## 1.17 Summary Product Characteristics (SPC)

### 1.1 Name of the medicinal product

**VELESTAMINE TABLETS** (Betamethasone USP 0.25mg and Dexchlorpheniramine Maleate USP 2.0mg)

### 1.2 Qualitative and quantitative composition

| ACTIVE INGREDIENTS | | | | |
|---|---|---|---|---|
| **APPROVED NAME** | **SPECIFICATION OR REFERENCE TEXT** | **QTY/ TABLET** | | **% OVERAGES** |
| | | **MG/ TABLET** | **%W/W/ TABLET** | |
| Betamethasone | USP | 0.250 mg | 0.13 | Nil |
| Dexchlorpheniramine Maleate | USP | 2.000 mg | 1.00 | Nil |
| **INACTIVE INGREDIENTS** | | | | |
| **APPROVED NAME** | **SPECIFICATION OR REFERENCE TEXT** | **QTY/ TABLET** | | **REASON FOR INCLUSION** |
| | | **MG/ TABLET** | **%W/W/ TABLET** | |
| Microcrystalline Cellulose | BP | 100.00 mg | 50.00 | Diluent |
| Maize starch * | BP | 70.25 mg | 35.13 | Diluent |
| Maize starch * | BP | 10.00 mg | 5.00 | Binder |
| Erythrosine colour | IH | 1.50 mg | 0.75 | Colour |
| Purified Talc | BP | 4.00 mg | 2.00 | Glidant |
| Magnesium stearate | BP | 2.00 mg | 1.00 | Lubricant |
| Colloidal Silicon Dioxide | BP | 2.00 mg | 1.00 | Glidant |
| Croscarmellose Sodium | BP | 8.00 mg | 4.00 | Disintegrant |

### 1.3 Pharmaceutical form

Oral Tablet.

## 2.Clinical particulars

### 2.1 Therapeutic indications

VELESTAMINE TABLETS are recommended in the treatment of difficult cases of respiratory, dermatologic and ocular allergies, as well as ocular inflammatory disorders, where adjunctive systemic corticosteroid therapy is indicated.

### 2.2 Posology and method of administration

Posology:

Dosage should be individualized and adjusted according to the specific disease being treated, its severity and the response of the patient. As improvement occurs, the dosage should be reduced gradually to the minimum maintenance level and discontinued where possible. When symptoms of respiratory allergies are adequately controlled, slow withdrawal of the combination product and treatment with an antihistamine alone should be considered.

The recommended initial dosage of Betamethasone and Dexchlorpheniramine Tablets for adults and children over 12 years is 1 to 2 tablets four times daily, after meals and at bedtime. The dose is not to exceed 8 tablets per day. In younger children dosage should be adjusted according to the severity of the condition, and the response of the patient, rather than by age or body weight.

Children 6 to 12 Years: The recommended dosage is ½ tablet three times a day. If an additional daily dose is required, it should be taken preferably at bedtime. The dose is not to exceed 4 tablets a day.

### 2.3 Contraindications

Hypersensitivity to Betamethasone and Dexchlorpheniramine Tablets is a contraindication. In addition, Betamethasone and Dexchlorpheniramine Tablets should not be used if you have the following conditions:

- Hypersensitivity
- Idiopathic thrombocytopenic purpura
- Infants
- Nursing mothers

### 2.4 Special warnings and precautions for use

Important counseling points are listed below.

- Asthma
- Bladder obstruction
- Bowel obstruction
- Consult your doctor about the intended route of administration of this drug

### 2.5 Interaction with other medicinal products and other forms of interaction

Betamethasone and Dexchlorpheniramine Tablets may interact with the following drugs and products:

- Alcohol
- Aminoglutethimide
- Amphotericin B
- Anticholinesterases
- Antidiabetics
- Antihistamines

### 2.6 Pregnancy and Lactation

The use of Betamethasone and Dexchlorpheniramine Tablets during pregnancy, in nursing mothers or in women of child-bearing age requires that the possible benefits of the drug be weighed against potential hazards to mother and fetus or infant. Infants born of mothers who have received substantial doses of corticosteroids during pregnancy should be observed carefully for signs of hypoadrenalism.

### 2.7Effects on ability to drive and use machines

No Data Found.

