

KETO FILM COATED TABLET

Ketorolac Tromethamine (10mg)

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What KETO TABLET is used for

KETO TABLET is used for short term management of moderate to severe acute after operation pain following surgical procedures associated with low risk of haemorrhage (bleeding).

How KETO TABLET works

KETO TABLET consists of active ingredient ketorolac tromethamine. Ketorolac tromethamine belongs to the group of medicines called Non-Steroidal Antiinflammatory Drug (NSAIDs) which work by relief of pain, and reduction of fever and swelling.

Before you use KETO TABLET

-When you must not use it

Do not take KETO TABLET if:

- you have history of hypersensitivity to ketorolac, aspirin as severe anaphylactic (severe allergic) reaction reported.
- you have history of asthma, nasal polyps, angioedema (swelling of your skin) or bronchospasm (constriction of your airway).
- you have history of stomach ulceration, stomach or intestinal bleeding.
- you have bleeding disorder or operation with high risk of bleeding.
- you have confirmed or suspected cerebrovascular bleeding.
- you have moderate or severe kidney disease
- you have hypovolaemia or dehydration.
- you are pregnant, delivery or breast feeding
- you are under the age of 16 years old.
- you are taking other NSAIDs (painkiller), oxpentifylline, probenecid, or lithium salts.
- you are taking blood thinning agent including low dose heparin.

-Before you start to use it

Tell your doctor if you have or have had:

- kidney or liver disease
- ulceration, bleeding or perforation of the stomach or intestinal
- fluid retention and oedema
- bradycardia (slow heart rate), hypertension

- bleeding disorder
- undergo surgery
- heart disease or stroke
- high blood pressure
- dyspepsia (discomfort at the epigastric region due to digestion problem)

Ketorolac 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.

Some medicines when taken with KETO TABLET may interfere with each other. These include:

- methotrexate, a medicine used to treat rheumatoid arthritis, as well as some types of cancer
- diuretics, water pills
- lithium, medicine for depression
- anticoagulants, medicines for blood thinning effect
- ACE inhibitors, medicines for high blood pressure
- probenecid, medicine for gout
- oxpentifylline
- other NSAIDs

Your doctor or pharmacist may have more information on medicines to be careful with or to avoid while taking medication.

How to use KETO TABLET

-How much to use

Adult over 16 years old: 10mg every 4-6 hours.

Elderly more than 65 years old: 10mg every 6-8 hours.

Maximum 40 mg daily.

-When to use it

KETO TABLET is to be taken every 4 to 6 hours for adult over 16 years old and every 6 to 8 hours for elderly more than 65 years old.

-How long to use it

KETO TABLET should not be taken more than 7 days.

-If you forget to use it

If you miss a dose of KETO TABLET and you are taking it regularly, take it as soon as possible. If it is approaching time for the next dose, do not double the dose to make up for the forgotten dose, unless advised by your health care provider. Do not take 2 doses at once.

-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

Follow your doctor's instruction when you are taking KETO TABLET.

-Things you must not do

Do not stop taking this medicine or change the dosing regimen without instruction of your doctor. Do not give KETO TABLET to anyone else, even if they have the same condition as you.

-Things to be careful of

Driving and operating machinery

Be careful driving or operating machinery until you know how KETO TABLET affects you.

Side effects

Like all medicines, KETO TABLET can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

KETO TABLET side effects include anaphylaxis (serious allergic reaction), fluid retention, nausea, abdominal discomfort, bowel changes, peptic ulcer, stomach and intestine bleeding, pancreatitis (inflammation of pancreas), drowsiness, dizziness, headache, sweating, dry mouth, excessive thirst, mental and sensory changes, convulsions, myalgia (muscle pain), aseptic meningitis (inflammation in the brain), hyponatraemia (low concentration sodium in blood), hyperkalaemia (high levels of potassium in blood), raised blood urea and creatinine, urinary symptoms and acute renal failure,

(high blood pressure), purpura (bleeding of blood vessel that caused spot in the skin), thrombocytopenia (decreased of platelet in blood), prolonged bleeding time, dyspnea (shortness of breath) and pulmonary oedema (fluid retention in lung), skin reactions some severe, including Stevens-Johnson and Lyell's syndromes, after operation wound haemorrhage (bleeding), haematoma (collection of blood within the tissue), epistaxis (nosebleed), oedema (fluid retention on the skin), and liver function changes.

Tell your doctor or pharmacist if you notice anything else that is making 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 visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of KETO TABLET

-Storage

Store below 30°C, protect from light and moisture.

-Disposal

KETO TABLET should be disposed when your doctor or pharmacist tells you to stop taking this tablet or it has passed the expiry date. Ask your pharmacist how to dispose medicines that are no longer required.

Product description

-What it looks like

A white tablet, one side impressed with the mark "N" and the other side with "YSP"

-Ingredients

-Active ingredient

Ketorolac Tromethamine

-Inactive ingredients

Lactose

Microcrystalline Cellulose

Magnesium Stearate

Sodium Starch Glycolate

Polyethylene Glycol

HPMC

Dimethylpolysiloxane

Titanium Dioxide

Purified Water

-MAL number

MAL20000081AZ

Manufacturer and Product registration Holder

Y.S.P. Industries (M) Sdn. Bhd.

Lot 3, 5, 7, 12 & 14, Jalan P/7, Section 13, Kawasan Perindustrian Bandar Baru Bangi, 43000 Kajang, Selangor, Malaysia.

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