## TILNOXCAM TABLET

Tenoxicam (20mg)

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#### What Tilnoxcam is used for

Tilnoxcam contains the active ingredient tenoxicam.

Tilnoxcam is used to relieve the pain, swelling, redness and inflammation that may occur in

- different types of arthritis, including osteoarthritis (degenerative joint disease), rheumatoid arthritis (systemic inflammatory disorder that affects joints), ankylosing spondylitis (chronic inflammatory disease of the skeleton)
- relieve of acute and chronic inflammatory pain

### How Tilnoxcam works

Tenoxicam belongs to the group of medicines called non-steroidal anti-inflammatory drug (NSAIDs). It works to reduce pain and inflammation (swelling and redness) by inhibiting the activity of certain hormones.

## Before you use Tilnoxcam

#### - When you must not use it

Do not take Tilnoxcam if you:

- Have ever had a reaction or been told that you are allergic to tenoxicam or to any of the excipients
- Have had nasal polyps, angioedema (swelling around the eyes and lips and sometimes of the genitals, hands, and feet) or bronchospasm (difficulty in breathing), urticaria (itching or hives) and the symptoms become worsen caused by Aspirin or NSAIDs.
- Have or have ever had any problems with your stomach or gut (intestine) like an ulcer or bleeding
- Have previously experienced bleeding or perforation in your stomach while taking

### NSAIDs

· Are undergoing anaesthesia or surgery.

## - Before you start to use it

Tell your doctor if you:

- Have allergies to any other medicines, food, preservatives or dyes
- Have heart problems, high blood pressure and previous stroke
- Have impaired kidney or liver functions
- Have thrombosis (blood clots inside the blood vessels)
- Have or have had ulceration, bleeding and perforation of the stomach or intestinal
- Have any stomach or bowel disorders including ulcerative colitis
- Are a smoker or alcoholic drinker
- An elderly patient

Tenoxicam may cause severe skin reactions, e.g. exfoliative dermatitis, toxic epidermal necrolysis, Steven-Johnson Sydrome. 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.

Please consult your doctor before start to use TILNOXCAM tablet if you are pregnant, plan to become pregnant, breast-feeding or intend to breast-feed. Your doctor will have weighed the risks of you taking TILNOXCAM tablet against the benefits they expect it will have for you.

If you are not sure whether you should start taking this medicine, consult your doctor.

## - Taking other medicines

Inform your doctor or pharmacist if you are taking or if you have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines and Tilnoxcam may interfere with each other. It is important to tell your doctor or pharmacist if you are taking:

- Protein-bound Drugs such as
  - Aspirin, salicylates or other NSAIDs to relieve pain and swelling
  - Warfarin, a medicine to stop blood clot
  - Sulfonylurea, a medicine for diabetic

- Methotrexate, a medicine to treat arthritis and some cancers
- Lithium for mental health problems
- Diuretics, medicines for high blood pressure
- Cholestyramine, a medicine to treat diarrhoea

This may not be a complete list of all interactions that may occur. Ask your doctor or pharmacist if tenoxicam may interact with other medicines that you take.

#### How to use Tilnoxcam

Always take Tilnoxcam tablets exactly as your doctor has told you.

The tablets should be swallowed whole together with a sufficient quantity of liquid, at the same time each day. It is best taken after meals for the patients who have sensitive stomach.

## - How much to use

Your doctor will decide your dose as it depends on your conditions.

## Adults

The usual dose is one Tilnoxcam tablet each day.

## Children under 18 years old

Tilnoxcam is not recommended for use in childrens.

# Elderly and patients with liver and kidney problems

Your doctor will decide your dose, it will usually be lower than that for other adults.

## - When to use it

Take your medicine as directed and the duration of treatment is to be determined by your doctor or pharmacist.

## - How long to use it

Continue taking your medicine for as long as your doctor tells you. This medicine helps to control your condition, but does not cure it. It is very important that you do not stop taking this medicine suddenly even if you feel well.

## - If you forget to use it

Take your dose as soon as you remember, and continue to take it as you would normally. If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Do not take a double dose to make up for the dose that you missed.

