Summary of Product Characteristics for Pharmaceutical Products

1. Name of the medicinal product:

Celeb Tablets
(Betamethasone and Dexchlorpheniramine Tablets)

2. Qualitative and quantitative composition

BETAMTHASONE	USP
DEX CHLORPHENIRAMINE MALEATE	USP
MICROCRSTALLINE CELLULOSE 102	USP
DIBASIC CALCIUM PHOSHPHATE	BP
STARCH	BP
MEGNESIUM STEARATE	BP
PURIFIED TALC	BP
SODIUM STARCH GLYCOLATE	BP
CROSS CARMELLOSE SODIUM	BP

Quantitative declaration
BATCH NO.: 1,00,000 Lac Tablets

Sr. No.	Name of Raw Material	Spec	Label claim / Tab	Qty per tablet (mg)	% Overage	Qty per tablet with Overages (mg)	Std. Qty for 1.0 Lac (kg)	Reason for inclusion
1.	Betamethasone	USP	0.25 mg	0.25	0.0125 %	0.26	0.026	Active Ingredien t
2.	Dexchlorpheniramine Maleate	USP	2 mg	2.00	0.1%	2.10	0.210	Active Ingredien t
3.	Microcrystalline cellulose 102	BP		38.14		38.14	3.814	Diluents
4.	Dibasic calcium phosphate	BP		25.00		25.00	2.500	Diluents
5.	Starch	BP		34.50		34.50	3.450	Binder

6.	Magnesium stearate	BP		2.00		2.00	0.200	Lubricant
7.	Purified talc	BP		2.00		2.00	0.200	Glidant
8.	Sodium starch glycolate	BP		2.00		2.00	0.200	Disintegrant
9.	Cross Carmellose sodium	BP		4.00		4.00	0.400	Disintegrant
	Total		**Total**	**109.89 MG**		**110.0 MG**	**11.00 KG**	

For further list of excipients check 6.1

3. Pharmaceutical form

A pale White colour Round shape uncoated tablet

4. Clinical particulars

4.1 Therapeutic indications

Betamethasone / Dexchlorpheniramine Maleate is used for the treatment, control, prevention, & improvement of the following diseases, conditions and symptoms:
Allergy
Skin inflammation
Itch or rash
Ataxia telangiectasia
Phimosis
Hay fever
Common cold
Perennial and seasonal allergic rhinitis
Vasomotor rhinitis
Allergic conjunctivitis

4.2 Posology and method of administration

Posology:

Betnesol Tablets/Betamethasone Tablets are best taken dissolved in water, but they can be swallowed whole without difficulty. The lowest dosage that will produce an acceptable result should be used; when it is possible to reduce the dosage, this must be accomplished by stages.
During prolonged therapy, dosage may need to be increased temporarily during periods of stress or in exacerbations of illness.

Adults:

The dose used will depend on the disease, its severity and the clinical response obtained. The following regimens are for guidance only. Divided dosage is usually employed.

Short term treatment:
2-3mg daily for the first few days, then reducing the daily dose by 250 or 500mcg (0.25 or
0.5mg) every two to five days, depending upon the response.

Rheumatoid arthritis:
500mcg (0.5mg) to 2mg daily. For maintenance therapy the lowest effective dosage is used.

Most other conditions:
1.5 to 5mg daily for one to three weeks, then reducing to the minimum effective dosage. Larger doses may be needed for mixed connective tissue diseases and ulcerative colitis.

Paediatric population:
A proportion of the adult dosage may be used (e.g. 75% at 12 years, 50% at 7 years and 25% at 1 year) but clinical factors must be given due weight (see section 4.4).

Method of Administration: Oral
Adults and children over 12 years: One tablet every 6 hours

4.3 Contraindications

Betamethasone / Dexchlorpheniramine Maleate should not be used if you have the following conditions:
Hypersensitivity
Hypersensitivity to dexchlorpheniramine
Idiopathic thrombocytopenic purpura
Infants
Nursing mothers

4.4 Special warnings and precautions for use

Before using Betamethasone / Dexchlorpheniramine Maleate, inform your doctor about your current list of medications, over the counter products (e.g. vitamins, herbal supplements, etc.), allergies, pre-existing diseases, and current health conditions (e.g. pregnancy, upcoming surgery, etc.). Some health conditions may make you more susceptible to the side-effects of the drug.

