SUMMARY OF PRODUCT CHARACTERISTICS
ACETAXO 500 (Paracetamol Tablets BP 500 mg)

1. NAME OF THE MEDICINAL PRODUCT

ACETAXO 500 (Paracetamol Tablets BP 500 mg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each uncoated tablet contains paracetamol BP 500 mg.

Excipients with known effect:

Contains methyl paraben and propyl paraben. For warnings, see section 4.4.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet (uncoated).

White coloured, round, flat, bevelled-edge, uncoated tablet with "PARA" and "500" embossed on one side and a single break-line on the same side; plain on the other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

ACETAXO 500 is indicated as a mild analgesic and antipyretic for the symptomatic relief of:

- Headache, including migraine and tension headache.
- Toothache.
- Backache.
- Rheumatic and muscle pains.
- Dysmenorrhoea.
- Sore throat.
- Fever, aches and pains of colds and influenza.
- Symptomatic relief of pain due to mild, non-serious arthritis.

4.2 Posology and method of administration

Adults, the elderly and children aged 16 years and over

One or two tablets (500 mg or 1,000 mg) every 4–6 hours when necessary, up to a maximum of four doses (4,000 mg) in any 24-hour period. The lowest effective dose should be used for the shortest duration necessary to relieve symptoms.

Children aged 10–15 years

One tablet (500 mg) every 4–6 hours when necessary, to a maximum of four doses in any 24-hour period. Doses should not be repeated more frequently than every 4–6 hours and not more than 4 doses given in any 24-hour period. Children in this age group should not be given tablets for more than 3 days without consulting a doctor.

Children under 10 years

Not suitable. Alternative formulations appropriate to body weight should be used.

Hepatic and renal impairment

Care is advised in the administration of paracetamol to patients with renal or hepatic impairment. The dose should not exceed 3,000 mg in 24 hours (or as determined clinically). In severe hepatic impairment, use is not recommended without medical supervision.

Method of administration

Oral. Tablets should be swallowed whole with a sufficient quantity of liquid.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

Hepatic effects

Care is advised in the administration of paracetamol to patients with hepatic impairment (including alcoholic liver disease) or renal impairment. The hazard of overdose is greater in those with non-cirrhotic alcoholic liver disease. Patients should not take other paracetamol-containing products concurrently, to avoid exceeding the maximum recommended daily dose.

Flucloxacillin interaction — HAGMA

Caution is advised if paracetamol is administered concomitantly with flucloxacillin due to an 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 in those using maximum daily doses of paracetamol. Close monitoring, including measurement of urinary 5-oxoproline, is recommended (see section 4.5).

Risk factors for hepatotoxicity

Patients at particular risk of hepatotoxicity include those: on long-term treatment with carbamazepine, phenobarbital, phenytoin, primidone, rifampicin, St. John's Wort or other drugs that induce liver enzymes; who regularly consume ethanol in excess of recommended amounts; who are likely to be glutathione-depleted (e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia).

Persistent headache

Patients should be advised to consult their doctor if their headaches become persistent, as regular use of analgesics can worsen headache.

Chronic pain

Patients with mild, non-serious arthritis who need to take painkillers every day should be advised to consult a doctor.

Paraben content

This product contains methyl paraben and propyl paraben, which may cause allergic reactions (possibly delayed).

4.5 Interaction with other medicinal products and other forms of interaction

Anticoagulants (warfarin and other coumarins):

Prolonged regular daily use of paracetamol at maximum doses may enhance the anticoagulant effect of warfarin and other coumarins, increasing the risk of bleeding. Occasional single doses have no clinically significant effect; INR should be monitored with regular paracetamol use.

Flucloxacillin:

Concomitant use of paracetamol and flucloxacillin has been associated with high anion gap metabolic acidosis (HAGMA), especially in patients with risk factors (severe renal impairment, sepsis, malnutrition, glutathione deficiency). Caution is required and close monitoring recommended (see section 4.4).

Metoclopramide and domperidone:

These drugs increase the rate of absorption of paracetamol, possibly increasing peak plasma concentration.

Colestyramine:

Reduces the rate and extent of absorption of paracetamol. Paracetamol should be taken at least 1 hour before or 4–6 hours after colestyramine if rapid analgesic effect is desired.

Enzyme-inducing drugs (carbamazepine, phenobarbital, phenytoin, primidone, rifampicin, St. John's Wort):

These drugs induce hepatic enzymes and may increase the risk of paracetamol-induced hepatotoxicity, particularly in overdose.

4.6 Fertility, pregnancy and lactation

Pregnancy

A large amount of data on pregnant women indicates neither malformative nor foeto/neonatal toxicity of paracetamol. 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 at therapeutic doses.

Fertility

No evidence of an effect on human fertility has been identified.

4.7 Effects on ability to drive and use machines

Paracetamol at therapeutic doses has no known effect on the ability to drive and use machines.

4.8 Undesirable effects

Summary of the safety profile

Adverse events from paracetamol at therapeutic doses are both infrequent and of generally limited severity. The frequency of adverse reactions in post-marketing experience is not known (cannot be estimated from available data); post-marketing experience indicates that adverse reactions to paracetamol are rare and serious reactions are very rare.