## 2.8 Undesirable effects

The physician should be alerted to the possibility of any adverse effects associated with the use of corticosteroids and antihistamines, especially of the sedating type.

Betamethasone: Adverse reactions to this component, which have been the same as those reported with other corticosteroids, are related to dose and duration of therapy. The small amount of corticosteroid in the combination makes the incidence of side effects less likely.

Adverse reactions reported for corticosteroids include: Fluid and Electrolyte Disturbances: Sodium retention, potassium loss, hypokalemic alkalosis; fluid retention; congestive heart failure in susceptible patients; hypertension.

- **Muskoskeletal:** Muscle weakness, corticosteroid myopathy, loss of muscle mass, aggravation of myasthenic symptoms in myasthenia gravis; osteoporosis; vertebral compression fractures; aseptic necrosis of femoral and humeral heads; pathologic fracture of long bones; tendon rupture.
- **Gastrointestinal:** Peptic ulcer with possible subsequent perforation and hemorrhage; pancreatitis, abdominal distention; ulcerative esophagitis.
- **Dermatologic:** Impaired would healing, skin atrophy, thin fragile skin; petechiae and ecchymoses; facial erythema; increased sweating; suppressed reactions to skin tests; reactions eg, allergic dermatitis, urticaria, angioneurotic edema.
- **Neurologic:** Convulsions; increased intracranial pressure with papilledema (pseudotumor cerebri) usually after treatment; vertigo; headache.
- **Endocrine:** Menstrual irregularities; development of Cushingoid state; suppression of fetal intrauterine or childhood growth; secondary adrenocortical and pituitary unresponsiveness, particularly in times of stress, as in trauma, surgery or illness; decreased carbohydrate tolerance, manifestations of latent diabetes mellitus, increased requirements of insulin or oral hypoglycemic agents in diabetics.
- **Ophthalmic:** Posterior subcapsular cataracts; increased intraocular pressure; glaucoma; exophthalmos.
- **Metabolic:** Negative nitrogen balance due to protein catabolism.
- **Psychiatric:** Euphoria, mood swings; severe depression to frank psychotic manifestations; personality changes; hyperirritability; insomnia.
- **Others:** Anaphylactoid or hypersensitivity and hypotensive or shock-like reactions.

Dexchlorphenamine Maleate: Adverse reactions to this component have been the same as those reported with other conventional (sedating) antihistamines, and rarely cause toxicity. Slight to moderate drowsiness is the most frequent side effect of dexchlorphenamine maleate. Adverse effects of sedating antihistamines vary in incidence and severity. Among these are cardiovascular, hematologic (pancytopenia, thrombocytopenia, hemolytic anemia), neurologic (confusion, hallucinations, tremor), gastrointestinal (urinary retention), respiratory adverse reactions, and mood changes. The most common effects include sedation, sleepiness, dizziness, disturbed coordination, epigastric distress, rash, dry mouth and thickening of bronchial secretions.

## 2.9 Overdose

Betamethasone and Dexchlorpheniramine Tablets is a combination product and, therefore, the potential toxicity of each of its components must be considered. Toxicity from a single excessive dose of Betamethasone and Dexchlorpheniramine Tablets results primarily from the dexchlorphenamine component. The estimated lethal dose of the antihistamine
3 dexchlorphenamine maleate is 2.5 to 5.0 mg/kg.

Overdosage reactions with conventional (sedating) antihistamines may vary from central nervous system depression (sedation, apnea, diminished mental alertness, cardiovascular collapse) to stimulation (insomnia, hallucinations, tremors, convulsions) to death. Other signs and symptoms may include dizziness, tinnitus, ataxia, blurred vision and hypotension. In children, stimulation is dominant, as are atropine-like signs and symptoms (dry mouth; fixed, dilated pupils; flushing; fever and gastrointestinal symptoms). Hallucinations, incoordination, and convulsions of the tonic-clonic type may occur. In adults, a cycle consisting of depression with drowsiness and coma, and an excitement phase leading to convulsions followed by
4 depression may occur.

A single excessive dose of betamethasone is not expected to produce acute symptoms. Except at the most extreme dosages, a few days of excessive glucocorticosteroid dosing is unlikely to
5 produce harmful results except in patients betamethasone.

