

Axcel Iridin-Hot

COMPOSITION:

Pholcodine 5mg
Triprolidine HCl 1.25mg
Paracetamol 250mg

PRESENTATION:

Orange coloured suspension with mango flavoured.

MECHANISMS OF ACTION:

Pholcodine is cough suppressant used for the relief of non-productive cough. It has central action on the cough centre in the medulla. Pholcodine has no analselsics properties and has little sedative effect although structurally related to morphine.

Triprolidine is an alkylamine derivative. It is a sedative antihistamine with antimuscarinic and mild sedative effect. Triprolidine is a histamine H1-receptor antagonist. It acts by competing with histamine for H1 receptor sites on the effector cells, to the exclusion of agonist molecules, without itself initiating a response. This antagonism is competitive and reversible. It does not inactivate or prevent the production of histamines.

Paracetamol, a para-aminophenol derivative, has analgesic, antipyretic properties and weak anti-inflammatory activity. Paracetamol relieves mild to moderate pain such as headache, in many muscle joint, and peripheral nerve disorders and fever. Paracetamol is an active inhibitor of prostaglandin synthetase of brain, but it is weak inhibitor of prostaglandin synthesis by a preparation from spleen. Paracetamol is often the choice for analgesic or antipyretic treatment especially in the elderly and in patients whom are hypersensitive to salicylates or other NSAIDs.

PHARMACOLOGY:

Pholcodine is absorbed from the gastrointestinal tract and crosses the blood brain barrier. It is metabolized in the liver and its action may be prolonged in hepatic insufficiency.

Triprolidine is absorbed from gastrointestinal. After metabolized, carboxylated derivatives that accounts for about half the dose are excreted in the urine. It is reported to have half-life vary from 3-5 hours or more.

Paracetamol is rapidly and practically completely absorbed from the gastrointestinal tract. Peak plasma concentrations occurring about 10 to 60 minutes after administration and the plasma half time is 1 – 3 hours. Paracetamol is distributed into most body tissues. Binding of the drug to plasma proteins is variable; 20 – 50% may be bound at the concentrations encountered during acute intoxication. Paracetamol is metabolised by the liver and excreted in the urine as the glucuronide and sulphate conjugates. Less than 5% is excreted as unchanged paracetamol. A minor hydroxylated metabolite (*N*-acetyl-*p*-benzoquinoneimine), is usually produced in very small amounts by cytochrome P450 isoenzymes (mainly CYP2E1 and CYP3A4) in the liver and kidney. It is usually detoxified by conjugation with glutathione but may accumulate following paracetamol overdosage and cause tissue damage.

INDICATIONS:

For the relief of unproductive or irritating coughs, nasal and bronchial congestion associated with common cold, minor aches, pain, headache and fever.

DOSAGE AND ADMINISTRATION:

For oral administration only.

Adult and children over 12 years: 10ml, every 4-6 hours

Children 6-12 years: 5ml, every 4-6 hours

Children 1-5 years: 2.5ml, every 4-6 hours

Not more than 4 doses daily; unless prescribed by the doctor

CONTRAINDICATIONS:

Contraindicated in patients with known hypersensitive to pholcodeine; triprolidine or paracetamol; patients at risk of developing respiratory failure, premature infants or neonates or patient with severe hepatic impairment.

PRECAUTIONS:

May cause drowsiness and hence impair ability to drive vehicles or operate machinery. Alcohol should be avoided. Use with care in patients with narrow angle glaucoma, prostatic hypertrophy, pyloroduodenal obstruction, patients with impaired kidney or liver function, history of asthma and it should not be given during an acute attack.

This preparation contains Paracetamol. Do not take any other Paracetamol containing medicines at the same time. Paracetamol overdose may harm the liver. Follow the recommended dose.

PREGNANCY AND LACTATION:

Special precaution required if this product would be to be given to pregnancy and breast-feeding mother.

SIDE EFFECTS:

Constipation, respiratory depression, drowsiness, thicken mucous, blurred vision, dry mouth, dysuria, nervousness, restlessness or irritability. Occasionally skin rash and gastrointestinal effects include nausea, vomiting, diarrhea or epigastric pain have been reported.

SYMPTOMS TREATMENTS FOR OVERDOSAGE:

Symptoms of overdosage are included severe liver damage, acute renal tubular necrosis, impaired consciousness, psychosis, seizures, constipation, drowsiness, excitation rhabdomyolysis and antimuscarinic symptoms such as mydriasis, tachycardia, tachyarrhythmias and respiratory failure. Immediate medical attention is essential in the event of overdose, even when there are no obvious symptoms. Administration of antidote such as acetylcysteine or methionine may be required. Activated charcoal may be used to reduce gastrointestinal absorption, if it can be given within 1 hour of the overdose, and if more than 150 mg/kg of paracetamol has been ingested. However, if acetylcysteine or methionine is to be given by mouth the charcoal is best cleared from the stomach to prevent it reducing the absorption of the antidote. The patient should be kept quiet to minimise the excitation that occurs particularly in children. Convulsion and marked CNS stimulation should preferably be treated with diazepam or phenobarbitone intramuscularly; paraldehyde, thiopentone sodium, and chlorpromazine have also been recommended. Severe hypotension may require fluid replacement, and assisted respiration may be necessary. Forced diuresis is of little value since antihistamine are rapidly metabolised and only traces are recovered in the urine. Respiratory depression may be reversed with Naloxone.

DRUG INTERACTION:

Concomitant use of this drug with alcohol and central nervous system depressants and antipsychotics may enhance the depressant effects on the central nervous system. It should not be given to patients receiving MAOIs, aminoglycosides antibiotics and atropine and tricyclic antidepressants.

Paracetamol toxicity may be increased in patients receiving other potentially hepatotoxic drugs or drugs that induce liver microsomal enzymes. The absorption of paracetamol may be accelerated by drugs such as metoclopramide. Excretion may be affected and plasma concentrations altered when given with probenecid. Colestyramine reduces the absorption of paracetamol if given within 1 hour of paracetamol.

The prothrombinopenic effect of the oral anticoagulants may be increased by chronic administration of full doses of Paracetamol; occasional doses of Paracetamol have no significant effect.

STORAGE:

Keep container well closed. Store below 30C. Protect from light.

PACKAGE QUANTITIES:

60 ml & 90 ml in PET plastic bottle and 90ml in amber glass bottle.

Further information can be obtained from your pharmacist, doctor and the manufacturer.



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