Chlorpheniramine Maleate BP

HISTACIN®

Tablet, Syrup & Injection

DESCRIPTION

Histacin® contains Chlorpheniramine Maleate which belongs to the alkylamine group of H_1-antihistamines. It is a potent antihistamine. Chlorpheniramine also has a weak antimuscarinic, moderate antiserotonin and local anaesthetic actions.

Oral absorption	> 80%
Presystemic metabolism	< 20%
t_{max}	about 2.5 - 6.0 hrs.
Plasma half-life	range 2 - 43 hrs.
Volume of distribution	1 - 10 $l.kg^{-1}$
Plasma protein binding	69 - 72%

t_{max} = Time to reach peak plasma concentration

COMPOSITION

Histacin® Tablet : Each tablet contains Chlorpheniramine Maleate BP 4 mg.

Histacin® Syrup : Each 5 mL contains Chlorpheniramine Maleate BP 2 mg.

Histacin® Injection : Each mL contains Chlorpheniramine Maleate BP 10 mg.

INDICATIONS

It is used for the symptomatic relief of allergic conditions including:

- ❑ Allergic rhinitis and conjunctivitis
- ❑ Urticaria
- ❑ Angioedema
- ❑ Pruritic skin disorders
- ❑ Emergency treatment of anaphylactic reactions (as an adjunct)

DOSAGE AND ADMINISTRATION

Oral dose

Syrup :

Adults & Children : 1 - 2 teaspoonfuls three times daily.

Infants : 1 teaspoonful daily.

Tablet

Adults : A dose of 4 mg every 4 to 6 hours upto a maximum of 24 mg daily.

Children

1 - 2 years : 1 mg twice daily.

2 - 5 years : 1 mg every 4 to 6 hours (maximum 6 mg daily).

6 - 12 years : 2 mg every 4 to 6 hours (maximum 12 mg daily).

Parenteral dose

It may be given by intramuscular, subcutaneous, or by slow intravenous injection over a period of 1 minute.

The usual dose is 10 - 20 mg, repeated if required and the total dose given by these routes in 24 hours should not normally exceed 40 mg.

For children, doses of 87.5 mcg per kg body-weight subcutaneously four times daily have been suggested.

CONTRAINDICATIONS

- ❑ Known allergy to chlorpheniramine
- ❑ Not recommended to be used during pregnancy.

DRUG INTERACTIONS

Centrally effective H_1-antihistamines might add to sedative effects of psychotropic drugs for example. This has not been proved with therapeutic doses of chlorpheniramine.

The combination of hypnotics and H_1-antihistamines are considered more dangerous than either agent alone but, again, no specific data with chlorpheniramine is available. MAO inhibitors may interact with antihistamines, chlorpheniramine included, in dangerous ways, particularly with the fixed combinations of antihistamines and indirectly-acting sympathomimetics.

Food may reduce the absorption of chlorpheniramine. Pharmacodynamic interactions (sedation, excitation) with alcohol can be dangerous with large doses.

SIDE EFFECTS/ADVERSE REACTIONS

Drowsiness, dizziness, blurred vision, dry mouth and gastrointestinal upsets may occur. Large doses produce central nervous system depression and occasionally tremors or convulsions. Reports of haematological disorders are rare. Injections may be irritant and cause transient hypotension or stimulation of the CNS.

PRECAUTIONS

It should be used with caution in patients with closed-angle glaucoma, urinary retention, prostatic hypertrophy, or pyloroduodenal obstruction, epilepsy, and severe cardiovascular disorders.

Many antihistamines may cause drowsiness; patients so affected should not drive or operate machinery. Patients should avoid alcoholic drink.

Antihistamines should not be given to premature infants or neonates; this group of patients has an increased susceptibility to antimuscarinic effects. Elderly patients are also more susceptible to many adverse effects of antihistamines, including antimuscarinic effects, sedation, and hypotension.

USE IN PREGNANCY AND LACTATION

The safety of chlorpheniramine in pregnancy has not been established.

The drug is excreted in small amounts in breast milk, and mothers taking the drug should not breast-feed.

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USE IN CHILDREN

It may be used in children in appropriate doses and not recommended in neonates.

PACKAGING

Histacin® Tablet : Box containing 10 x 10 & 50 x 10 tablets of blister pack.

Histacin® Syrup : Bottle containing 60 mL & 100 mL syrup.

Histacin® Injection : Box containing 10 x 1 mL & 10 x 2 mL Ampoules.

PHARMACEUTICAL PRECAUTIONS

Store below 25°C in a dry place, away from light.

WARNING

Keep out of the reach of children.

Jayson