Treatment of Acute Overdosage: Immediately induce emesis (in a conscious patient) or
6 administer gastric lavage. Dialysis has not been found helpful.

Treatment of the signs and symptoms of overdosage is symptomatic and supportive. Stimulants should not be used. Vasopressors may be used to treat hypotension. Convulsions are best treated with a short-acting depressant, such as thiopental. Maintain adequate fluid intake and monitor electrolytes in serum and urine, with particular attention to sodium and potassium balance. Treat electrolyte imbalance if necessary.

# 3 Pharmacological properties

## 3.1 Pharmacodynamic properties

**Betamethasone:** Betamethasone and its derivatives, betamethasone sodium phosphate and betamethasone acetate, are synthetic glucocorticoids. Used for its antiinflammatory or immunosuppressive properties, betamethasone is combined with a mineralocorticoid to manage adrenal insufficiency and is used in the form of betamethasone benzoate, betamethasone dipropionate, or betamethasone valerate for the treatment of inflammation due to corticosteroid-responsive dermatoses. Betamethasone and clotrimazole are used together to treat cutaneous tinea infections.

**Dexchlorphenamine:** In allergic reactions, an allergen binds to IgE antibodies on mast cells and basophils. Once this occurs IgE receptors crosslink with each other triggering a series of events that eventually leads to cell-degranulation and the release of histamine (and other chemical mediators) from the mast cell or basophil. Histamine can react with local or widespread tissues through histamine receptors. Histamine, acting on H1-receptors, produces pruritis, vasodilatation, hypotension, flushing, headache, tachycardia, and bronchoconstriction. Histamine also increases vascular permeability and potentiates pain. Dexchlorpheniramine, is a histamine H1 antagonist of the alkylamine class. It competes with histamine for the normal H1-receptor sites on effector cells of the gastrointestinal tract, blood vessels and respiratory tract. It provides effective, temporary relief of sneezing, watery and itchy eyes, and runny nose due to hay fever and other upper respiratory allergies.

## 3.2 Pharmacokinetic properties

**Betamethasone:**

Absorption: Absorbed readily after oral administration.
Distribution: Removed rapidly from the blood and distributed to muscle, liver, skin, intestines, and kidneys. Betamethasone is bound weakly to plasma proteins (transcortin and albumin). Only the unbound portion is active. Adrenocorticoids are distributed into breast milk and through the placental barrier.
Metabolism: Metabolized in the liver to inactive glucuronide and sulfate metabolites.
Excretion: Inactive metabolites and small amounts of unmetabolized drug are excreted by the kidneys. Insignificant quantities of drug also are excreted in feces. Biological half-life of drug is 36 to 54 hours.

**Dexchlorphenamine:**

Absorption: Slowly absorbed orally, bioavailability is about 25 to 50%.
Distribution: Widely distributed in a protein bound form.
Metabolism: Extensively metabolized in the body.
Excretion: Excreted through urine both as metabolites and parent drug.

## 3.3 Preclinical safety data

No Data Found.

## 4 Pharmaceutical particulars

### 4.1 List of excipients

| Excipients | Specification | Qty in mg/tab |
|---|---|---|
| Microcrystalline Cellulose | BP | 100.00 |
| Maize starch * | BP | 70.25 |
| Maize starch * | BP | 10.00 |
| Erythrosine colour | BP | 1.50 |
| Purified Talc | BP | 4.00 |
| Magnesium stearate | BP | 2.00 |
| Colloidal Silicon Dioxide | BP | 2.00 |
| Croscarmellose Sodium | BP | 8.00 |
| | | |

### 4.2 Incompatibilities

None known

### 4.3 Shelf life

24 Months

### 4.4 Special precautions for storage

Store in a dry place at a temperature below 30°C.

### 4.5 Nature and contents of container

30 , 50& 100 Tablets in pilfer proof jar , packed in printed and laminated carton.

### 4.6 Special precautions for disposal and other handling

Not applicable.

## 5 Marketing authorisation

**Eastleigh Pharmaceuticals Co. Ltd**
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**Manufacturer :**

**Zain Pharma limited**

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## 6 Date of first authorisation/renewal of the authorisation

Not applicable.

## 7 Date of revision of the text

NOV 2020