SW-DEXASONE TABLET

Dexamethasone (0.5mg)

What is in this leaflet

- 1. What SW-Dexasone Tablet is used for
- 2. How SW-Dexasone Tablet works
- 3. Before you use SW-Dexasone Tablet
- 4. How to use SW-Dexasone Tablet
- 5. While you are using it
- 6. Side effects
- 7. Storage and disposal of SW-Dexasone Tablet
- 8. Product description
- 9. Manufacturer and Product Registration Holder
- 10. Date of revision

What SW-Dexasone Tablet is used for

It is used for primary or secondary adrenocortical insufficiency (lack of cortisol hormone), rheumatic disorders (affecting muscles, tendons, joints, bones), collagen diseases (systemic lupus erythematosus), skin diseases (pemphigus, severe psoriasis, severe seborrheic dermatitis), bronchial asthma, eye diseases (eye inflammation, herpes zoster ophthalmicus, allergic conjunctivitis), blood disorders, cancer diseases (leukemias), swelling states and gastrointestinal diseases (ulcerative colitis).

How SW-Dexasone Tablet works

The active ingredient in the medicine is Dexamethasone. It has the capacity to prevent or suppress the development of the local heat, redness, swelling and tenderness by which inflammation is recognized at the gross level of observation. At the microscopic level, they inhibit not only the early phenomena of the inflammatory process but also the later manifestations.

Naturally occurring glucocorticoids which also have salt- retaining properties are used as replacement therapy in adrenocortical (hormone) deficiency states. Their synthetic analogs including dexamethasone are primarily used for their potent anti-inflammatory effects in disorders of many organ systems. Glucocorticoids can cause various metabolic effects. It can change a person's body immune response.

Before you use SW-Dexasone Tablet

- When you must not use it

Do not use SW-Dexasone Tablet if:-

- you have systemic fungal infections.
- you have hypersensitivity to dexamethasone or any ingredients listed at the end of this leaflet.
- You have injected with live virus vaccinations.

- Before you start to use it

You should check with your doctor before you take this medicine if you have the following:-

- congestive heart failure
- · diabetes mellitus
- chronic renal failure
- high blood pressure
- recent intestinal operation
- infectious diseases
- muscle weakness
- eye inflammation due to herpes simplex virus
- tuberculosis disease (bacterial infection that mainly affects the lungs)
- hypothyroidism (underactive thyroid disease)
- elderly person
- cirrhosis (scarring of the liver)

Some medicines may increase the effects of SW-Dexasone Tablet and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV such as cobicistat).

Corticosteroids may mask some signs of infection, and new infections may appear during their use.

Prolonged use of corticosteroids may produce cataracts (clouding of eye lens) and glaucoma (increased pressure in the eye) with possible damage to the optic nerves, and may increase the risk of secondary eye infections due to fungi or viruses.

Pregnancy and breastfeeding

You should check with your doctor if you are or think you may be pregnant, planning to become pregnant or if you are breastfeeding. It is not recommended for pregnant women and nursing mothers unless the expected benefit outweighs any potential risks. Corticosteroids appear in breast milk and can cause other unwanted effects.

- Taking other medicines

There are a few medicines which may interact with SW-Dexasone Tablet. It is important to tell your doctor or pharmacist about all the medicines that you are taking, including those obtained without doctor's prescription. You should talk to your doctor or pharmacist if you are taking:-

- Aspirin, treatment for pain and inflammation
- Phenytoin and Phenobarbital, treatment for fits
- Ephedrine, medicine for asthma

- Rifampicin treatment for bacterial infections
- Coumarin anti-coagulants (treatment for blood thining)
- Diuretic, as water tablets

How to use SW-Dexasone Tablet

- How much to use

You should take SW-Dexasone Tablet exactly as advised by your doctor or pharmacist. The amount you take each day will depend on your condition. Do not take more or less than what your doctor prescribes.

The initial dosage varies from 0.75 to 9 mg a day depending on the disease being treated. In less severe diseases, doses lower than 0.75 mg may suffice, while in severe diseases, doses higher than 9mg may be required.

- When to use it

Use SW-Dexasone Tablet when needed and according to your doctor's prescription.

- How long to use it

It is important to take SW-Dexasone Tablet as long as your doctor prescribes.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking SW-Dexasone Tablet.

• Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not stop taking the medicine unless advised by your doctor because too rapid withdrawal of corticosteroids may cause adrenocortical insufficiency and may be minimized by gradual reduction of dosage. Other may include fever, joint pain, muscle pain and feeling of uneasiness.
- Do not take any new medicines without consulting your doctor.
- Do not give SW-Dexasone Tablet to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

If you experience any side effects, consult your doctor or pharmacist for advice.

Side effects

Like all medicines, SW-Dexasone Tablet can cause side effects, although not everybody gets them. Adverse reactions include fluid and electrolyte disturbance, muscle weakness, osteoporosis(brittle bone) acute pancreas inflammation, cushing syndrome, growth retardation, menstrual irregularities, increased pressure in the eye, visual disturbances, manifestations of latent diabetes mellitus, stomach ulcer with possible perforation and bleeding, impaired wound healing, convulsion and increased pressure in brain with eye nerve swelling.

Any other effects not listed above may also occur in some people. Please refer to your doctor or pharmacist if you experience any other symptoms while taking this medication.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of SW-Dexasone Tablet

- Storage

Store at temperature 30°C. Protect from light.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Round, white, flat plain tablet with 'SW' debossed on one side only.

- Ingredient(s)

- Active Ingredient Dexamethasone
- Inactive Ingredients
- Lactose
- Maize Starch
- Magnesium stearate

<u>- MAL number</u> MAL06071071ASZ MAL19870650AZ

Manufacturer

(MAL19870650AZ) Sunward Pharmaceutical PTE.LTD No.11, Wan Lee Road, 627943 Singapore.

(MAL06071071ASZ)

Sunward Pharmaceutical Sdn. Bhd. No. 9,11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

Product Registration Holder

Sunward Pharmaceutical Sdn. Bhd. No. 9,11 & 17, Jalan Kempas 4, Taman Perindustrian Tampoi Indah, 81200 Johor Bahru, Johor, Malaysia.

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