AXCEL DICLOFENAC-50 TABLET

Diclofenac Sodium (50mg)

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What Axcel Diclofenac-50 Tablet is used for

Axcel Diclofenac-50 tablet is used for:

1. To treat inflammatory, degenerative, non-articular forms of rheumatism (musculoskeletal aches and pains which do not arise from joints).
2. Juvenile arthritis (inflammation of the joint in children).
3. Acute gout.
4. For inflammation and swelling after trauma event and after operation.
5. Primary dysmenorrhea (period pain).

How Axcel Diclofenac-50 Tablet works

Axcel Diclofenac-50 Tablet contains a substance call Diclofenac. Diclofenac is a non-steroidal anti-inflammatory drugs (NSAIDs) which reduces inflammation, pain and fever.

Before you use Axcel Diclofenac-50 Tablet

– *When you must not use it*

Do not take Axcel Diclofenac-50 Tablet:

- If you suffer attacks of asthma, urticaria (itching or hives) or acute rhinitis (inflammation of the nasal mucous membrane).
- If you are allergic or hypersensitive to Aspirin (medication used to reduce fever, reduce pain and prevent blood clot) or any other NSAIDs.
- If you have severe heart failure
- Please consult to your doctor before start to use Axcel Diclofenac-50 Tablet if you are pregnant, plan to become pregnant, breast-feeding or intent to breast-feed. Your doctor will have weighed the risks of you taking Axcel Diclofenac-50 Tablet against the benefits they expect it will have for you.
- If children below 1 year old.

– *Before you start to use it*

Tell your doctor:

- If you are hypersensitive to, or have had an allergic reaction to aspirin or other NSAIDs. Symptoms of an allergic reaction may include: cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, blister, itching or hives on the skin; fainting; or hay fever-like symptoms. If you think you are having an allergic reaction, stop taking the medicine and contact your doctor immediately or go to the nearest hospital.
- If you are elderly
- If you suffering from dyspepsia (discomfort at the epigastric region due to digestion problem).
- If you have or have had gastric and intestinal ulceration, bleeding and perforation.
- If you suffering from heart disease
- If you suffer haemorrhagic (bleeding) disorders, asthma, a history of hypersensitivity reactions to aspirin and other NSAIDs, hypertension (high blood pressure) and impaired kidney, liver or heart function and stroke.
- If you recently had or you are going to have a surgery of the stomach or intestinal tract before receiving/ taking/ using Axcel Diclofenac-50 Tablet, Axcel Diclofenac-50 Tablet can sometimes worsen wound healing in your gut after surgery.

Diclofenac may cause severe skin reactions, e.g. exfoliative dermatitis, toxic epidermal necrolysis, Steven-Johnson Syndrome. Symptoms may include skin rash, blisters and peel off. These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

– *Taking other medicines*

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

You should tell your doctor if you are taking the following medicine as it may interact with your Axcel Diclofenac-50 Tablet:

- Lithium for depression
- Methotrexate, medicine used to treat rheumatoid arthritis, as well as some types of cancer
- Other analgesics (pain killer)
- Cyclosporin (a medicine used after organ transplants, as well as to treat rheumatoid arthritis)
- Antibiotic medicine such as quinolone (e.g. ciprofloxacin or norfloxacin)
- Diuretics, also called fluid or water tablets
- Anticoagulants (e.g. warfarin) for thinning of the blood
- Oral hypoglycaemic agents for diabetes
- An antibiotics aminoglycoside
- Probenecid as adjunct in antibiotic therapy or for gout
- Anti-hypertensive for high blood pressure
- Cardiac glycosides, Digoxin, a heart tablet
- Mifepristone, hormonal medicine
- Corticosteroids (anti-inflammatory medicines).

How to use Axcel Diclofenac Tablet

– *How much to use*

For oral administration only.

To be taken after meal. Treatment should begin at the onset of

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symptoms and continue for 1-2 weeks for non-chronic conditions.