Take as directed by your doctor or follow the direction printed on the product insert. Dosage is based on your condition. Tell your doctor if your condition persists or worsens. Important
counseling points are listed below.

- Asthma
- Avoid excessive usage of cream in children
- Bladder obstruction
- Bowel obstruction
- Consult your doctor about the intended route of administration of this drug
- Cream is for external use only
- Do not take within 2 weeks of taking a monoamine oxidase inhibitor medication
- Do not use cream across large areas of the body
- Do not use the cream on your face for more than 5 days
- Either discontinue this drug or discontinue nursing during lactation

4.5 Interaction with other medicinal products and other forms of interaction

If you use other drugs or over the counter products at the same time, the effects of Betamethasone / Dexchlorpheniramine Maleate may change. This may increase your risk for side-effects or cause your drug not to work properly. Tell your doctor about all the drugs, vitamins, and herbal supplements you are using, so that you doctor can help you prevent or manage drug interactions. Betamethasone / Dexchlorpheniramine Maleate may interact with the following drugs and products:

- Alcohol
- Aminoglutethimide
- Amphotericin B
- Anticholinesterases
- Antidiabetics
- Antihistamines
- Atropine
- Barbiturates
- Carbamazepine
- Central nervous system depressants

4.6 Pregnancy and Lactation

Pregnancy

The ability of corticosteroids to cross the placenta varies between individual drugs, however, betamethasone readily crosses the placenta. Administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate, intra-uterine growth retardation and effects on brain growth and development. There is no evidence that corticosteroids result in an increased incidence of congenital abnormalities, such as cleft palate/lip in man. However, when administered for prolonged periods or repeatedly during pregnancy, corticosteroids may increase the risk of intra-uterine growth retardation. Hypoadrenalism may, in theory, occur in the neonate following prenatal exposure to corticosteroids but usually resolves spontaneously following

birth and is rarely clinically important. Myocardial hypertrophy and gastroesophageal reflux have been reported in association with in-utero exposure to betamethasone.
As with all drugs, corticosteroids should only be prescribed when the benefits to the mother and child outweigh the risks. When corticosteroids are essential however, patients with normal pregnancies may be treated as though they were in the non-gravid state. Patients with preeclampsia or fluid retention require close monitoring.

Betamethasone, systemically administered to a woman during pregnancy may result in a transient suppression of the foetal heart rate parameters and biophysical activities that are widely used for the assessment of foetal well – being. These characteristics can include a reduction in foetal breathing movements, body movements and heart rate.

Breast-feeding
Corticosteroids may pass into breast milk, although no data are available for betamethasone.
Infants of mothers taking high doses of systemic corticosteroids for prolonged periods may have a degree of adrenal suppression.

Dexchlorpheniramine Maleate
Pregnancy (Category A)
Safety during pregnancy has not been established. Polaramine should be used during the first two trimesters of pregnancy only if clearly needed.
Dexchlorpheniramine maleate should not be used in the third trimester of pregnancy because newborn and premature infants may have severe reactions to antihistamines.
Polaramine has been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects of on the foetus having been observed.

Lactation
Polaramine is excreted in breast milk. Therefore caution should be exercised when administered to nursing mothers.

4.7 Effects on ability to drive and use machines

Betamethasone and Dexchlorpheniramine tablets has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

The following is a list of possible side-effects that may occur in medicines that contain Betamethasone / Dexchlorpheniramine Maleate. This is not a comprehensive list. These side-effects are possible, but do not always occur. Some of the side-effects may be rare but serious. Consult your

doctor if you observe any of the following side-effects, especially if they do not go away.

- Skin atrophy
- Burning
- Itching
- Irritation
- Allergic contact dermatitis
- Hypertrichosis
- Milia
- Drowsiness
- Dizziness
- Headache

Reporting of suspected adverse reactions Helathcare professionals are asked to report any suspected adverse reactions via pharmacy and poisons board pharmacovigilance Eletronic Reporting system (PvERS) https://pv.phamacyboardkenya.org

4.9 Overdose

- Do not use more than prescribed dose. Taking more medication will not improve your symptoms; rather they may cause poisoning or serious side-effects. If you suspect that you or anyone else who may have overdosed of Betamethasone / Dexchlorpheniramine Maleate, please go to the emergency department of the closest hospital or nursing home. Bring a medicine box, container, or label with you to help doctors with necessary information.

