SCHEDULING STATUS: **S0**

PROPRIETARY NAME: **CEPACOL MEDSIP HONEY LEMON**

(AND DOSAGE FORM) **(POWDER)**

COMPOSITION:

Each 5 g sachet contains:

Paracetamol	800 mg
Caffeine	50 mg
Ascorbic acid	10 mg

Contains sugar:

Sucrose	3 368mg

Contains sweeteners:

Sodium saccharin	25mg
Sodium cyclamate	128 mg

Tartrazine free

Excipients: Citric acid anhydrous; Menthol - spray dried; Quinolene yellow; Silicon dioxide; Sunset yellow; Trusil honey; Trusil lemon juice J2424

PHARMACOLOGICAL CLASSIFICATION:

A:5.8 Preparations for the common cold, including nasal decongestants and antihistaminics

PHARMACOLOGICAL ACTION:

Paracetamol has analgesic (relief of pain) and antipyretic (fever reducing) properties.

INDICATIONS:

Symptomatic relief of minor aches and pains, headaches and fever associated with the common cold and influenza.

CONTRAINDICATIONS:

Known sensitivity to any of the ingredients.

Severe liver function impairment.

WARNINGS AND SPECIAL PRECAUTIONS:

Paracetamol:

This product contains paracetamol which may be fatal in overdose. In the event of overdosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or Poison Centre must be contacted immediately.

Dosages in excess of those recommended may cause severe liver damage.

Patients suffering from liver or kidney disease should take paracetamol under medical supervision.

Do not use continuously for more than 10 days without consulting a doctor.

Consult a doctor if no relief is obtained from the recommended dosage.

Caffeine:

It should be given with caution to patients with peptic ulceration, hyperthyroidism, hypertension, cardiac arrhythmias or other cardiovascular disease, as these conditions may be exacerbated.

It should be used with caution in alcoholics, patients with cor pulmonale, elderly patients, patients with hypoxia, patients with acute pulmonary oedema, or any other lung disease, or in patients with impaired respiratory function.

Prolonged high intake of caffeine may lead to tolerance of some of the pharmacological actions and physical signs of withdrawal including irritability, lethargy and headache may occur if intake is discontinued abruptly.

Ascorbic acid:

Ascorbic acid should be given with care to patients with hyperoxaluria.

Contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-absorption or sucrase-isomaltase insufficiency should not take **CEPACOL MEDSIP HONEY LEMON.**

Contains Sucrose which may have an effect on the glycaemic control of patients with diabetes mellitus.

Effects on ability to drive and use machines

CEPACOL MEDSIP HONEY LEMON has no or negligible influence on the ability to drive and use machines.

PREGNANCY AND LACTATION:

Safety in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:

DO NOT EXCEED THE RECOMMENDED DOSE

Not recommended for children under the age of 12 years.

Adults and children over 12 years: One sachet 3 times per day. Do not exceed 4 doses in any 24 hours. Empty the contents of a sachet into a tumbler and fill with very hot water. Stir to dissolve. Cold water may be added if necessary, but drink as hot as possible.

SIDE EFFECTS

Paracetamol:

Skin rashes and other allergic reactions may occur. The rash is usually erythematous or urticarial but sometimes more serious and may be accompanied by fever and mucosal lesions. The use of paracetamol has been associated with the occurrence of neutropenia, pancytopenia and leucopenia.

Caffeine:

Commonly encountered side effects are gastrointestinal irritation and stimulation of the central nervous system. Caffeine may cause nausea, vomiting, abdominal pain, gastrointestinal bleeding, insomnia, headache, anxiety, restlessness, vertigo and palpitations.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Paracetamol:

Prompt treatment is essential. In the event of an overdosage, consult a doctor immediately, or take the person directly to a hospital. A delay in starting treatment may mean that antidote is given too late to be effective. Evidence of liver damage is often delayed until after the time for effective treatment has lapsed.

Susceptibility to paracetamol toxicity is increased in patients who have taken repeated high doses (greater than 5 -10 g/day) of paracetamol for several days, in chronic alcoholism, chronic liver

disease, AIDS, malnutrition, and with the use of drugs that induce liver microsomal oxidation such as barbiturates, isoniazid, rifampicin, phenytoin and carbamazepine.

Symptoms of paracetamol overdosage in the first 24 hours include pallor, nausea, vomiting, anorexia and possibly abdominal pain. Mild symptoms during the first two days of acute poisoning, do not reflect the potential seriousness of the overdosage.

