

PRITAREN SUPPOSITORIES 12.5MG

Diclofenac sodium 12.5mg

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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.
- has 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 has 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

Children (1-12 years): 12.5mg suppository: 1-3 mg/kg/day in divided doses.

When to use it

Use 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 use a double dose to make up for a missed dose.

If you use too much (overdose)

If used 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 using medication although feeling better after a few days, until the prescribed course is finished. Do not take this product orally, as this product is for rectal use only.

Things to be careful of

If pregnant or become pregnant or breast-feeding during treatment, should not use *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. Rectal use of diclofenac may cause local reactions (itching, burning or exacerbation of piles).

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: 03-78835400, or visiting the website 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?

White suppositories.

Ingredients:

- Active ingredient: diclofenac sodium

- Inactive ingredient: cremphor and polyethylene glycols.

MAL No:

MAL19991901A

Manufacturer

Prime Pharmaceutical Sdn. Bhd.
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Taman Perindustrian Bukit Tengah
14000 Bukit Mertajam, Penang, Malaysia.

Product registration holder

Prime Pharmaceutical Sdn. Bhd.
Penang, Malaysia.

Date of revision

15/08/2013