SUMMARY OF PRODUCT CHARACTERISTICS[SmPC]
Xaga Tablets 1mg

1. NAME OF THE MEDICINAL PRODUCT

Xaga Tablets 1mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Tablet contains

Dexamethasone 1mg

Excipients qs

3. PHARMACEUTICAL FORM

Oral solid preparation

4. CLINICAL PARTICULARS

4.1Therapeutic indications

XAGA Tablets is indicated for the suppression of inflammatory and allergic disorders; diagnosis of Cushing's disease, congenital adrenal hyperplasia; cerebral oedema associated with malignancy; croup; nausea and vomiting with chemotherapy; rheumatic disease, asthma.

4.2 DOSAGE: Adults: 0.5 to 10mg daily

4.3 CONTRAINDICATIONS: Dexamethasone administration is contraindicated in Diabetes mellitus, psychosis, osteoporosis, tuberculosis, congestive heart failure, pregnancy.

WARNINGS: Dexamethasone should be avoided in Glaucoma, epilepsy, hypertension, hepatic dysfunction. It should be avoided in children and adolescents as it can cause possible irreversible growth restriction. Dexamethasone may reduce response of pituitary adrenal axis to stress. It should be used with caution during pregnancy and/or lactation.

4.5 drug interaction

Barbiturates, Carbamazepine, Primidone, Ephedrine, Hydantoins, Rifampicin decrease the efficacy of Dexamethasone. Ketoconazole increases the efficacy of Dexamethasone. Dexamethasone affects the actions of the following drugs: Anticholinesterase efficacy is antagonized in myasthenia gravis. Oral anticoagulant produces altered response when given with Dexamethasone. Cyclosporine: Dexamethasone increases the efficacy of Cyclosporine leading to enhanced toxicity of Cyclosporine. Digitalis glycosides: Increased toxicity associated with hypokalaemia when given with Dexamethasone. Dexamethasone causes a decrease in serum levels of Isoniazid when the two drugs are taken together. Dexamethasone causes decreased serum levels of Salicylates. When Dexamethasone is administered with Diuretics, it causes increased efficacy of Diuretics and consequential hypokalemia and increased hyperglycemia. When used with Theophylline, there is altered response of both

Theophylline and Dexamethasone . There is contraception failure when Dexamethasone is administered with intra uterine contraceptive device (IUCDs) .

5.1 Pharmacology and toxicology

1. Dexamethasone is a selective and potent glucocorticoid. It influences carbohydrate, protein, and lipid metabolism; electrolyte and water balance; and the functions of the cardiovascular system, the kidney, skeletal muscle, the nervous system, and other organs and tissues. It has the capacity to prevent or suppress the development of local heat, redness, and swelling, and tenderness by which inflammation is recognized. Dexamethasone also has the following pharmacological actions:
2. a) Increased gluconeogenesis
3. b) Increased lipolysis
4. c) Increased liver store of glycogen
5. d) CNS effects: euphoria
6. e) Increased haemoglobin synthesis
7. f) Anti-allergic effects

5.2 MODE OF ACTION: After binding to the receptor , the steroid receptor complex binds to chromatin and stimulates the formation of mRNA. The mRNA stimulates the synthesis of enzymes. The anti-inflammatory action is due to inhibition of prostaglandins and leukotrienes synthesis.

5.3 DURATION OF ACTION: Some effects of Dexamethasone may last several days

5.4 Pharmacokinetics

Dexamethasone is readily absorbed from the gastrointestinal tract. It is rapidly distributed to all body tissues. Its biological half- life in plasma is about 190 minutes. Binding of dexamethasone to plasma protein is about 77%, which is less than for most other corticosteroids. Dexamethasone is metabolized mainly in the liver but also in other tissues. Up to 65% of a dose is excreted in urine within 24 hours. Clearance in premature neonates is reported to be proportional to gestational age, with a reduced elimination rate in the most premature. It readily crosses the placenta with minimal inactivation and may be distributed in small amounts into breast milk.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch

microcrystalline cellulose

polysorbate 80

pregelatinized starch

sodium carboxymethyl starch

magnesium stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

3years.

6.4 Special precautions for storage

Store below 30ºC in a Cool and Dry Place

Protect from Light

Keep out of Reach of Children

6.5 Nature and contents of container

PVC/Aluminium foil blister packs of 10 tablets.Such 10 blistersachets

In a packet

6.6 Special precautions for disposal and other handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

MANUFACTURED BY:

Shandong Xier Kangtai Pharmaceutical Co., Ltd.

Private Economy Garden, Xinyan Town,Yanzhou Jining City, Shandong China.

MARKETED BY:

Charlyking Drugs Ltd

Address: 3 Okey Banjo Street, Ago Palace Way, Okota, Lagos, Nigeria.