- Do not give your medicines to other people even if you know that they have the same condition or it seems that they may have similar conditions. This may lead to overdosage.

- Please consult your physician or pharmacist or product package for more information.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Betamethasone and dexchlorpheniramine are used to treat allergic reactions, respiratory problems, skin conditions or reactions. The combination belongs to the steroid family and works by inhibiting the production of compound in the body causing pain and inflammation.

Betamethasone/Dexchlorpheniramine maleate Tablet combine the anti-inflammatory and antiallergic effects of the corticosteroid betamethasone with the antihistaminic activity of dexchlorphenamine

maleate.

By using betamethasone and dexchlorphenamine maleate in combination, comparable results usually are obtained with smaller amounts of corticosteroid than when the corticosteroid is given alone.

Dexchlorpheniramine, the d-isomer of the racemic compound chlorpheniramine, is two times more active than chlorpheniramine. Dexchlorpheniramine does not prevent the release of histamine, but rather, competes with free histamine for binding at the H1-receptor sites, and competitively antagonizes the effects of histamine on H1-receptors in the GI tract, uterus, large blood vessels, and bronchial muscle. Blockade of H1-receptors also suppresses the formation of oedema, flare, and pruritus that result from histaminic activity. Since dexchlorpheniramine binds to central and peripheral H1-receptors, sedative effects are likely to occur. H1- antagonists are structurally similar to anticholinergic agents and therefore possess the potential to exhibit anticholinergic properties of varying degrees. They also have antipruritic effects. Dexchlorpheniramine has high antihistaminic activity, moderate anticholinergic effects and minimal sedative effects. The medicine does not possess antiemetic properties.

5.2 Pharmacokinetic properties

Betamethasone:

Absorption:

The vast majority of corticosteroids, including betamethasone, are absorbed from the gastrointestinal tract

Biotransformation:

Corticosteroids are metabolised mainly in the liver but also in the kidney, and are excreted in the urine.

Synthetic corticosteroids, such as prednisolone, have increased potency when compared to the natural corticosteroids, due to their slower metabolism and lower protein-binding affinity.

Dexchlorpheniramine:

The absorption, distribution, metabolism and elimination of dexchlorpheniramine have not been specifically described. However, since dexchlorpheniramine is the primary active isomer of the racemic compound chlorpheniramine, the pharmacokinetics of dexchlorpheniramine are likely to be similar to that of chlorpheniramine. Dexchlorpheniramine is administered orally. H1-antagonists are generally well absorbed from the GI tract. The onset of action of immediate release formulations of chlorpheniramine is about 30-60 minutes. The Cmax of chlorpheniramine occurs in about 2 hours, the maximum therapeutic effect in about 6 hours, and the duration of action lasts between 4-8 hours. Protein binding is approximately 72%. Chlorpheniramine is widely distributed in body tissues and fluids, and it crosses the placenta and is excreted into breast milk. The metabolism of chlorpheniramine is extensive and rapid, first occurring in the gastric mucosa and then on first-pass through the liver, which may be saturable. N-dealkylation produces several metabolites, which are excreted in the urine along with the parent compound. The half-life in healthy adults and children is 20-24 hours and 10-13 hours, respectively. Excretion rates are dependent on the pH of urine and urinary flow, with the rate decreasing as the pH rises and urinary flow decreases.

5.3 Preclinical safety data

Not Applicable

6. Pharmaceutical Particulars

6.1 List of Excipients

MICROCRYSTALLINE CELLULOSE 102	BP
DIBASIC CALCIUM PHOSHPHATE	BP
STARCH	BP
MEGNESIUM STEARATE	BP
PURIFIED TALC	BP

SODIUM STARCH GLYCOLATE	BP
CROSS CARMELLOSE SODIUM	BP

6.2 Incompatibilities

Not applicable

6.3 Shelf-Life

36 Months

6.4 Special Precautions for storage

Store in a cool, dry place. Protect from light.

6.5 Nature and Content of container

30 Tablets in a Bottle

6.6 Special precautions for disposal and other handling

No special requirements

7. Marketing Authorization Holder

NEDAH PHARMA LIMITED

8. Marketing Authorization Number

CTD9173

9. Date of first authorization/renewal of the authorization

3/28/2023

10. Date of revision of the text

12/5/2024