Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Paracetamol 500 mg Film-Coated Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains paracetamol 500 mg.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Film-coated tablet
White, capsule shaped, film-coated tablets with a break line on one side. The break line is only to facilitate breaking for ease of swallowing and do not divide into equal doses.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Paracetamol tablets are a mild analgesic and antipyretic. The tablets are recommended for use in the short term management of headaches, including migraine and tension headaches, backache, rheumatic and muscle pain, period pains, nerve pains, toothache and for relieving of fever, aches and pains of colds and flu.

4.2 Posology and method of administration

Oral administration only.

Age	How much	How often
Adults and children over 16 years	1 or 2 tablets	Every 4-6 hours, as required. Don't take more than 8 tablets (4 doses) in any 24 hours.
Children 10-15 years	1 tablet	Every 4-6 hours, as required. Don't take more than 4 tablets (4 doses) in any 24 hours.

Paracetamol tablets are not suitable for children under 10 years of age.

These doses should not be repeated more frequently than every 4 hours and not more than 4 doses should be given in any 24 hour period.

Maximum duration of continued use without medical advice: 3 days.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1. Use in children under 10 years of age.

4.4 Special warnings and precautions for use

Hepatic impairment
Underlying liver disease increases the risk of paracetamol-related liver damage. Patients with renal or

hepatic impairment should seek medical advice prior to treatment with paracetamol. The hazard of overdose is greater in those with non-cirrhotic alcoholic liver disease.

Do not exceed the stated dose.

Patients should be advised not to take other paracetamol-containing products concurrently. If symptoms persist, consult your doctor.

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.

Keep out of the sight and reach of children.

Consult your doctor if you are taking warfarin or have been diagnosed with liver or kidney disease

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. The rate of paracetemol absorption may be reduced by colestyramine. Colestyramine should not be administered within one hour of taking 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.

In case of concomitant treatment with probenecid, the dose of paracetemol should be reduced because the probenecid reduces the clearance of paracetemol by 50% because it prevents the conjugation of paracetamol with glucuronic acid.

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)

There is limited evidence to suggesting that paracetamol may affect cholaramphenicol pharmacokinetics but its validity has been criticised and evidence of a clinically relevant interaction appears to lack. Although no routine monitoring needed, it is important to bear in mind this potential interaction when these two medications are concomitantly administered, especially in malnourished patients.

4.6 Fertility, pregnancy and lactation

Pregnancy
A large amount of data on pregnant women indicate neither malformative, nor feto/neonatal 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.

Fertility
There are no available data on the effect of paracetamol on fertility.

4.7 Effects on ability to drive and use machines

Paracetamol tablets have no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse events associated with paracetamol from historical clinical trial data are both infrequent and from small patient exposure. Accordingly, events reported from extensive post-marketing experience at therapeutic/labeled dose and considered attributable are tabulated below by System Organ Class and frequency. Frequencies are defined as: very common (>1/10), common (>1/100, <1/10), uncommon (>1/1000,<1/100), rare (>1/10,000, <1/1000) and very rare (<1/10,000), not known

(cannot be estimated from the available data).

Immune system disorders	Allergies (not including angioedema)	Rare
Skin and subcutaneous tissue disorders	Cutaneous hypersensitivity reactions, including skin rashes, pruritus, sweating, purpura, urticaria and angioedema.	Very rare
	Serious skin reactions, such as Toxic epidermal necrolysis (TEN), drug-induced dermatitis, Stevens Johnson syndrome. Anaphylaxis.	Very rare
Haematological system disorders	Thrombocytopaenia	Very rare
Respiratory system disorders	Aggravation of bronchospasm has been reported in asthmatic patients known to be sensitive to aspirin and other non-steroidal anti-inflammatory drugs	Very rare
Hepatobiliary disorders	Liver dysfunction	Very rare
Renal and urinary disorders	Sterile pyuria (cloudy urine)	Very rare

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 HPRA Pharmacovigilance. Website: www.hpra.ie

4.9 Overdose

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, coma and death. Acute renal failure with

acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported. Liver damage is possible in adults who have taken 10g or more of paracetamol. It is considered that excess quantities of a toxic metabolite (usually adequately detoxified by glutathione when normal doses of paracetamol are ingested), become irreversibly bound to liver tissue.

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 and any patient who has ingested around 7.5g or more of paracetamol in the preceding 4 hours should undergo gastric lavage. Administration of oral methionine or intravenous N-acetylcysteine which may have a beneficial effect up to at least 48 hours after the overdose, may be required.

General supportive measures must be available.

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 deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: N02BE01
Paracetamol is an analgesic and antipyretic. Its mechanism of action is believed to include inhibition of prostaglandin synthesis, primarily within the central nervous system.

5.2 Pharmacokinetic properties

Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract.
Concentration in plasma reaches a peak in 30-60 minutes.
Plasma half-life is 1-4 hours.
Paracetamol is relatively uniformly distributed throughout most body fluids.
Plasma protein binding is variable.
Excretion is almost exclusively renal, in the form of conjugated metabolites.

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

- Pregeletanised starch
- Povidone
- Stearic acid
- Hypromellose
- Polyethylene Glycol
- Carnauba Wax

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

4 years.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Opaque PVC/aluminium foil blister strips packed into cardboard boxes containing 16 or 24 tablets.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Chefaro Ireland DAC
The Sharp Building
Hogan Place
Dublin 2
Ireland

8 MARKETING AUTHORISATION NUMBER

PA1186/009/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20 August 1992

Date of last renewal: 20 August 2007

10 DATE OF REVISION OF THE TEXT

April 2024