### **AXCEL PREDNISOLONE-5MG EC TABLET**

Prednisolone (5mg)

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# What Axcel Prednisolone-5mg EC Tablet is used for

Axcel Prednisolone-5mg EC Tablet is used for the treatment of inflammatory condition such as

- Rheumatic fever.
- Rheumatoid arthritis (joint pain and inflammation).
- Allergic diseases.
- Nephritic syndrome.
- Asthma.
- Other corticosteroid-indicated conditions.

## How Axcel Prednisolone-5mg EC Tablet work

Axcel Prednisolone-5mg EC Tablet is an anti-inflammatory agent. It is a steroid that decrease or prevent tissue responses to inflammatory processes, thereby reducing symptoms of inflammation without affecting the underlying cause. It is also prevent production and /or release of several chemical that initiate inflammation.

#### Before you use Axcel Prednisolone-5mg EC Tablet

#### -When you must not use it

Do not take Axcel Prednisolone-5mg EC Tablet if:

- You are having allergy to any component of this medication.
- You are having active osteoporosis (fragile bone), active ulcer on your stomach, esophagus or small intestine or mental disorder.

- It is not prescribed by a qualified doctor or pharmacist for you.
- You are having acute infections.
- You are taking medicines to treat tuberculosis (bacterial infection that mainly affects the lungs).
- You are pregnant, trying to get pregnant or think you may be pregnant.
- You are having systemic fungal infections.
- You are having vaccination.
- You are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

#### -Before you start to use it

Tell your doctor if:

- You are allergic to any medicines, food and dyes.
- You are having congestive heart failure, diabetes, chronic kidney failure, fits, increased pressure in the eyes.
- You are postmenopausal women.
- You are having cirrhosis (liver disease), low level of thyroid hormone, high blood pressure, and recent intestinal surgical procedure.
- You are having infectious disease, raised toxins level in the blood, inflammation of the diverticulum especially in colon and weakness in the skeletal muscles.
- You have infection in the cornea.
- You are having history of stomach ulcer or psychotic tendencies, family history of diabetes and tuberculosis infection.

#### -Taking other medicines

You should tell your doctor if you are taking any medicine as it may interact with your Axcel Prednisolone-5mg EC Tablet:

- Barbiturates (used to relieve anxiety).
- Phenylbutazone (used to treat fever, pain and inflammation).
- Phenytoin (used to prevent seizures).
- Rifampicin (used for treatment of tuberculosis).

- Anticoagulants (used to reduce blood clot).
- Salicylates (relieve pain and inflammation).

It may still be all right for you to take Axcel Prednisolone-5mg EC Tablet and your doctor will be able to decide what is suitable for you.

## How to use Axcel Prednisolone-5mg EC Tablet

-How much to use

For oral use only.

Should be taken with food (take immediately after meal).

Usual adult and adolescent dose:

5-60mg daily in divided doses.

For acute exacerbations of multiple sclerosis (abnormal hardening of body tissue) – 200mg per day for one week, followed by 80mg every other day for one month.

Usual adult dose limits: up to 250mg a day.

Usual children dose:

Adrenocortical (hormones) insufficiency – 0.14mg per kg of body weight a day in three divided doses.

Other indications – 0.5mg to 2mg per

Other indications – 0.5mg to 2mg per kg of body weight a day in three or four divided doses.

Growth retardation, which cannot be overcome with external growth hormone, may occur in children given relatively low doses.

#### -When to use it

Your doctor will decide when it is appropriate for you to use Axcel Prednisolone-5mg EC Tablet according to the type of condition you have.

#### -How long to use it

Taking Axcel Prednisolone-5mg EC Tablet for as long as doctor recommends.

#### -If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

### AXCEL PREDNISOLONE-5MG EC TABLET

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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)

 It is advisable for you to contact and inform your doctor if you did take Axcel Prednisolone-5mg EC Tablet too much.

#### 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 Axcel Prednisolone-5mg EC Tablet.
- Tell your doctor immediately if you become pregnant while talking this medication.

#### -Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give Axcel Prednisolone-5mg EC Tablet to anyone else, even if they have the same symptoms or condition as you.

#### -Things to be careful of

- Avoid prolonged usage in high dosage.
- Do not use on elderly person.

#### **Side effects**

Like all medicines, Axcel Prednisolone-5mg EC Tablet can cause side effects although not everybody gets them. You are advised to consult doctor/ pharmacist for further information. The following side effects have been reported:

- Cushing's syndrome (high level of cortisol hormone in the body).
- Acne.
- Abnormal growth of hair.
- Osteoporosis (fragile bone).
- Death of bone tissue.
- Growth disturbances in children.
- Muscle weakness.
- Susceptibility of infections.

- Gastric and intestinal ulcers with bleeding.
- High level of glucose in the blood.
- Glaucoma (damage of the optic nerve).
- Clouding of the natural lens of the eye.
- Physic disturbances.
- Increased appetite.
- Low level of potassium in blood.
- Unusual bruising wounds.
- Stretch mark, skin thinning.
- Loss of skin color.
- Dizziness or lightheadedness.
- Flushing of face and cheeks.
- Increased sweating.
- Withdrawal syndrome (abdominal or back pain, dizziness, fainting, low grade fever, prolonged loss of appetite, muscle or joint pain, nausea, vomiting, shortness of breath, continuing frequent or unexplained headaches, unusual tiredness or weakness, rapid weight loss, reappearance of disease symptoms).

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website <a href="mailto:npra.moh.gov.my">npra.moh.gov.my</a> (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

# Storage and disposal of Axcel Prednisolone-5mg EC Tablet

#### <u>-Storage</u>

Keep Axcel Prednisolone-5mg EC Tablet out of reach of children. Store in a dry place below 30°C. Keep container well closed and protect from light.

#### -Disposal

Do not use Axcel Prednisolone-5mg EC Tablet after the expiry date which is stated on the carton.

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

Axcel Prednisolone-5mg EC Tablet is a white, round, biconvex enteric coated tablet, 5.0mm diameter.

#### -Ingredients

-Active Ingredient: Prednisolone.

-Inactive Ingredients:

Magnesium Stearate, Microcrystalline cellulose, Aerosil R972, Sodium Starch Glycolate, Colorcon Acryl-EZE Clear, Lactose and Purified Water.

#### <u>-MAL Number</u> MAL12020029AZ

# Manufacturer and product registration holder

Kotra Pharma (M) Sdn Bhd No. 1, 2 & 3, Jalan TTC 12, Cheng Industrial Estate, 75250 Melaka, Malaysia.

### Date of revision

19/03/2018

#### Serial number

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