# SUMMARY OF PRODUCT CHARACTERISTICS (SPC)

## 1. NAME OF THE MEDICINAL PRODUCT

**DEXAMETHASONE TABLETS BP 1 MG**

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

**Batch size:** 10,000 Tablets

| Sr. No. | Ingredients | Specification | Qty. (mg/ Tab) | Ovg. | Qty/ batch (in kg) |
|---|---|---|---|---|---|
| 1. | Dexamethasone | BP | 1.00 | -- | -- |
| 2. | Maize Starch | BP | 81.48 | -- | -- |
| 3. | Dicalcium Phosphate | BP | 35.98 | -- | -- |
| 4. | Calcium Carbonate | BP | 17.45 | -- | -- |
| 5. | Gelatin | BP | 0.77 | -- | -- |
| 6. | PVPK 30 | BP | 1.50 | -- | -- |
| **LUBRICANTS** | | | | | |
| 7. | Magnesium Stearate | BP | 1.74 | -- | -- |
| 8. | Purified Talc | BP | 2.19 | -- | -- |
| 9. | Aerosil | BP | 0.57 | -- | -- |
| 10. | *Maize Starch(Additional) | BP | 8.15 | -- | -- |
| | **TOTAL** | | **150.83** | | |

**Note:**

*** Purified water is used as solvent and is not found in the final product.

*Includes 10% additional quantity of maize starch to compensate the loss on drying

BP : British Pharmacopoeia

Average Weight of Uncoated tablet: 150.83 mg ±7.5%

## 3. PHARMACEUTICAL FORM

Tablet

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

i) Having Antiinflammatory or Immunosuppressive properties

ii) Treatment of number of different diseases of the immune system

### 4.2 Posology and method of administration

Route of administration: Oral

**Adults:** The usual dose is 0.5 mg to 10 mg each day

**Children:** The usual dose is 0.01 to 0.1 milligrams per kilogram of body weight

### 4.3 Contraindications

Contraindicated in systemic fungal infections and patients with known hypersensitivity to the product and its constituents.

### 4.4 Special warnings and precautions for use

i) Rare instances of anaphylactoid reactions have occurred in patients receiving corticosteroid therapy.

ii) Increased dosage of rapidly acting corticosteroids is indicated in patients on corticosteroid therapy subjected to any unusual stress before, during, and after the stressful situation.

iii) Literature reports suggest an apparent association between use of corticosteroids and left ventricular free wall rupture after a recent myocardial infarc-tion;therefore, therapy with corticosteroids should be used with great caution in these patients.

iv) Corticosteroids may exacerbate systemic fungal infections and therefore should not be used in the presence of such infections unless they are needed to control life-threatening drug reactions.

v) Corticosteroids should not be used in cerebral malaria.

vi) If corticosteroids are indicated in patients with latent tuberculosis or tuberculin reactivity, close observation is necessary as reactivation of the disease may occur.

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

Following medicines can affect the way Dexamethasone works or Dexamethasone can affect the way they work.

1. Medicines to treat heart and blood problems, such as warfarin and water tablets (diuretics)
2. Antibiotics such as rifampicin and rifabutin
3. Medicines to treat epilepsy, such as phenytoin, carbamazepine, phenobarbitone and primidone
4. Medicines to treat stomach problems, such as antacids
5. Medicines that control pain or lower inflammation, such as aspirin, ibuprofen
6. Medicines used to treat diabetes
7. Medicines used to lower potassium levels
8. Medicines used to treat myasthenia
9. Ritonavir, indinavir or saquinavir used to treat HIV
10. Oral contraceptives containing oestrogen and progestogen
11. Anti-cancer treatments, such as aminoglutethimide

## 4.6 Pregnancy and lactation

Talk to your doctor before taking this medicine if you are pregnant, planning to become pregnant or are breast-feeding.

## 4.7 Undesirable effects

Steroids including Dexamethasone can cause serious mental health problems. These are common in both adults and children.

