CENTAMOL SUSPENSION

Analgesic & Antipyretic

COMPOSITION

Each 5 ml contains:
Paracetamol 250mg

CLINICAL PHARMACOLOGY

Mode of Action

Paracetamol is a centrally acting analgesic and antipyretic agent. Paracetamol does not possess any anti-inflammatory action.

Although the exact site and mechanism of analgesic action is not clearly defined, Paracetamol appears to produce analgesia by elevation of the pain threshold. The mechanism may involve inhibition of the nitric oxide pathway mediated by a variety of neurotransmitter receptors including N-methyl-D-aspartate and substance P.

Paracetamol has been shown to inhibit the action of endogenous pyrogens on the heat-regulating centers in the brain by blocking the formation and release of prostaglandins in the central nervous system. Inhibition of arachidonic acid metabolism is not requisite for the antipyretic effect of paracetamol.

Paracetamol is equal to aspirin in analgesic and antipyretic effectiveness but it is unlikely to produce many of the side effects associated with aspirin and aspirin-containing products.

Pharmacokinetics

Paracetamol is readily absorbed from the gastrointestinal tract with peak plasma concentrations occurring about 10 to 60 minutes after oral administration. Paracetamol is distributed into most body tissues. Plasma protein binding is negligible at usual therapeutic doses. The elimination half-life varies from about 1 to 3 hours.

Paracetamol is metabolized extensively in the liver and excreted in the urine mainly as inactive glucuronide and sulfate conjugates. Less than 5% is excreted unchanged.

Paracetamol is metabolized differently by premature infants, newborns, infants and young children compared to adults, the sulfate conjugate being predominant.

INDICATIONS

Centamol [Paracetamol] **Suspension** is recommended for the temporary relief of mild to moderate pain, including headache, migraine, neuralgia, toothache, sore throat, menstrual cramps and bodyache.
Centamol [Paracetamol] **Suspension** is also recommended for the reduction of fever and may be used as an adjunct in the treatment of cold and flu, and for post immunization pyrexia.

DOSAGE & ADMINISTRATION

Children:

<3 months: 10 mg/kg body weight [reduce to 5mg per kg if jaundiced]
3months–1year: 1.25ml-2.5ml
1 - 5 years: 2.5-5ml (125-250mg)

6-12 years: 5-10ml (250-500 mg]
>12 years: 10ml [500mg]
These doses may be given 3-4 times daily as required.
For post immunization pyrexia a dose of 60mg has been recommended for children 2-3 months of age. A second dose may be given after 4-6 hours.

Adults: 10-20ml (500-1000mg) every 4 - 6 hours up to a maximum of 4g daily. It has been recommended that if paracetamol is used for long-term therapy then the daily dose should not exceed 2.6gm unless the patient is monitored.

CONTRAINDICATIONS
- Hypersensitivity to Paracetamol or constituent of this preparation.
- Patients with severe hepatic dysfunction

WARNINGS & PRECAUTIONS
Alcohol
Chronic heavy alcohol abusers may be at increased risk of liver toxicity from excessive paracetamol use, although reports of this event are rare. These reports usually involve cases of severe chronic alcoholics and dosages of paracetamol that most often exceed recommended doses. Chronic alcoholics should not exceed 2 g/day of paracetamol.

Hepatic/Renal Impairment
Paracetamol should be given with care to patients with impaired kidney or liver function and patients taking other drugs that affect the liver.

Pregnancy: **Category A:** Paracetamol has been used for over 40 years and available data indicate that paracetamol in therapeutic doses does not adversely affect the pregnant mother or the fetus.

Lactation: Maternal ingestion of paracetamol in recommended analgesic doses does not present a risk to the nursing infant. Amounts in milk range from 0.1% to 1.85% of the ingested maternal dose. Accordingly, breast feeding need not be interrupted.

DRUG INTERACTIONS
- Anticoagulant drugs (warfarin) - dosage may require reduction if paracetamol and anticoagulants are taken for a prolonged period of time
- Paracetamol absorption is increased by substances that increase gastric emptying, e.g. metoclopramide
- Paracetamol absorption is decreased by substances that decrease gastric emptying, e.g. propantheline, antidepressants with anticholinergic properties, and narcotic analgesics
- Paracetamol may increase chloramphenicol concentrations
- The risk of paracetamol toxicity may be increased in patients receiving other potentially hepatotoxic drugs or drugs that induce liver microsomal enzymes such as alcohol and anticonvulsant agents
- Paracetamol excretion may be affected and plasma concentrations altered when given with probenecid
- Colestyramine reduces the absorption of paracetamol if given within 1 hour.
- Antivirals: Regular use of paracetamol possibly reduces metabolism of Zidovudine (increased risk of neutropenia).

ADVERSE EFFECTS
There have been reports of blood dyscrasias including thrombocytopenia and agranulocytosis, but these were not necessarily related to paracetamol. Paracetamol has been widely used and reports of adverse reactions are rare, and are generally associated with over dosage. Allergic reactions occur occasionally.
Nephrotoxic effects are uncommon and have not been reported in association with therapeutic doses, except after prolonged administration.

PRESENTATION
Paracetamol is available in bottles of 60ml

STORAGE
Store below 25°C. Protect from light