## - If you use too much (overdose)

If you or anyone else takes too many tablets, tell your doctor and go to your nearest hospital emergency department immediately. Do this even if there are no signs of discomfort or poisoning. Take the carton or any remaining tablets you have with you.

## While you are using it

- Things you must do
- Always take Tilnoxcam exactly according to the instructions given to you by your doctor or pharmacists. If you are unsure, check with your doctor or pharmacist.
- Inform your doctor or pharmacist if you are taking or if you have recently taken any other medicines, including medicines obtained without a prescription such as supplements or traditional medicines.
- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Tilnoxcam.
- Tell your doctor or pharmacist immediately if you notice any side effects, or if the side effects gets serious or anything else that make you feel unwell.
- Inform your doctor immediately if you are pregnant or planned to get pregnant while taking Tilnoxcam.

## - Things you must not do

- Do not give this medication to anyone else, even if they have the same condition as you.
- Do not stop taking your medicines without consulting your doctor. It is important to keep taking your medicine even if you feel well.
- Do not use Tilnoxcam after the expiry date which is stated on the blister and carton.

## - Things to be careful of

Be careful driving or operating machinery until you know how this drug affects you.

Taking Tilnoxcam may cause dizziness or headaches. If you have any of these

symptoms, do not drive, operate machinery or do anything else that could be dangerous.

#### **Side effects**

Like many medicines, Tilnoxcam may cause side effects in some patients, particularly when you are first taking them but not everyone will get it.

Tell your doctor or pharmacist if you notice the following side effects and it worries you:

- Stomach upset including nausea, indigestion, gas
- Vomiting, diarrhoea, epigastric pain
- Headache, dizziness, tiredness and depression

The following are serious side effects. You may need urgent medical attention.

- Allergy reaction: skin rashes, itching, blisters or sudden swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- Skins become more sensitive to the sunlight
- Increase in serum creatinine and blood urea nitrogen
- Blood disorders: reduction in the blood cells causing anaemia (skin pale and weakness), unexplained bleeding and bruising or frequent illness

Tell your doctor or pharmacist if you notice anything else that makes you feel unwell. Other side effects not listed above may also occur in some people.

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:portal.bpfk.gov.my">portal.bpfk.gov.my</a> (Consumers -> Reporting)

## Storage and Disposal of Tilnoxcam

## - Storage

Store in a cool dry place, not above 30°C. Keep in the original package to protect from light and moisture.

Do not store Tilnoxcam or any other medicines in the bathroom, near a sink or leave it at the window sill or in the car.

Keep out of reach of children.

## - Disposal

Do not use Tilnoxcam after the expiry date which is stated on the carton and blister.

Medicines should not be disposed of via household waste. Ask your doctor and pharmacist the proper way to dispose the remaining medicines if your doctors tell you to stop taking Tilnoxcam or the expiry date has passed.

## **Product Description**

#### - What it looks like

TILNOXCAM TABLET is a yellow oval biconvex, film-coated tablet with bisec-line engraved on one side.

#### - Ingredients

- Active ingredient Each tablet contains tenoxicam 20mg.

- Inactive ingredients Sodium starch glycolate, corn starch, polyethylene glycol, titanium dioxide, iron oxide yellow, hydroxypropyl methylcellulose, lactose, colloidal silicon dioxide, magnesium stearate, sodium lauryl sulfate, povidone, talcum and purified water.

## - Packing

It comes in a blister strip of 10 tablets and packed in a box of 500 tablets.

<u>- MAL Number</u> MAL19973335A

#### Manufacturer

T.O. Pharma Co., Ltd. 101 Ladprao 124, Wangthong Lang, Bangkok 10310, Thailand.

## **Product Registration Holder**

IMEKS Pharma Sdn Bhd. No. 5&9, Jalan Udang Harimau 2, Medan Niaga Kepong, 51200 Kuala Lumpur, Malaysia.

## **Date of revision**

21/8/2015

# **Serial Number** BPFK(R4/1)210815/00271