Adult: 75-150mg (3 – 6 tablets) daily in 2 – 3 divided doses. In primary dysmenorrhoea: The daily dosage which should be individually adapted is generally 50 – 150mg (2 – 6 tablets). The initial dose should be 50 – 100mg (2 – 4 tablets) and, if necessary, this dose can be raised over a number of menstrual cycles up to a maximum dose of 200mg (4-8 tablets) daily. Treatment should be started when the period pain starts, and stopped after it goes away.
Mild and prolonged use for Rheumatoid Arthritis (systemic inflammatory disorder that affects joints): 75mg once daily. Max: 100-150mg daily.
Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

– *When to use it*
Your doctor will decide when it is appropriate for you to take Axcel Diclofenac-50 Tablet according to the type of condition you have.

– *How long to use it*
- Take this medicine as stated in the leaflet without exceeding the dosage.
- Follow any recommendations and advices from your doctor or pharmacist.

– *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)*
- Symptoms of over dosage include gastric and intestinal complaints, vomiting, confusion, drowsiness or general hypotonia (low muscle tone).
- It is advisable for you to contact your doctor immediately or go to the Emergency Department of your nearest hospital if you did take Axcel Diclofenac-50 Tablet too much.

While you are using it
– *Things you must do*
- Tell your doctor if you need to take any other medicines.
- Take the Axcel Diclofenac-50 Tablet according to the recommended dosage.
- Tell your doctor or pharmacist if you experience any side effects that are not listed in this leaflet.

– *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 Diclofenac-50 Tablet to anyone else, even if they have the same symptoms or condition as you.

– *Things to be careful of*
- Avoid prolonged use with high dosage.
- Be careful while driving or operating machinery until you know how Axcel Diclofenac-50 tablet affects you.

Side effects
Like all medicines, Axcel Diclofenac-50 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:

Stomach and intestinal tract:
Typical reactions include epigastric pain, nausea, vomiting and diarrhoea. Rarely stomach ulcer and stomach and intestinal bleeding have occurred. Diclofenac has also been implicated as the causative agent in colonic ulceration, small bowel perforation and pseudomembranous colitis (inflammation of the colon).

Hematological (blood disease) reactions:
Blood disorders have also occurred such as haemolytic anaemia (bone marrow unable to replace the destroyed red blood cells), thrombocytopenia (low platelet count), neutropenia (abnormally low level of neutrophils, a type of white blood cell) and agranulocytosis (a condition where bone marrow does not make enough neutrophils).

Hepatic (liver):
Elevations of serum aminotransferase activity and clinical hepatitis (inflammation of the liver), including fatal fulminant hepatitis have occurred. Rarely, liver failure.

Dermatological (skin) reactions:
Occasional – rashes or skin eruptions. Cases of hair loss, bullous eruptions (fluid-filled blisters or bullae), erythema multiforme (hypersensitivity reaction). Steven-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), and photosensitivity reactions have been reported.

Renal (kidney):
Renal papillary necrosis (kidney disorder) and nephrotic syndrome (nonspecific kidney disorder) have been reported. Other side effects include hypersensitivity reaction, headache, dizziness, vertigo, hearing disturbances such as tinnitus (ringing in the ear) and photosensitivity.

Cardiac (heart) disease:
Heart attack, heart failure, rapid heartbeat and chest pain has been reported.

Serious GI toxicity such as bleeding, ulceration and perforation can occur at any time, with or without warning symptoms, in patients treated with NSAIDs therapy.

Frequency "not known": Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the

website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and disposal of Axcel Diclofenac-50 Tablet

– *Storage*

Keep Axcel Diclofenac Tablet out of reach of children.
Store below 30ºC. Keep container well closed and 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*

Orange colour, round and biconvex enteric coated tablet, 8mm in diameter.

– *Ingredients*

- Active Ingredient (s):
  Diclofenac Sodium

- Inactive Ingredients:
  Tablettose 80, Microcrystalline Cellulose, Sodium Starch Glycollate, Silicon Dioxide, Magnesium Stearate, Opadry II White, Purified Water and Acryl-EZE Orange.

– *MAL Number*

MAL20034642AZ

Manufacturer and product registration holder

Kotra Pharma (M) Sdn. Bhd.
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