

PACK INSERT

For the use only of a Registered Medical Practitioner or a Hospital or a Laboratory.

XITCOLD (Paracetamol, Chlorpheniramine Maleate, Sodium Citrate & Menthol Syrup)

COMPOSITION:

Each 5 ml Contains:

Paracetamol BP.....125 mg

Chlorpheniramine Maleate BP...2 mg

Sodium Citrate BP.....60 mg

Menthol BP.....1 mg

PHARMACEUTICAL GROUP WITH ATC Code:

Paracetamol: Analgesics and Antipyretics

ATC Code: N02BE01

Chlorpheniramine Maleate: Antihistamines

ATC Code: R06AB04.

Sodium Citrate : Anticoagulant

ATC Code:B05CB02

INDICATIONS:

XITCOLD 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 antibacterial in sinusitis, tonsillitis and otitis media.

DOSAGE & ADMINISTRATION:

6 months to 1 year: 1 spoonful, 4 times daily

1 to 5 years: 2 spoonfuls, 4 times daily

6 to 12 years: 2 -4 spoonfuls, 4 times daily

Method of Administration

For oral administration.

CONTRAINDICATIONS:

The use of **XITCOLD** is contraindicated in patients with:

- Hypersensitivity to any of the ingredients of the formulation.
- Severe hypertension.

WARNING & PRECAUTIONS:

In case a hypersensitivity reaction occurs which is rare, **XITCOLD** should be discontinued.

XITCOLD contains Paracetamol and therefore should not be used in conjunction with other Paracetamol containing products.

XITCOLD 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 **XITCOLD**.

PREGNANCY AND LACTATION:

There are no adequate and well-controlled studies in pregnant women. **XITCOLD** Syrup should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

UNDESIRABLE EFFECTS:

XITCOLD 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 **XITCOLD** Syrup may cause sedation.

OVERDOSE

In case of any overdose, treatment will be symptomatic.

STORAGE:

Store in a cool & dry place. Protect from light, below 25⁰C.

PRESENTATION:

An amber coloured PET bottle of 60 ml syrup packed in a primary carton along with measuring spoon and pack insert.

LEGAL STATUS:

Prescription Drug

KEEP OUT OF REACH OF CHILDREN.

Carefully read the accompanying instructions before use.

MANUFACTURED FOR:

NEW GLOBAL PHARMACEUTICALS LTD.

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ACCRA-GHANA.