SUMMARY OF PRODUCT CHARACTERISTICS COSMOL 500 MG TABLET

1. **Name of the Medicinal Product**

   Cosmol 500 mg Tablet BP

2. **Qualitative and Quantitative Composition**

   Each tablet contains 500 mg Paracetamol BP

   For the full list of excipients, see section 6.1.

3. **Pharmaceutical Form**

   Uncoated Tablets

   White, circular, flatbevelled edge tablet embossed 'COSMOL' on one side and P500 with a breakline on the other side

4. **Clinical Particulars**

4.1 Therapeutic Indications

Paracetamol is a mild analgesic and antipyretic, and 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

Adults, including the elderly, and children aged 16 years and over: One or two tablets up to four times daily as required.

Children:

10-15 years: One tablet up to four times daily as required.

Not suitable for children under 10 years of age.

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

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.

Oral administration only.

4.3 Contraindication

Hypersensitivity to Paracetamol or any of the other constituents.

4.4 Special warnings and precautions for use

Care is advised in the administration of paracetamol to patients with renal or hepatic impairment. The hazard of overdose is greater in those with noncirrhotic alcoholic liver disease.

Do not exceed the stated dose.

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

Patients should be advised not to take other paracetamol-containing products concurrently.

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

Sodium methyl-, sodium ethyl- and sodium propyl- parahydroxybenzoates (E219, E215, E217) may cause allergic reactions (possibly delayed).

If symptoms persist consult your doctor.

Keep out of the reach and sight of children.

<u>Pack Label:</u>

Immediate medical advice should be sought in the event of an overdose, even if you feel well.

Do not take with any other Paracetamol-containing products.

<u>Patient Information Leaflet:</u>

Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed, serious liver damage.

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.

4.6 Pregnancy and lactation

Epidemiological studies in human pregnancy have shown no ill effects due to 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. Available published data do not contraindicate breast feeding.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Body System	**Undesirable effect**
Blood and lymphatic system disorders	Thrombocytopenia Agranulocytosis
Immune system disorders	Anaphylaxis Cutaneous hypersensitivity reactions including skin rashes, angiodema and Stevens Johnson syndrome/toxic epidermal necrolysis
Respiratory, thoracic and mediastinal disorders	Bronchospasm*
Hepatobiliary disorders	Hepatic dysfunction

4.9 Overdose

Liver damage is possible in adults who have taken 10g or more of paracetamol.

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.

Human pharmacokinetic data demonstrate that the time taken to reach plasma paracetamol therapeutic threshold (4-7mcg/ml) is at least 37% faster with Cosmol 500 mg Tablets compared to standard paracetamol tablets ($P<0.05$).

Total extent of absorption of paracetamol from Cosmol 500 mg Tablets is equivalent to that from standard paracetamol tablets.

6. Pharmaceutical Particulars

6.1 List of Excipients

Microcrystalline cellulose BP
Maize starch BP
Aerosil BP
Povidone BP
Potassium sorbate BP
Magnesium stearate BP
Stearic acid BP

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store in a dry place below 30ºC. Protect from light and moisture. Keep the medicine reach out of the children.

6.5 Nature and contents of container

PVC 250 micron Blister Packing

6.6 Instructions for use, handling and disposal

No special requirements for disposal.

7 Registrant

Cosmos Limited

8 Manufacturer

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