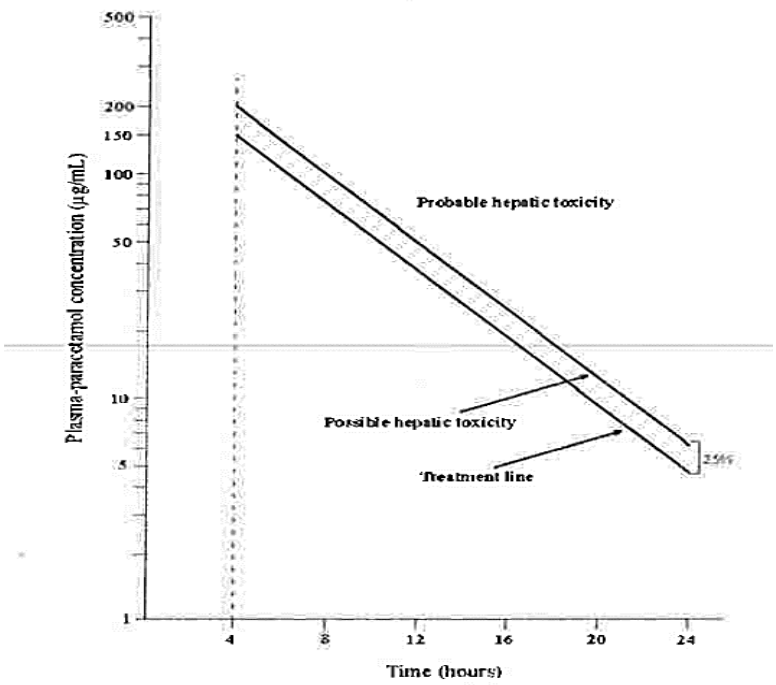
Liver damage may become apparent 12 to 48 hours, or later after ingestion, initially by elevation of the serum transaminase and lactic dehydrogenase activity, increased serum bilirubin concentration and prolongation of the prothrombin time. Liver damage may lead to encephalopathy, coma and death.

Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Abnormalities of glucose metabolism and metabolic acidosis may occur. Cardiac arrhythmias have been reported.

Treatment for paracetamol overdosage:
Although evidence is limited it is recommended that any adult person who has ingested 5 - 10 grams or more of paracetamol (or a child who has had more than 140 mg/kg) within the preceding four hours, should have the stomach emptied by lavage (emesis may be adequate for children) and a single dose of 50 g activated charcoal given via the lavage tube. Ingestion of amounts of paracetamol smaller than this may require treatment in patients susceptible to paracetamol poisoning (see above). In patients who are stuperose or comatose endotracheal intubation should precede gastric lavage in order to avoid aspiration.

N-acetylcysteine should be administered to all cases of suspected overdose as soon as possible preferably within eight hours of overdosage, although treatment up to 36 hours after ingestion may still be of benefit, especially if more than 150 mg/kg of paracetamol was taken. An initial dose of 150 mg/kg N-acetylcysteine in 200 ml dextrose injection given intravenously over 15 minutes, followed by an infusion of 50 mg/kg in 500 ml dextrose injection over the next four hours, and then 100 mg/kg in 1 000 ml dextrose injection over the next sixteen hours. **The volume of intravenous fluid should be modified for children.**

Although the oral formulation is not the treatment of choice, 140 mg/kg dissolved in water may be administered initially, followed by 70 mg/kg every four hours for seventeen doses.
A plasma paracetamol level should be determined four hours after ingestion in all cases of suspected overdosage. Levels done before four hours, may be misleading. Patients at risk of liver damage, and hence requiring continued treatment with N-acetylcysteine, can be identified according to their 4-hour plasma paracetamol level. The plasma paracetamol level can be plotted against time since ingestion in the nomogram below. The nomogram should be used only in relation to a single acute ingestion.



Source: Martindale: The Complete Drug Reference -37th Edition.

Those whose plasma paracetamol levels are above the “normal treatment line”, should continue N-acetylcysteine treatment with 100 mg/kg IV over sixteen hours repeatedly until recovery. Patients with increased susceptibility to liver damage as identified above, should continue treatment if concentrations are above the “high risk treatment line”. Prothrombin index correlates best with survival.

Monitor all patients with significant ingestions for at least ninety six hours.

Caffeine:

Large doses may cause nausea, vomiting, abdominal pain, restlessness, anxiety, insomnia, gastro-intestinal bleeding, vertigo, palpitations and stimulation of the central nervous system.

Ascorbic acid:

Large doses may cause diarrhoea and other gastro-intestinal disturbances and are associated with the formation of renal calcium oxalate calculi.

IDENTIFICATION:

An off-white powder with a characteristic honey lemon taste.

PRESENTATION:

Single dose sachets containing 5 g of powder and cartons containing 5 or 8 single dose sachets.

STORAGE INSTRUCTIONS:

Store in a cool, dry place at or below 25 °C. Protect from light.

KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBER:

27/5.8/0508

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

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