**CIAN COLD**

Paracetamol, Phenylephrine Hydrochloride, Chlorphenamine Maleate & Caffeine Anhydrous Tablets

**COMPOSITION:**

Each uncoated tablet contains:

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|---|---|
| Paracetamol BP | 325 mg |
| Phenylephrine Hydrochloride BP | 5 mg |
| Chlorphenamine Maleate BP | 2 mg |
| Caffeine Anhydrous BP | 30 mg |
| Excipients | q.s. |

**INDICATION:**

Cian Cold is indicated for:
Relief of nasal and sinus congestion.
Relief of allergic symptoms of the nose or throat due to upper respiratory tract allergies.
Relief of sinus pain and headache.
Adjunct with antibacterials in sinusitis, tonsillitis and otitis media.
Post-operative after tonsillectomy.

**PHARMACOKINETICS:**

Paracetamol is metabolised by the hepatic microsomal enzymes. It is rapidly and completely absorbed from the gastro-intestinal tract. Plasma concentration reaches a peak in half to one hour, the plasma half-life is one to three hours and it is uniformly distributed throughout the body.
Phenylephrine hydrochloride is irregularly absorbed from the gastro-intestinal tract. When injected intramuscularly it takes 10- 1 5 minutes to act and subcutaneous and intramuscular injections are effective for about one hour. Intravenous injections are effective for about 20 minutes.
Caffeine is readily absorbed from the gastro-intestinal tract.
It is readily absorbed from the GI Tract, following oral administration, and is normally effective in 30 to 60 minutes. The effects last to 4 to 6 hours. The plasma half life is estimated to be 12 – 15 hours. There is significant plasma protein binding. The drug is largely inactivated in the liver and excreted as metabolites in the urine. Chlorphenamine is metabolised to the monodesmethyl and didesmethyl derivative. About 22% of an oral dose is excreted unchanged.

**PHARMACODYNAMICS:**

Cian Cold contains a clinically proven analgesic-antipyretic Paracetamol with decongestant Phenylephrine and an antihistamine Chlorphenamine. Paracetamol produces analgesia by elevation of the pain threshold and antipyretic effect through action on the hypothalamic heat-regulating center. Paracetamol is equal to aspirin in analgesic and antipyretic effectiveness, and it is unlikely to produce many of the side effects associated with aspirin and aspirin-containing products.
Sympathomimetic decongestants reduce the nasal congestion due to increased nasal blood flow associated with colds and influenza. Phenylephrine is sympathomimetic vasoconstrictor that has been used as a decongestant. It is a relatively selective alpha-adrenoceptor agonist. The majority of the sympathomimetic action is due to direct stimulation of the adrenoceptors and relatively little is due to an indirect effect via release of noradrenaline. Its pressor action is weaker than that of noradrenaline but of longer duration. At therapeutic doses, it does not cause significant stimulation of the central nervous system.
Chlorphenamine in Cian Cold provides prompt relief of itchy-watery eyes, runny nose, sneezing, itching of the nose or throat due to respiratory allergies. Cian Cold contains, in addition to the above ingredients, a decongestant, Phenylephrine, which is a sympathomimetic amine. It provides prompt relief of nasal and sinus congestion.
Caffeine in Cian Cold Tablets enhances the analgesic activity of Paracetamol and serves to reduce incidence of sedation due to Chlorphenamine.

**DOSAGE AND ADMINISTRATION:**

The usual recommended dose of Cian Cold Tablets in adults is 1-2 tablets tid or qid.

**CONTRAINDICATIONS:**

The use of Cian Cold is contraindicated in patients with hypersensitivity to any of the ingredients of the formulation.
Cian Cold is contraindicated in patients with severe hypertension.

**SPECIAL WARNING AND PRECAUTION FOR USE:**

In case a hypersensitivity reaction occurs which is rare, Cian Cold should be discontinued.
Cian Cold contains Paracetamol therefore should not be used in conjunction with other Paracetamol containing products.
Cian Cold should be used with caution in patients with renal or hepatic dysfunction, diabetes mellitus, hyperthyroidism, cardiovascular problems, epilepsy and closed angle glaucoma.
It is advisable not to drive or operate machinery when on treatment with Cian Cold.

**INTERACTION WITH OTHER MEDICINE AND CONCOMITANT USE:**

Clinically significant drug interactions may occur on concomitant administration of Cian Cold with monoamine oxidase inhibitors, tricyclic antidepressants, beta-adrenergic agents, methyldopa, reserpine and veratrum alkaloids.

**PREGNANCY AND LACTATION:**

This product is not recommended for use in pregnancy due to the phenylephrine and caffeine content. There is a potential increased risk of lower birth weight and spontaneous abortion associated with caffeine consumption during pregnancy.
This product should not be used while breast-feeding without medical advice
Caffeine in breast milk may have a stimulating effect on breast-fed infants.
Phenylephrine may be excreted in breast milk.
Chlorphenamine may be secreted in breast milk. The use in breast feeding mothers is not recommended

**EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:**

Patients should be advised not to drive or operate machinery if affected by dizziness.