An allergic reaction may include:

i) Any kind of skin rash or itching of the skin

ii) Difficulty in breathing or collapse

**Stomach and gut problems:** ulcers in the throat, stomach ulcers, which may perforate or bleed, indigestion, feeing sick (nausea) or being sick (vomiting), a swollen stomach, having more of an appetite than usual, hiccups, diarrhoea

**Inflamed pancreas**: this may cause severe pain in the back or tummy

**Heart and blood problems**: high blood pressure, blood clots, problems with the muscles in your heart after a recent heart attack

**Bone problems**: thinning of the bones (osteoporosis) with an increased risk of fractures, bone disease

**Recurring infections** that get worse each time such as thrush. Also chicken pox

**Skin problems**: wounds that heal more slowly, bruising, acne

**Eye problems**: increased pressure in the eye including glaucoma, eye disorders such as cataracts

**General problems**: may make you feel generally unwell or tired

## 4.8 Overdose

Treatment of overdosage is by supportive and symptomatic therapy. In the case of acute overdosage, according to the patient's condition, supportive therapy may include gastric lavage or emesis.

## 4.9 Pharmacodynamic properties

**Mechanism of action:**

Dexamethasone is a glucocorticoid agonist. Unbound dexamethasone crosses cell membranes and binds with high affinity to specific cytoplasmic glucocorticoid receptors. This complex binds to DNA elements which results in a modification of transcription and hence protein synthesis in order to achieve inhibition of leukocyte infiltration at the site of inflammation. The antiinflammatory actions of dexamethasone are thought to involve phospholipase $A_2$ inhibitory proteins, lipocortins, which control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes. Thus used for its antiinflammatory or immunosuppressive properties and ability to penetrate the CNS, dexamethasone is used alone to manage cerebral edema.

## 5.1 Pharmacokinetic properties

Absorption

Corticosteroids, are, in general, readily absorbed from the gastro-intestinal tract. They are also well absorbed from sites of local application. Water-soluble forms of corticosteroids are given by intravenous injection for a rapid response; more prolonged effects are achieved using lipid-soluble forms of corticosteroids by intramuscular injection.

Distribution

Corticosteroids are rapidly distributed to all body tissues. They cross the placenta and may be excreted in small amounts in breast milk.

Most corticosteroids in the circulation are extensively bound to plasma proteins, mainly to globulin and less so to albumin. The corticosteroid-binding globulin has high affinity but low binding capacity, while the albumin has low affinity but large binding capacity. The synthetic corticosteroids are less extensively protein bound than hydrocortisone (cortisol). They also tend to have longer half-lives.

Biotransformation and Elimination

Corticosteroids are metabolised mainly in the liver but also in the kidney, and are excreted in the urine. The slower metabolism of the synthetic corticosteroids with their lower protein-binding affinity may account for their increased potency compared with the natural corticosteroids.

## 5.2 Preclinical safety data

Nonclinical data reveal no special hazard for humans based on studies of safety pharmacology, genotoxicity and toxicity to reproduction.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

| NO. | INGREDIENTS | SPECIFICATION |
|---|---|---|
| 1. | Maize Starch | BP |
| 2. | Dicalcium Phosphate | BP |
| 3. | Povidone K-30 | BP |
| 4. | Calcium Carbonate | BP |
| 5. | Gelatin | BP |
| 6. | Magnesium Stearate | BP |
| 7. | Purified Talc | BP |
| 8. | Aerosil | BP |

### 6.2 Shelf life

36 Months

### 6.3 Special precautions for storage

Store at a temperature below 30ºC. Protect from light and moisture.

### 6.4 Nature and contents of container

10 Tablets in one Blister and such 10 blister in Carton (10x10 Tablets)

### 6.5 Special precautions for disposal and other handling

No special requirements

## 7. APPLICANT/MANUFACTURER

**MANUFACTURER BY:**

**Head Office Address:**

**FREDUN PHARMACEUTICALS LIMITED**

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