SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

YSP Betamethasone (Betamethasone 0.5mg tablet)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 0.5 mg betamethasone

Excipient(s) with known effects:

Each tablet contains 25.0 mg of lactose monohydrate

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet

A white color round tablet break line on one side and embossed written of Y S 5604 on other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indication:

Acute and chronic rheumatic fever, rheumatoid arthritis, bronchial asthma, myolitis, dermatitis.

4.2 Posology and method of administration:

Usual adult dose: Initiate with 1.5 to 3mg. Maintenance dose: 0.5 to 1.5mg/day in divided doses 2 to 4 times daily, after meals or at bedtime. The daily dosage may be reduced by 0.25mg every 2 – 3 days until the lowest dosage, which will maintain an adequate clinical response is reached. To be dispensed on physician’s prescription.

Method of administration: Oral

4.3 Contraindication:

Betamethasone is contraindicated in patients with systemic fungal infections and those who have shown hypersensitivity to any component of this product. Unless considered life-saving, systemic administration of corticosteroid is contraindicated in patients with peptic ulcer, osteoporosis, psychoses or severe psychoneuroses. Live vaccines should not be given to patients receiving high-dose systemic corticosteroid therapy. Killed vaccines or toxoids may be given although the response may be attenuated.

4.4 Special warnings and special precautions for use:

Corticosteroids may mask some signs of infection, and new infections may appear during their use. There may be decreased resistance and inability to localize infection when corticosteroid are used.

1. Corticosteroids should be given concomitantly with chemotherapeutic agents or antibiotics in the treatment of acute or chronic infections.
2. Should be given with caution in patients with gastric intestinal ulcer, kidney disorder, hypertension, and diabetes.
3. Patients should be supplemented with high protein diet during therapy.
4. Because of possibility of fluid retention, care must be taken when steroids are administered to patients with congestive heart failure.
5. Steroids may worsen diabetes mellitus, osteoporosis, hypertension, glaucoma and epilepsy.
6. Care should be taken when there is a history of severe affective disorders, especially a previous history of steroid psychosis, previous steroid myopathy or peptic ulceration.
7. Should be used only with great caution in elderly persons.

4.5 Interaction with other FPPs and other forms of interaction:

Beclomethasone is less dependent on CYP3A metabolism than some other corticosteroids, and in general interactions are unlikely; however the possibility of system effects with concomitant use of strong CYP3A inhibitors (e.g. cobicistat) cannot be excluded, and therefore caution and appropriate monitoring is advised with the use of such agents.

4.6 Pregnancy and lactation:

The use of Betamethasone in pregnancy, nursing mothers, or women of childbearing potential requires that the possible benefits of the drug be weighed against the potential hazards, to the mother and embryo or fetus.

4.7 Effects on ability to drive and use machines:

No information available.

4.8 Undesirable effects:

Side effects of Betamethasone include fluid and electrolyte disturbances, muscle weakness, osteoporosis, peptic ulcer with possible perforation and haemorrhage, impaired wound healing, facial

erythema, convulsions, menstrual irregularities, suppression of growth in children, decreased carbohydrate tolerance, increased intraocular pressure and negative nitrogen balance due to protein catabolism. Prolonged treatment with corticosteroids in high dosage is occasionally associated with subcapsular cataract, and skin thinning.

4.9 Overdose:

There is no specific antidote for its overdosage, therefore, management of the patients should consist of symptomatic and supportive therapy.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties:

1. Betamethasone is a glucocorticoid. It has 16β-methyl group that enhances the anti-inflammatory action of the molecule and reduces the sodium and water retaining properties of the Fluorine atom bound at Carbon 9.
2. Betamethasone has the ability to decrease or prevent tissue response to an inflammatory processes by inhibiting the accumulation of inflammation cells, including macrophage and leukocytes at sites of inflammation. It can also inhibit phagocytosis, lysosomal enzyme release, and synthesis and/or release of several chemical mediator of inflammation.
3. Betamethasone is primarily used for its potent anti-inflammatory effects in disorders of many organ systems. In addition, it also modifies the body's immune response to diverse stimuli.
4. Betamethasone's anti-inflammatory property is stronger than other glucocorticoids. Its mineralocorticoid side effect is appreciably lower than drugs belonging to that group.
5. Betamethasone is a long-acting glucocorticoid with a half-life of 3 - 5 hours.

5.2 Pharmacokinetic properties:

1. Betamethasone is rapidly and almost completely absorbed from the gastrointestinal tract.
2. Primarily metabolized in the hepatic; also in renal and tissue; mostly to inactive metabolites and excreted in the urine, mainly as inactive metabolites.

5.3 Preclinical safety data:

No information available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients:

Lactose Monohydrate

Microcrystalline Cellulose

Sodium Starch Glycolate

Magnesium Stearate

6.2 Incompatibilities:

No information available.

6.3 Shelf life:

3 years from the date of manufacture.

6.4 Special precautions for storage:

Keep in a tight container. Store at room temperature below 30°C. Protect from light and moisture.

6.5 Nature and contents of container:

Blister packing of 10's x 10

6.6 Instructions for use and handling <and disposal>:

None has been mentioned.

7. MARKETING AUTHORIZATION HOLDER

Y. S. P. INDUSTRIES (M) SDN. BHD.
Lot 3, 5 & 7, Jalan P/7, Section 13,
Kawasan Perindustrian Bandar Baru Bangi,
43000 Kajang, Selangor Darul Ehsan,
Malaysia.

8. MARKETING AUTHORIZATION NUMBER

07839/NMR/2019

9. Date of first authorization ~~/ renewal of the authorization:~~

16 Feb 2022

10. Date of revision of the text:

27 Jul 2023