare ( $< 1/10,000$ ), not known (cannot be estimated from available data).

Adverse event frequencies have been estimated from spontaneous reports received through post-marketing data.

Post marketing data

Body System	Undesirable effect	Frequency
Blood and lymphatic system disorders	Thrombocytopenia Agranulocytosis	Very rare
Immune system disorders	Anaphylaxis Cutaneous hypersensitivity reactions including, among others, skin rashes and angiodema. Very rare cases of serious skin reactions have been reported.	Very rare
Respiratory, thoracic and mediastinal disorders	Bronchospasm*	Very rare
Hepatobiliary disorders	Hepatic dysfunction	Very rare

\* There have been cases of bronchospasm with paracetamol, but these are more likely in asthmatics sensitive to aspirin or other NSAIDs.

### 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](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

## 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 over dosage 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.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

ATC code: N02B E01, Other analgesics and antipyretics.

Paracetamol is an antipyretic analgesic. The mechanism of action is probably similar to that of aspirin and dependant on the inhibition of prostaglandin synthesis. This inhibition appears, however to be on a selective basis.

### **5.2 Pharmacokinetic properties**

Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract. The concentration in plasma reaches a peak in 30 to 60 minutes and the plasma half-life is 1 - 4 hours after therapeutic doses.

Paracetamol is relatively uniformly distributed throughout most body fluids. Binding of the drug to plasma proteins is variable; 20 to 30% may be bound at the concentrations encountered during acute intoxication.

Following therapeutic doses 90 - 100% of the drug may be recovered in the urine within the first day.

However, practically no paracetamol is excreted unchanged and the bulk is excreted after hepatic conjugation.

### **5.3 Preclinical safety data**

Conventional studies using the currently accepted standards for the evaluation of toxicity to reproduction and development are not available.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

#### **Capsule content**

Sodium starch glycolate (Type-A)

Pregelatinised starch

Colloidal anhydrous silica

Magnesium stearate

### **Capsule shell constituents**

#### **Cap**

Gelatin

Titanium dioxide (E171)

Ferric oxide red (E172)

#### **Body**

Gelatin

Titanium dioxide (E171)

## **6.2 Incompatibilities**

Not applicable

## **6.3 Shelf life**

36 months

## **6.4 Special precautions for storage**

This medicinal product does not require any special storage conditions.

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

Paracetamol Capsules are available in blisters of Aluminium-PVC/PVDC containing packs of 4, 6, 8, 12, 16 capsules.

Not all pack sizes may be marketed.

## **6.6 Special precautions for disposal**

No special requirements for disposal. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

**7      MARKETING AUTHORISATION HOLDER**

Flamingo Pharma UK Ltd.  
1<sup>st</sup> floor, Kirkland House,  
11-15 Peterborough Road,  
Harrow, Middlesex,  
HA12AX, United Kingdom.

**8      MARKETING AUTHORISATION NUMBER(S)**

PL 43461/0087

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

03/05/2024

**10     DATE OF REVISION OF THE TEXT**

03/05/2024