

# METHACID TABLET

Indomethacin (25mg )

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## What Methacid Tablet is used for

It is used for effective in active stages of the following :-

- Moderate to severe rheumatoid arthritis (systemic inflammatory disorder that affects joints) including acute flares of chronic disease.
- Moderate to severe ankylosing spondylitis (chronic inflammatory disease of the skeleton).
- Moderate to severe osteoarthritis (degenerative joint disease).
- Acute painful shoulder Bursitis (Inflammation of the bursa) and Tendinitis (inflammation of the tendon)
- Acute gouty arthritis.

Indomethacin may enable the reduction of steroid dosage if you are receiving steroids for the more severe forms of rheumatoid arthritis.

## How Methacid Tablet Works

Methacid Tablet contains a substance called Indomethacin. It belongs to a group of medicines called non steroidal anti-inflammatory agents (NSAIDs) which reduces fever, pain and inflammation.

## Before you use Methacid Tablet

### - When you must not use it

Do not use Methacid Tablet:-

- If you have allergy or hypersensitivity to Indomethacin, Aspirin, other NSAIDs or any other ingredients listed at the end of this leaflet.
- If you have had nasal polyps (growth in the nasal), angioedema (swelling around the eyes and lips and sometimes of the genitals, hands, and feet), bronchospastic (constriction of the airway) and the symptoms become worsen caused by Aspirin or NSAIDs.

### - Before you start to use it

You should check with your doctor:-

- If you have heart problem or stroke
- If you have high blood pressure
- Indomethacin may cause severe skin reactions, e.g. 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.
- If you have or have had ulceration, bleeding and perforation of the stomach and intestinal
- If you suffering from dyspepsia (discomfort at the epigastric region due to digestion problem).
- If you have vision problem
- If you have kidney problem
- Please consult your doctor before start to use Methacid 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 Methacid Tablet against the benefits they expect it will have for you.

### - Taking Other Medicines

Some medicines when taken with Methacid Tablet may interfere with each other. It is important to tell your doctor or pharmacist about all the medicines that you are taking, including those obtained without doctor's prescription. You should talk to you doctor or pharmacist if you are on the following:-

- Diflunisal, medicine to reduce inflammation
- Probenecid, as an adjunct therapy in anti biotics or for gout
- Frusemide and thiazides, water pill
- Triamterene, as an adjunct therapy in anti-biotics or for gout.
- Lithium, for depression
- Beta-blocker, for high blood pressure

## How to use Methacid Tablet

### - How much to use

Oral administration.

The usual initial dose is 25 mg two to four times daily, increased if required, to 150 to 200 mg daily. In acute gout, 50 mg may be given 3 or 4 times daily.

### - When to use it

It should be given with food, immediately after meals, or with antacids to reduce gastric irritation.

### - How long to use it

It is important to take Methacid Tablet as long as your doctor prescribes.

### - If you forget to use it

Do not take extra tablet to make up for a missed dose. Just take your next dose at usual the time.

### - 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.

Taking too many capsule may cause nausea (with or without vomiting), abdominal distress or pain, headache, dizziness, muscle weakness, mental confusion, flushing or sweating and acute respiratory distress.

## While you are using it

### - Things you must do

Take Methacid Tablet exactly the way as prescribed. Tell all the doctors, dentists and pharmacists treating you that you are taking Methacid Tablet. Inform your doctor immediately if you become pregnant while taking this medication.

### - Things you must not do

- Do not share your medicines with others even if they have the same diagnosis as you.
- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.

### - Things to be careful of

Be careful driving or operating machinery until you know how Methacid Tablet affects you. If you experience any side effects, consult your doctor or pharmacist for advise

## Side Effects

Like all medicines, Methacid Tablet can cause side effects, although not everybody gets them. Adverse reactions to Indomethacin mainly involve the Gastrointestinal (GI) tract disturbance, headache and dizziness. Gastrointestinal ulceration and bleeding may also occur.

Others include such as depression, drowsiness, inability to sleep (insomnia), psychiatric disturbance, dizziness, coma, peripheral neuropathy ( peripheral nervous system malfunction) and blurred vision can be occur. Reduction of white blood cell, deficiency of platelets in the blood, bleeding from the nose, an excess of glucose in the bloodstream and vaginal bleeding are also have been reported.

If you encounter any other side effects not in this list, please inform your doctor or Pharmacist as well.

You may report any side effect or adverse drug reaction directly to the National Centre for Adverse Drug Reaction Monitoring by calling 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers→Reporting)

### **Storage and Disposal of Methacid Tablet**

#### - Storage

Store at below 30°C. 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

Round, deep convex, blue, film coated tablets

#### - Ingredients

- Active Ingredients

- Indomethacin

- Inactive Ingredients

(MAL06100576AS)

- Cellosolve Solvent (M.E.)
- Lake Blue No 1 (28-31%)
- Lactose
- Corn Starch
- Hydroxypropyl Methylcellulose
- Sodium Starch Glycolate
- Calcium Carbonate Light
- Magnesium Stearate
- Aerosil 200/Cab-o-Sil
- Talcum
- Isopropyl alcohol

- Inactive Ingredients

(MAL19861097A)

- Cellosolve Solvent (M.E.)
- Lake Blue No 1 (28-31%)
- Lactose
- Corn Starch
- Hydroxypropyl Methylcellulose
- Sodium Starch Glycolate
- Calcium Carbonate Light
- Magnesium Stearate
- Aerosil 200/Cab-o-Sil
- Talcum
- Isopropyl alcohol
- PVP

#### - MAL number

- MAL06100576ASZ
- MAL19861097AZ

### **Manufacturer**

(MAL06100576AS)

Sunward Pharmaceutical Sdn. Bhd.  
9,11 & 17 Jalan Kempas 4,  
Taman Perindustrian Tampoi Indah,  
81200 Johor Bahru, Johor, Malaysia.

(MAL19861097A)

Sunward Pharmaceutical PTE.LTD  
No.11, Wan Lee Road, Jurong 2262,  
Singapore.

### **Product Registration Holder**

Sunward Pharmaceutical Sdn. Bhd.  
9,11 & 17 Jalan Kempas 4,  
Taman Perindustrian Tampoi Indah,  
81200 Johor Bahru, Johor, Malaysia.

### **Date of revision**

18/12/2015

### **Serial Number**

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