

DICLAC[®] RETARD TABLET

Diclofenac sodium (100mg)

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What Diclac[®]Retard is used for

Diclac[®]Retard 100mg Tablet is used for intense pain with:

1. Rheumatism (joint/tissue disease) that causes forms of inflammation and degeneration (e.g. rheumatoid arthritis, ankylosing spondylitis (Bechterew's disease), osteoarthritis (degenerative joint disease), and spondylarthritis (inflammation of the joint), painful conditions in the vertebral column (spine) and non-articular rheumatism (musculoskeletal aches and pains which do not arise from joints)

2. Pain, inflammation and swelling due to trauma and /or operations.

3. Menstrual pain

How Diclac[®]Retard works

Diclac[®]Retard contains the active ingredient diclofenac sodium.

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

Before you use Diclac[®]Retard

- When you must not use it

Do not take this medicine if you have an allergy to:

- diclofenac sodium, the active ingredient
- any of the other ingredients listed at the end of this leaflet
- any other similar medicines, such as aspirin or other NSAIDs

Do not take Diclac[®]Retard tablets if:

- you have had asthma, rhinitis (inflammation of the nasal mucous membrane), urticaria (itching or hives) and the symptoms become worsen caused by Aspirin or NSAIDs.
- you have stomach and intestinal ulcers
- you have blood cells disorder
- you have severe heart, kidney or liver problems
- you are children or adolescents

- Before you start to use it

Tell your doctor if you:

- have inherited iron disorder (porphyria)
- have heart, kidney or liver disease
- have or have had ulceration, bleeding and perforation of stomach and intestinal
- have any stomach or bowel disorders including ulcerative colitis or Crohn's disease
- just underwent large operations
- an elderly patient
- have blood disorder
- have infection

Cautions to be taken:

- must restrict your sodium intake
- Diclac[®]Retard 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.

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 Diclac[®]Retard may interfere with each other. It is important to tell your doctor or pharmacist if you are taking:

- Aspirin or other NSAIDs to relieve pain and swelling
- Methotrexate, a medicine to treat cancer

- Medicines to stop blood clot such as warfarin
- Medicines for bacteria infections such as quinolone antibiotics
- Phenytoin, medicine for epilepsy
- Medicines for depression called as Selective Serotonin Reuptake Inhibitors, (SSRIs)
- Medicine for diabetics
- Lithium for mental health problems
- Digoxin, a medicine to treat heart problems
- Diuretics, medicines used to increase the amount of urine
- Medicines known to cause increase of potassium, e.g. potassium-sparing diuretics, ciclosporin, tacrolimus, or trimethoprim
- Medicines to control the immune system such as Ciclosporin
- CYP2C9 enzyme inhibitors such as Voriconazole that used to treat serious fungal infections.
- Corticosteroids, medicines to reduce inflammation.

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

- Pregnancy and lactation

Please consult your doctor before start to use Diclac[®]Retard tablets 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 Diclac[®]Retard tablets against the benefits they expect it will have for you.

How to use Diclac[®]Retard

Always take Diclac[®]Retard tablets exactly as your doctor has told you. The tablets should be swallowed whole together with a sufficient quantity of liquid.

- How much to use

Your doctor will decide your dose as it depends on your conditions. The recommended daily dose ranges between 50 and 150mg of diclofenac sodium

Adults

One Diclac[®]Retard tablet per day. The dosage can be increased to 150mg with the

additional administration of one tablet containing 50mg diclofenac sodium.

Children and adolescents

Diclac®Retard 100mg tablet is not appropriate for children and adolescents due to its high content of active ingredient.

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 take 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.

The following symptoms may be observed in overdose:

- Nausea, vomiting headache, dizziness
- Abdominal pain, bleeding and ulceration (holes) in the stomach or bowel
- Reduced urine output
- Changes in the liver function
- Jaundice (yellowing of the skin and eyes)

While you are using it

Things you must do

- Always take your Diclac®Retard 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 Diclac®Retard.
- 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 Diclac®Retard

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 Diclac®Retard 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 Diclac®Retard may cause dizziness, headaches, or problems with your vision. 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, Diclac®Retard may cause side effects in some patients, particularly when you are taking them for the first time but not everyone will get it.

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

Common side effects:

- Headache, dizziness, nausea, vomiting, diarrhoea
- Indigestion or heartburn, abdominal pain, bloating, decrease of appetite
- Problems with balance (vertigo)
- Increase of liver enzymes
- Skin rash

Rare side effects:

- Immune system disorders: allergic reactions (throat swelling, itchy rash, low blood pressure and shock)
- Nervous system disorder: drowsiness

- Respiratory disorder: asthma (including shortness of breath)
- Gastrointestinal disorders: inflammation of the stomach lining, gastrointestinal bleeding, vomiting of blood, diarrhoea with bleeding, black sticky faeces associated with upper gastrointestinal bleeding, stomach ulcers
- Liver function disorders: inflammation of the liver, yellowing of the skin and eye, dark urine
- Skin disorder: skin rash, hives
- General disorders: fluid retention

Very rare side effects:

- Blood disorders: low platelet count (associated with abnormal bleeding and bruising), low white blood cells (associated with skin pale, weakness and frequent illness), low red blood cells (anaemia)
- Immune system disorders: rapid swelling of the skin
- Psychiatric disorders: altered mental status, depression, difficulty in sleeping, nightmare, irritability (hot temper, impatience and easy to get anger)
- Nervous system disorders: abnormal sensation (tingling and numbness on hands or legs), loss of memory, shaking of hands or body, nervousness, involuntary muscle contraction, inflammation of the brain linings, distortion of the sense of taste, stroke
- Eye disorders: blurred or double vision, loss of vision
- Ear disorders: hearing loss, ringing in the ears
- Heart disorders: rapid heartbeat, chest pain, heart failure and heart attack
- Blood vessel disorder: high blood pressure, blood vessels inflammation
- Respiratory disorder: inflammation of lung tissue
- Gastrointestinal disorders: inflammation of the inner lining of colon and stomach, constipation, inflammation of the mouth and lips, swollen tongue, difficulty in swallowing, inflammation of the pancreas
- Liver function disorders: loss of liver function, liver failure
- Skin disorders: skin inflammation, redness of the skin, skin rash, skin cell death, peeling of skin, hair loss, photosensitivity, red or purple discolorations on the skin, skin itching
- Renal and urinary disorders: blood in urine, protein in urine, inflammation of kidney, kidney failure

The above list includes very rare side effects. You may need urgent medical attention.

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 portal.bpfk.gov.my (Consumers -> Reporting)

Storage and Disposal of Diclac®Retard

- Storage

Store in a cool dry place, not above 25°C. Keep in the original package to protect from light and moisture.

Do not store Diclac®Retard 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 Diclac®Retard 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 Diclac®Retard or the expiry date has passed.

Product Description

- What it looks like

Diclac®Retard 100mg Tablet is a white, round and biconvex tablet.

- Ingredients

Active ingredient

Each tablet contains 100mg of diclofenac sodium

Inactive ingredients

Lactose monohydrate, magnesium stearate and methylhydroxypropylcellulose

- Packing

Boxes of 20, 50 and 100 modified release tablets.

MAL Number

MAL05121170ACZ

Manufacturer

Salutas Pharma GmbH
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D-39179 Barleben

For:

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Product Registration Holder

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