SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

1. NAME OF THE MEDICINAL PRODUCT

ZICOLD DROPS (Phenylephrine Hydrochloride and Chlorphenamine Maleate Paediatric Drops)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains 2.5 mg phenylephrine hydrochloride and 2.0 mg chlorphenamine Maleate
Excipient(s) with known effect:

Colour: Sunset yellow FCF
For the full list of excipients, see section 6.1

3. PHARMACEUTICAL DOSAGE FORM AND DESCRIPTION OF TABLET

Oral drops
Orange colored syrupy liquid with flavored odor.

4. CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

ZICOLD DROPS is a combination of antihistamine & decongestant. it is used to treat symptoms of an allergy, cold or sinus inflammation .it will help relieve runny nose Sneezing and congestion in the nose & for fever associated with cold.

ZICOLD DROPS is used for the temporary relief of:

- Headache
- Sinus congestion and pressure
- nasal congestion
- Runny nose and sneezing
- Minor aches and pains
- Reduces swelling of nasal passages
- Helps decongest sinus openings and passages

4.2 POSOLOGY AND METHOD OF ADMINISTRATION

AGE	Dose	Frequency
6- 12 Months	0.1 -0.4 ml	3-4 times a day
1-2 years	0.2- 0.5 ml	3-4 times a day
2-4 years	0.3 -0.75 ml	3-4 times a day
4-6 years	0.5 -1 ml	3-4 times a day

Or as directed by the Physician.

4.3 CONTRAINDICATION

Hypersensitivity to any of the ingredients.
Do not use this product if you are being treated with monoamine oxidase inhibitors, or

within two weeks of stopping treatment with these medications.
Concomitant use of other sympathomimetic decongestants

Phaeochromocytoma, Closed angle glaucoma.
Hepatic or severe renal impairment, hypertension, hyperthyroidism, diabetes, and heart disease. Patients taking tricyclic antidepressants, or beta-blocking drugs and those who are taking or who have taken within the last two weeks monoamine oxidase inhibitors.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Consult the physician if you have any of these conditions:

- Renal or hepatic dysfunction
- Juvenile Diabetes Mellitus
- Cardiovascular Problem
- Epilepsy
- Closed angle glaucoma

4.5 INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION

This medicine may interact with the following Medication:

- MAOIs
- Tricyclic antidepressants
- Beta-adrenergic agent ,
- Methyldopa
- Reserpine
- Veratrum alkaloids.
- Consult the Physician if you are taking any of these medicines

4.6 PREGNANCY AND LACTATION

There are no adequate and well-controlled studies in pregnant or lactating women.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

None

4.8 UNDESIRABLE EFFECTS:

Some of the mild side effects are as follows:

- Dry Mouth, Nose ,throat
- Headache
- Loss of appetite
- sleepy
- Stomach upset. Nausea
- weakness

Major side effects includes following:

- Fear
- Anxiety
- Restlessness
- Tremor
- Dysuria
- Insomnia
- Hallucinations & convulsions
- Sedation

4.9 **OVERDOSE**

Chlorphenamine Maleate

Symptoms and signs

The estimated lethal dose of Chlorphenamine is 25 to 50 mg/kg body weight. Symptoms and signs include sedation, paradoxical excitation of the CNS, toxic psychosis, convulsions, apnoea, 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 and 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). Treat hypotension and arrhythmias vigorously. CNS convulsions may be treated with i.v. diazepam. Haemoperfusion may be used in severe cases.

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

5. PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Phenylephrine hydrochloride

Phenylephrine hydrochloride is a sympathomimetic agent with mainly direct effects on adrenergic receptors (predominantly alpha-adrenergic activity) producing nasal decongestion.

Chlorphenamine Maleate
Chlorphenamine is a potent antihistamine (H1-antagonist).
Antihistamines diminish or abolish the actions of histamine in the body by competitive reversible blockade of histamine H1-receptor sites on tissues. Chlorphenamine also has anticholinergic activity.
Antihistamines act to prevent the release of histamine, prostaglandins and leukotrines and have been shown to prevent the migration of inflammatory mediators. The actions of Chlorphenamine include inhibition of histamine on smooth muscle, capillary permeability and hence reduction of oedema and wheal in hypersensitivity reactions such as allergy and anaphylaxis.

5.2 PHARMACOKINETIC PROPERTIES:

Phenylephrine hydrochloride
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.

Chlorphenamine Maleate
Chlorphenamine is well absorbed from the gastro-intestinal tract, following oral administration. The effects develop within 30 minutes, are maximal within 1 to 2 hours and last 4 to 6 hours. The plasma half-life has been estimated to be 12 to 15 hours.
Chlorphenamine is metabolised to the monodesmethyl and didesmethyl derivatives. About 22% of an oral dose is excreted unchanged in the urine.

5.3 PRECLINICAL SAFETY DATA

None

6. PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Sorbitol 70 % solution
Sucrose
Polyethylene Glycol 400
Benzoic acid
Di Sodium EDTA
Mango Ripe Flavour
Bubble Gum Flavour
Sodium Hydroxide Pellets
Sunset yellow FCF
Purified Water

6.2 INCOMPATIBILITIES

Not applicable.

6.3 **SHELF LIFE**

36 Months

6.4 **SPECIAL PRECAUTIONS FOR STORAGE**

Store below 30^0 C in dry place protect from light.

6.5 **NATURE AND CONTENTS OF CONTAINER**

15 ml & 30 ml amber pet bottle. Such amber pet bottle packed in carton along with dropper & Pack insert.

6.6 **SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING**

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Company Name	**:**	**CORAL LABORATORIES LIMITED**
Address	**:**	Plot No.27/28, Pharmacity, Selaqui, Dehradun, Uttarakhand,
Country	**:**	INDIA
Telephone	**:**	0135-2698422/466
Telefax	**:**	0135-2699121
E-Mail	**:**	doon@corallab.com

8 MARKETING AUTHORIZATION NUMBER

Renewal Registration Number: 07412/07806/VAR/2022

9 DATE OF FIRST AUTHORIZATION / RENEWAL OF AUTHORIZATION

19.05.2017

10. DATE OF REVISION OF THE TEXT

12-07-2023

11. REFERENCES