

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Ilonamol 500 mg Tablets  
Ardimol 500 mg Tablets  
Paracetamol 500 mg Tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 500 mg Paracetamol.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Tablet

White capsule-shaped tablets, scored on one side.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Paracetamol is a mild analgesic and antipyretic. The tablets are 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

#### Posology

#### *Adults, Elderly and Children over 16 years*

1 or 2 tablets up to four times daily as required.

These doses should not be repeated more frequently than every four hours nor should more than 4 doses be given in any 24-hour period.

#### ***Children aged 10 – 15 years:***

One tablet every 4-6 hours when necessary to a maximum of 4 doses in 24 hours.

Children should not be given Paracetamol 500 mg Tablets for more than 3 days without consulting a doctor.

***Children under 10 years:***

Not recommended.

Alternative presentations of paracetamol are recommended for paediatric usage in order to obtain suitable doses.

Method of administration

Oral administration only.

**4.3 Contraindications**

Hypersensitivity to paracetamol and/or to 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.

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 recommended dose.

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

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

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.

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.

If symptoms persist the patient should consult his/her doctor.

Pack Label:

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

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

Keep out of the sight and reach of children

#### Patient Information Leaflet:

Talk to you doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause serious, delayed liver damage.

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

Hepatotoxicity is enhanced by alcohol, phenobarbitone and doxorubicin. Paracetamol increases blood concentrations of aspirin.

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.

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 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 it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

##### Breast feeding

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

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

None

#### **4.8 Undesirable effects**

Adverse effects of paracetamol from historical clinical trial data are both infrequent and from small patient exposure. Accordingly, events reported from extensive postmarketing 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:

<b>Body System:</b>	<b>Undesirable effect:</b>	<b>Frequency</b>
Blood and lymphatic system disorders	Thrombocytopenia Agranulocytosis	Very rare
Immune system disorders	Anaphylaxis Cutaneous hypersensitivity reactions including, among others, skin rashes and angioedema Very rare cases of serious reactions have been reported.	Very rare
Respiratory, thoracic and mediastinal disorders	Bronchospasm*	Very rare
Hepatobiliary disorders	Hepatic dysfunction	Very rare
Metabolism and nutrition disorders	High anion gap metabolic acidosis	Not known

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

#### 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 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.

## **4.9 Overdose**

Paracetamol overdose may cause liver failure which may require liver transplant or lead to death.

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 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 hospital urgently for immediate medical attention. Symptoms may be limited to nausea or vomiting and may not reflect the severity of the 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 24 hours from ingestion should be discussed with the NPIS or a liver unit.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Other analgesics and antipyretics; Anilides, ATC code: N02BE01

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 gastro-intestinal tract. Peak plasma concentration half to two hours after ingestion and the plasma half-life is 1 - 4 hours.

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 mainly as the glucuronide and sulfate.

A hydroxylated metabolite may accumulate and cause liver damage. Considerable "first pass" in activation takes place in the gut wall and liver.

## **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**

Povidone

Starch

Magnesium Stearate

Stearic Acid

## **6.2 Incompatibilities**

Not applicable

## **6.3 Shelf life**

Containers: 48 months

Blister packs: 36 months

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

Containers: Do not store above 25°C. Keep the container tightly closed. Store in the original container.

Blister packs: This medicinal product does not require any special temperature storage conditions. Store in the original package. Keep blister in the outer carton.

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

##### Containers

High-density polyethylene containers with child-resistant polyolefin (a combination of polyethylene and polypropylene) lids.

Pack size: 100.

##### Blister packs

1. PVC/Child resistant push through foil (Paper/30 µm soft Al laminated film with Al side heat sealed to PVC).
2. PVC/Child-resistant composite film (15 µm PVC/20 µm Al).
3. PVC/child-resistant composite film (20 µm PVC/20 µm Al).
4. PVC/child-resistant composite film (20 µm PVC/16 µm Al).

Pack sizes: 2, 4, 8, 12, 16 and 100.

Not all pack sizes may be marketed.

#### **6.6 Special precautions for disposal**

Not applicable

### **7 MARKETING AUTHORISATION HOLDER**

Chelonia Healthcare Limited

Boumpoulinas 11, 3rd Floor

Nicosia, P.C. 1060

Cyprus

### **8 MARKETING AUTHORISATION NUMBER(S)**

PL 33414/0126

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

15/01/2025

**10 DATE OF REVISION OF THE TEXT**

10/03/2025