

# AXCEL PIROXICAM-10 CAPSULE

Piroxicam (10mg)

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## What Axcel Piroxicam-10 Capsule is used for

Axcel Piroxicam-10 Capsule is used for the symptomatic relief of pain stiffness and inflammation in people with osteoarthritis (degenerative joint disease), and ankylosing spondylitis (chronic inflammatory disease of the skeleton). However, it should not be the first choice of non-steroidal anti-inflammatory drug (NSAIDs) treatment in these conditions.

## How Axcel Piroxicam-10 Capsule works

Axcel Piroxicam-10 Capsule contains a substance called Piroxicam. Piroxicam is a non-steroidal anti-inflammatory drug (NSAIDs) agent with analgesic (medicine to reduce pain) and antipyretic (medication used to reduce or prevent fever) properties. Its mechanism of action is not completely known.

## Before you use Axcel Piroxicam-10 Capsule

### – When you must not use it

Do not take Axcel Piroxicam-10 Capsule:

- If you are allergic or hypersensitive to the medicine or Piroxicam. 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, itching or hives on the skin;

fainting; or have 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 recently or recurrently you have a history of peptic ulceration (gastric ulceration) or active inflammatory tract.
- If you have or have had a stomach or intestinal bleeding.
- If you have history of allergy skin reactions to other medicines.
- If you have had asthma, rhinitis (inflammation of the nasal mucous membrane), urticaria (itching or hives) or the symptoms become worsened caused by Aspirin or non-steroidal anti-inflammatory agents (NSAIDs).
- Do not take Axcel Piroxicam-10 Capsule if you are pregnant, trying to get pregnant or think you may be pregnant.
- Do not take Axcel Piroxicam-10 Capsule if you are breastfeeding. Ask your doctor or pharmacist for advice before taking any medicine.

### – Before you start to use it

Tell your doctor:

- If you have a history of upper stomach and intestinal disease.
- If you have heart disease, heart failure or stroke, hypertension (high blood pressure) or other condition predisposing to fluid retention.
- If you have any liver problem.
- If you have problem with your vision.
- If you are suffering from dyspepsia (discomfort at the epigastric region due to digestion problem)
- Axcel Piroxicam-10 Capsule may cause severe skin reactions, e.g. exfoliative dermatitis, toxic epidermal necrolysis, Steven-Johnson Syndrome. Symptoms

may include skin 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

You should tell your doctor if you are taking the following medicine as it may interact with your Axcel Piroxicam-10 Capsule:

- Lithium, used to treat depression
- Methotrexate, to treat some types of cancer or rheumatoid arthritis
- Cardiac glycosides, to treat heart failure and irregular heartbeat
- ACE inhibitor, to treat high blood pressure and congestive heart failure
- Cyclosporine, medicine to prevent organ transplant rejection
- Potassium-sparing diuretics, to promote production of urine without promoting the secretion of potassium into the urine.
- Anti-hypertensive drugs, to treat high blood pressure
- Aspirin, used to reduce pain.
- Oral anticoagulants, blood thinning agent
- Avoid concomitant use of other NSAIDs.

## How to use Axcel Piroxicam-10 Capsule

### – How much to use

For oral administration only.

In rheumatoid arthritis and ankylosing spondylitis, a starting single dose of 20mg/day is recommended. The usual maintenance dose is 10-20mg/day.

In osteoarthritis, the recommended starting dose is 20mg daily. If desired, this dose may be given as 10mg twice daily. The usual maintenance dose is 10-20mg/day.

If you are elderly, debilitated or have renal impairment, a starting dose of 10mg per day is recommended. The dose may be increased to 20mg

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perday. Do not exceed the daily dosage of 20mg.

Follow the instruction given by your doctor or pharmacist. Your doctor will prescribe the most suitable dose for you.

## – When to use it

Your doctor will decide when it is appropriate for you to take Axcel Piroxicam-10 Capsule according to the type of condition you have.

## – How long to use it

- Your doctor may review you after 14 days of treatment.
- 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.
- Do not double up the dosage as Axcel Piroxicam-10 Capsule may give you unacceptable side effects.

## – If you use too much (overdose)

- Symptoms and signs included nausea, abdominal pain, gastric and intestinal bleeding, multiple superficial gastric and intestinal ulcers.
- 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 Piroxicam-10 Capsule 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 Piroxicam-10 Capsule.

### – 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 Piroxicam-10 Capsule to anyone else, even if they have the same symptoms or condition as you.

### – Things to be careful of

- If you take Axcel Piroxicam-10 Capsules for a long term, you should be checked by a physician to avoid occurrence of unwanted effects.
- Be careful while driving and operating machinery until you know how Axcel Piroxicam-10 Capsule affects you.
- Caution to elderly and in people with compromised cardiac function as congestive heart failure may be precipitated.
- Avoid taking alcoholic beverages of Aspirin while being treated with Piroxicam as stomach problems may be more likely occur.

## Side effects

Like all medicines, Axcel Piroxicam-10 Capsule 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:

- Gastrointestinal disturbances such as abdominal discomfort, flatulence, nausea, epigastric distress (abdominal discomfort), constipation, diarrhea, peptic (stomach) ulceration, stomatitis (inflammation of the mucous membrane of the mouth), anorexia (eating disorder), vomiting, indigestion and gastrointestinal bleeding.
- Liver function abnormalities, jaundice, hepatitis (inflammation of the liver), hematemesis (vomiting of blood), melena (dark sticky feces containing partly digested blood). Dry mouth are rarely seen.

- Adverse reactions on central nervous system (CNS) include dizziness, headache, drowsiness, sedation, amnesia (loss of memory), anxiety, depression, insomnia (inability to sleep), nervousness, paresthesia (abnormal sensation of the body), personality change, tremors and vertigo.
- Dermatological adverse reactions include rash, pruritus (itching), alopecia (hair loss), sweating, erythema (superficial reddening of the skin), bruising, desquamation (peeling), exfoliative dermatitis erythema multiforme, toxic epidermal necrolysis, Steven Johnson syndrome, vesiculobullous reaction (skin disease with the presence of blisters) and photoallergic reactions.

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.

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 [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers -> Reporting).

## Storage and disposal of Axcel Piroxicam-10 Capsule

### – Storage

Keep Axcel Piroxicam-10 Capsule out of reach of children. Store below 30°C. 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

Axcel Piroxicam-10 Capsule is a white powder in a size 2 hard gelatin

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capsule with scarlet cap and powder blue body.

– *Ingredients*

*Active Ingredient (s):*

Piroxicam

*Inactive Ingredients:*

PVP K30, Sodium Starch Glycollate, PVP-CL, Talc, Lactose, Sodium Lauryl Sulphate, Isopropyl Alcohol, Magnesium Stearate and Purified Water.

– *MAL Number*

MAL19910832A

**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**

23/07/2015

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