

# PRITAREN TABLET 50MG

*Diclofenac sodium 50mg*

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## **What *Pritaren* is used for**

It is used for pain, reduce swelling and inflammation in a number of conditions affecting the joints and muscles-rheumatism, rheumatoid arthritis, osteoarthritis, spinal arthritis and painful inflammation of joints mainly, in feet and hands.

## **How *Pritaren* works**

Diclofenac, is a non-steroidal anti-inflammatory drug (NSAID) which reduces pain, fever and inflammation.

## **Before you use *Pritaren***

*When you must not use it*

- allergic to *Pritaren* or other ingredients of *Pritaren*, aspirin, ibuprofen or any other NSAID.
- has stomach or intestinal ulcer or bleeding in the digestive tract.
- have stomach or bowel problems (bleeding or perforation) after taken other NSAIDs
- have heart, kidney or liver failure.
- more than six months pregnant

*Before you start to use it*

Consult the doctor before taking *Pritaren*.

- if elderly or suffering from kidney or liver disease.
- if suffering from stomach or bowel disorders (ulcerative colitis or Crohn's disease).
- if had asthma, seasonal allergic rhinitis, swelling of the nasal mucosa (nasal polyps), chronic pulmonary diseases or infections of the respiratory tract.
- if there's heart problems, stroke, or risk of conditions (for example, high blood pressure, diabetes, high cholesterol or a smoker)
- if Systemic Lupus Erythematosus (SLE) (inflammatory, auto-immune disorder causing joint pain & inflammation, skin rashes,

fever or any similar condition.

## *Taking other medicines*

Triamterene, cyclosporin – deterioration of renal function in concomitant use.

Digoxin, lithium and methotrexate – increased in blood concentration.

Salicylates – interactions when co-administered with diclofenac.

Quinolone antibiotics – increased in central nervous system effects leading to convulsion.

Other NSAIDs and steroids – increased frequency of side effects.

Anticoagulants – increased haemorrhage risk.

## **How to use *Pritaren***

*How much to use*

Adults: Oral, 25-50mg three times daily, or as directed. Children: As directed by doctor.

*When to use it*

Take this medicine with or after food.

*How long to use it*

You should check with your doctor or pharmacist.

*If you forget to use it*

Do not take a double dose to make up for a forgotten tablet.

*If you use too much (overdose)*

If taken too much *Pritaren*, contact your doctor, an emergency department or a poisoning center immediately.

## **While you are using *Pritaren***

*Things you must do*

Inform doctor of medications taking.

*Things you must not do*

Do not stop taking medication although feeling better after a few days, until the prescribed course is finished.

*Things to be careful of*

If pregnant or become pregnant or breast-feeding during treatment, should not take *Pritaren* unless doctor advised.

## **Side effects**

The most frequent are gastrointestinal effects, usually mild, transient and appear to be unrelated to the dose of the drug.

Gastrointestinal: gastric pain, nausea, vomiting and diarrhoea. Peptic ulcer and gastrointestinal bleeding rarely occurs.

Kidneys: swelling, particularly of ankles, high or low blood pressure, presence of blood or protein in the urine, unexpected change in the amount of urine produced and/or its appearance.

Liver: elevated liver enzymes in blood.

Blood: disorders resulting in unusual bruising or bleeding, pinpoint red spots, fever, sore throat, mouth ulcers, extreme pallor or weakness.

Central nervous system: headache, dizziness, tinnitus, insomnia, depression and drowsiness. Special senses: sensory disturbances, vision, memory, taste and tremor.

Skin: occasionally, rashes or skin eruptions may occur. Hair loss, Stevens-Johnson syndrome, Lyell's syndrome, and photosensitivity reactions have been reported.

Cardiovascular: cases of palpitation, chest pains and hypertension.

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 *Pritaren***

*Storage*

Store in cool, dry place below 30°C. Protect from light. Keep out of reach of children.

*Disposal*

Ask your pharmacist how to dispose of medicines no longer required.

## **Product description**

*What it looks like?*

Light brown, round, biconvex, top-scored, enteric-coated tablet.

*Ingredients:*

- Active ingredient: diclofenac sodium.
- Inactive ingredients: lactose, cornstarch, simethicone, polyvinylpyrrolidone, magnesium stearate, enteric coating materials, talc, titanium dioxide, colour pigment, carbowax.

*MAL No:*

MAL19930134A

## **Manufacturer**

Prime Pharmaceutical Sdn. Bhd.  
1505, Lorong Perusahaan Utama 1  
Taman Perindustrian Bukit Tengah  
14000 Bukit Mertajam, Penang, Malaysia.

## **Product registration holder**

Prime Pharmaceutical Sdn. Bhd.  
Penang, Malaysia.

## **Date of revision**

15/08/2013