System Organ Class	Adverse Reaction (frequency not known)
Blood and lymphatic system disorders	Thrombocytopenia, agranulocytosis
Immune system disorders	Anaphylaxis; cutaneous hypersensitivity reactions including skin rashes and angioedema
Respiratory, thoracic and mediastinal disorders	Bronchospasm (more likely in aspirin-sensitive asthmatics or those sensitive to other NSAIDs)*
Hepatobiliary disorders	Hepatic dysfunction (particularly in overdose or with risk factors)
Skin and subcutaneous tissue disorders	Very rare cases of serious skin reactions (Stevens-Johnson syndrome, toxic epidermal necrolysis, acute generalised exanthematous pustulosis) have been reported
Metabolism and nutrition disorders	High anion gap metabolic acidosis (HAGMA) when used with flucloxacillin in patients with risk factors (see sections 4.4 and 4.5)

** Bronchospasm cases are more likely in patients with aspirin or NSAID sensitivity.*

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 National Regulatory Authority.

4.9 Overdose

Risk factors

Liver damage is possible in adults who have taken 10 g or more of paracetamol. Ingestion of 5 g or more may lead to liver damage if the patient has one or more of the following risk factors: long-term treatment with enzyme-inducing drugs (carbamazepine, phenobarbital, phenytoin, primidone, rifampicin, St. John's Wort or similar); regular excess alcohol consumption; glutathione depletion (eating disorders, cystic fibrosis, HIV infection, starvation, cachexia).

Symptoms

Symptoms in the first 24 hours include pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12–48 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 (loin pain, haematuria, proteinuria) may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have also been reported.

Management

Immediate treatment is essential. Despite a lack of significant early symptoms, patients should be referred to hospital urgently. Treatment should be in accordance with established guidelines. 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). N-acetylcysteine may be used up to 24 hours after ingestion; the maximum protective effect is obtained up to 8 hours post-ingestion. If

vomiting is not a problem, oral methionine may be a suitable alternative for remote areas outside hospital. Management of patients presenting with serious hepatic dysfunction beyond 24 hours from ingestion should be discussed with the NPIS (National Poisons Information Service) or a liver unit.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

Paracetamol is an analgesic and antipyretic. The mechanism of action involves inhibition of prostaglandin synthesis, primarily in the central nervous system. Unlike NSAIDs, paracetamol has only weak peripheral anti-inflammatory activity and does not inhibit platelet function at therapeutic doses. The antipyretic effect is mediated centrally.

5.2 Pharmacokinetic properties

Absorption

Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract; peak plasma concentrations are reached within 30–60 minutes after therapeutic doses.

Distribution

Paracetamol is relatively uniformly distributed throughout most body fluids. Plasma protein binding is variable; approximately 20–30% may be bound at the concentrations encountered during acute intoxication.

Biotransformation

Paracetamol is extensively metabolised by the liver, primarily via conjugation with glucuronide and sulphate (>90% at therapeutic doses). A minor fraction is oxidised by CYP2E1 and CYP3A4 to the reactive intermediate N-acetyl-p-benzoquinoneimine (NAPQI), which is normally detoxified by conjugation with glutathione. In overdose, or when glutathione is depleted, NAPQI accumulates and causes hepatocellular necrosis.

Elimination

The plasma half-life is 1–4 hours after therapeutic doses. Following therapeutic doses, 90–100% of the drug may be recovered in urine within the first day, predominantly as conjugated metabolites; practically no paracetamol is excreted unchanged.

5.3 Preclinical safety data

Conventional studies using currently accepted standards for the evaluation of toxicity to reproduction and development are not available. No special hazard for humans has been identified based on available data at therapeutic doses.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

No.	Excipient	Specification
1	Starch	BP
2	Dicalcium phosphate	BP
3	Methyl paraben (excipient with known effect)	BP
4	Propyl paraben (excipient with known effect)	BP
5	Povidone K-30 (PVP K-30)	BP
6	Gelatin	BP
7	Purified talc	BP
8	Magnesium stearate	BP
9	Sodium starch glycolate	BP
10	Sodium lauryl sulphate	BP
11	Colloidal silicon dioxide	BP

6.2 Incompatibilities

Not applicable.

6.3 Shelf life
36 months.

6.4 Special precautions for storage
Store at a temperature not exceeding 25°C. Protect from light and moisture. Keep out of the reach and sight of children.

6.5 Nature and contents of container
ALU-PVC blister of 10 tablets; 10 such blisters packed in a printed carton with package insert. Pack size: 100 tablets.

6.6 Special precautions for disposal and other handling
No special requirements. Any unused product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER
ZAIN PHARMA LTD.

Plot No. 209/13741, Colchester Park,

Go-Down No. 1, 2, 3, Off Mombasa Road,

Behind Nice and Lovely House,

P.O. Box: 100167-00101, Nairobi, Kenya.

8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)
H2026/CTD12514/25483

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