**UNDESIRABLE EFFECT:**

Cian Cold is generally well tolerated and adverse events are rare.
Hypersensitive individuals may display ephedrine-like reactions such as tachycardia, palpitations, headache, dizziness and nausea. Use of sympathomimetics has been associated with fear, anxiety, restlessness, tremor, weakness, dysuria, insomnia, hallucinations and convulsions. Chlorpheniramine in Cian Cold may cause sedation.

**OVERDOSE:**

**Paracetamol:**

Liver damage is possible in adults who have taken 10g or more of paracetamol. Ingestion of 5g or more of paracetamol may lead to liver damage if the patient has risk factors.
Risk factors
If the patient
a) Is on long term treatment with carbamazepine, phenobarbitone, phenytoin, primidone, rifampicin, St John's Wort or other drugs that induce liver enzymes.
Or
b) Regularly consumes ethanol in excess of recommended amounts.
Or
c) Is likely to be glutathione deplete e.g. eating disorders, cystic fibrosis, HIV infection, starvation, cachexia.
Symptoms
Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 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, strongly suggested by loin pain, haematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis have been reported.
Management
Immediate treatment is essential in the management of paracetamol overdose. Despite a lack of significant early symptoms, patients should be referred to hospital urgently for immediate medical attention. Symptoms may be limited to nausea or vomiting and may not reflect the severity of overdose or the risk of organ damage. Management should be in accordance with established treatment guidelines, see BNF overdose section.
Treatment with 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). Treatment with N-acetylcysteine may be used up to 24 hours after ingestion of paracetamol, however, the maximum protective effect is obtained up to 8 hours post-ingestion. The effectiveness of the antidote declines sharply after this time. If required the patient should be given intravenous N-acetylcysteine, in line with the established dosage schedule. If vomiting is not a problem, oral methionine may be a suitable alternative for remote areas, outside hospital. Management of patients who present with serious hepatic dysfunction beyond 24h from ingestion should be discussed with the NPIS or a liver unit.

**Caffeine:**

Symptoms and signs
Overdose of caffeine may result in epigastric pain, vomiting, diurese, tachycardia or cardiac arrhythmia, CNS stimulation (insomnia, restlessness, excitement, agitation, jitteriness, tremors and convulsions).
It must be noted that for clinically significant symptoms of caffeine overdose to occur with this product, the amount ingested would be associated with serious paracetamol-related liver toxicity.
Treatment
No specific antidote is available, but supportive measures may be used.

**Phenylephrine:**

Symptoms and signs
Phenylephrine overdosage is likely to result in effects similar to those listed under adverse reactions. Additional symptoms may include, hypertension, and possibly reflex bradycardia. In severe cases confusion, hallucinations, seizures and arrhythmias may occur. However the amount required to produce serious phenylephrine toxicity would be greater than that required to cause paracetamol-related liver toxicity.
Treatment
Treatment should be as clinically appropriate. Severe hypertension may need to be treated with alpha blocking drugs such as phentolamine.

**Chlorphenamine:**

Symptoms and signs
The estimated lethal dose of Chlorphenamine 4mg Tablets is 25 to 50mg per kg body weight. Symptoms and signs include sedation, paradoxical stimulation of CNS, toxic psychosis, seizures, apnoea, convulsions, anticholinergic effects, dystonic reactions and cardiovascular collapse including arrhythmias.
Treatment
Symptomatic and supportive measures should be provided with special attention to cardiac, respiratory, renal and hepatic functions, and fluid electrolyte balance.
If overdosage is by the oral route, treatment with activated charcoal should be considered provided there are no contraindications for use and the overdose has been taken recently (treatment is most effective if given within an hour of ingestion).
Hypotension and arrhythmias should be treated vigorously; CNS convulsions may be treated with I.V. diazepam. Haemoperfusion may be used in severe cases.

**INCOMPATIBILITY:**

None

**SHELF LIFE:**

3 years

**PACKAGING:**

10 tablets are packed in Alu-Alu blister and such 10 blisters are packed in a carton along with insert.

**STORAGE CONDITION:**

Store in dry place below 30°C.
Keep out of reach of children.

**MARKETED AND DISTRIBUTED BY:**

**ZIA PHARMACEUTICAL**
151B St.12 BT,Krom 5, Phum Sonsomkosol 4,
Sangkat Boeung Tompun Khan Meanchey,
Phnom Penh,Cambodia

**MANUFACTURED BY:**

**CIAN HEALTH CARE PVT. LTD.**
Khasra No.: 248, Village Sisona, Bhagwanpur,
Roorkee, Haridwar, Uttarakhand, India.