SUMMARY OF PRODUCT CHARACTERISTICS COSMOL SUSPENSION

1. **Name of the Medicinal Product**

   Cosmol Suspension 120 mg/5mL

2. **Qualitative and Quantitative Composition**

   Each 5mL contains 120 mg Paracetamol BP

3. **Pharmaceutical Form**

   Suspension

4. **Clinical Particulars**

4.1 Therapeutic Indications

To relieve mild to moderate pain and to reduce fever in many conditions including headache, toothache, teething, feverishness, colds and influenza and following vaccination.

4.2 Posology and Method of administration

For oral use only.

It is important to shake the bottle for at least 10 seconds before use.

Children aged 3 months – 6 years:

Child's Age	How Much	How Often (in 24 hours)
3 months up to 6 months	2.5 ml	4 times
6 months up to 2 years	5 ml	4 times
2 years up to 4 years	7.5 ml	4 times
4 years up to 6 years	10 ml	4 times
Don't give more than 4 doses in any 24 hours		

4.3 Contraindication

Hypersensitivity to Paracetamol or any of the other constituents.

4.4 Special warnings and precautions for use

Caution in patients with severely impaired liver or kidney function.
The hazards of overdose are greater in those with non-cirrhotic alcoholic liver disease.Methyl hydroxybenzoate (E218) may cause allergic reactions (possibly delayed). Very rare cases of serious skin reactions have been reported.
The label should contain the following statements:
Contains paracetamol.
Do not give this medicine with any other paracetamol-containing product.
For oral use only.
Do not take more medicine than the label tells you to. If you do not get better talk to your doctor.
Always use the syringe supplied with the pack.
Do not give to babies less than 2 months of age.
Do not give more than 4 doses in any 24 hour period.
Leave at least 4 hours between doses.
Do not give this medicine to your child for more than 3 days without speaking to your doctor or pharmacist.

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 use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

Patients who have taken barbiturates, tricyclic antidepressants and alcohol may show diminished ability to metabolise large doses of paracetamol, the plasma half-life of which can be prolonged.

Alcohol can increase the hepatotoxicity of paracetamol overdosage and may have contributed to the acute pancreatitis reported in one patient who had taken an overdose of paracetamol.

Chronic ingestion of anticonvulsants or oral steroid contraceptives induce liver enzymes and may prevent attainment of therapeutic paracetamol levels by increasing first pass metabolism or clearance.

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

Adverse effects of paracetamol are rare but hypersensitivity including skin rash may occur.

Very rare cases of serious skin reactions have been reported.

Very rarely there have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily causally related to paracetamol.

5. Overdose

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

6. Pharmacological Properties

6.1 Pharmacodynamic Properties

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.

6.2 .Pharmacokinetic Properties

Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 30 minutes to 2 hours after ingestion. Paracetamol is metabolised in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates, with about 10% as glutathione conjugates. Less than 5% is

excreted as unchanged paracetamol. Plasma protein binding is negligible at usual therapeutic concentrations, although this is dose dependent. The plasma elimination half life varies from about one to four hours.

Pharmaceutical Particulars

6.3 List of Excipients

Sodium methyl paraben
Sodium propyl paraben
Sucrose
Saccharin sodium
Xanthan gum
Sorbitol
Glycerine
Citric acid anhydrous
Strawberry liquid flavour
Vanilla liquid flavour
Carmoisine color

Incompatibilities

Not applicable.

6.4 Shelf life

3 years

6.5 Special precautions for storage

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

6.6 Nature and contents of container

Amber glass bottle.

6.7 Instructions for use, handling and disposal

No special requirements for disposal.

7 Registrant

Cosmos Limited

8 Manufacturer

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