

DICLAC[®] 150 ID MODIFIED RELEASE TABLET

Diclofenac Sodium (150mg)

What is in this leaflet

1. What Diclac[®]150 ID is used for
2. How Diclac[®]150 ID works
3. Before you use Diclac[®]150 ID
4. How to use Diclac[®]150 ID
5. While you are using it
6. Side effects
7. Storage and Disposal of Diclac[®]150 ID
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Diclac[®]150 ID is used for

Diclac[®]150 ID contains the active ingredient diclofenac sodium.

It is indicated for the treatments of:

- Inflammatory and degenerative forms of rheumatism: rheumatoid arthritis (systemic inflammatory disorder that affects joints), Juvenile arthritis (inflammation of the joint in children), ankylosing spondylitis (chronic inflammatory disease of the skeleton), osteoarthritis (degenerative joint disease), spondylarthritis (inflammation of the joint), painful syndromes of the vertebral column, non-articular rheumatism (musculoskeletal aches and pains which do not arise from joints)
- Acute attack of gout
- Post-traumatic and post-operative pain, inflammation and swelling
- Primary dysmenorrhoea (period pain)

How Diclac[®]150 ID works

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

Before you use Diclac[®]150 ID

- When you must not use it

Do not take Diclac[®]150 ID if you:

- Have ever had a reaction or been told that you are allergic to diclofenac sodium or to any of the excipients.
- Any other similar medicines, such as aspirin or other NSAIDs
- Have asthma or have had a skin rash, facial swelling or runny nose after taking other NSAIDs

- Had or have stomach and intestinal ulcers or bleeding in the digestive tract (including fresh blood in the faeces or blood in vomit)
- Have severe heart, kidney or liver problems
- Have blood cells disorder (anaemia) or blood clotting defects
- During the last trimester of pregnancy

- Before you start to use it

Tell your doctor if you:

- History of, or having bleeding or perforation (stomach or intestinal) and any other gastrointestinal problems
- Have brain or other active bleeding
- Have any stomach or bowel disorders including ulcerative colitis or Crohn's disease
- Have ever had asthma
- Have kidney or liver disease
- Have a rare liver condition called porphyria
- Have heart problems, previous stroke or think that you might be at risk of these conditions (e.g. if you have high blood pressure, diabetes or high cholesterol or are a smoker)
- Suffer from any blood or bleeding disorder
- Have an intolerance to some sugars
- Are an elderly patient

Diclofenac 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[®]150 ID may interfere with each other. It is important to tell your doctor or pharmacist if you are taking:

- Aspirin, ibuprofen or other NSAIDs to relieve pain and swelling

- Methotrexate, a medicine used to treat arthritis and some types of cancers
- Medicines used to stop blood clot eg. warfarin
- Digoxin, a medicine for heart failure
- Phenytoin, medicine for seizures
- Lithium or selective serotonin reuptake inhibitors (SSRIs), medicines used to treat depression
- Diuretics, medicines used to increase the amount of urine
- Medicines to suppress the immune system such as Ciclosporin
- Glucocorticoids, anti-inflammatory medicine, used to treat arthritis
- Corticosteroids, anti-inflammatory drug or as steroid hormones
- Diabetic medicines
- Probenecid or sulfinpyrazone, medicines used to treat gout
- Medicines for high blood pressure eg. ACE inhibitors
- CYP2C9 enzyme inhibitors such as Voriconazole, an antifungal medicine

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 breast-feeding

Please consult your doctor before start to use Diclac[®]150 ID 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[®]150 ID against the benefits they expect it will have for you.

How to use Diclac[®]150 ID

Always take Diclac[®]150 ID modified release tablets exactly as your doctor has told you.

The tablet is to be taken unchewed together with a full glass of water. You may take them with, or immediately after food in order to reduce the chance of stomach upset.

- 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® 150 ID modified release tablet daily which corresponds to the maximum daily dose.

Do not exceed the recommended dosage.

Children and adolescents

Diclac® 150 ID modified release 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 takes 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
- Pain and bleeding from the stomach or bowel
- Perforation (hole) and ulceration of the stomach
- 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 Diclac® 150 ID exactly according to the instructions given to you by your doctor or pharmacist. 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.
- 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® 150 ID.
- If you are about to be started on any new medicine, remind your doctor that you are taking Diclac® 150 ID.

- 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® 150 ID 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. This medicine may cause dizziness or light-headedness in some people. 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® 150 ID may cause side effects in some patients, but not everyone will get it.

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

- Stomach upsets including nausea (feeling sick), vomiting, indigestion, loss of appetite, gas, abdominal pain
- Diarrhoea, constipation, tiredness
- Headache, dizziness or spinning sensation
- Drowsiness, disorientation, forgetfulness

- Altered taste sensation
- Change in mood eg. feeling depressed, anxious and irritable
- Nightmares and shakiness
- Tingling or numbness of the hands or feet
- Difficulty hearing, ringing of the ears and blurred vision
- Skin rash and itching
- Symptoms of sunburn that happen more quickly than usual (redness, itching, swelling, blistering of the lips, eyes, mouth and skin)
- Hair loss
- Hypertension (high blood pressure)
- Feeling fast or irregular heart beat
- Swelling of ankles or legs due to fluid build up

If any of the following happen, tell your doctor immediately, or go to Accident and Emergency at your nearest hospital:

- Severe pain or tenderness in the stomach, vomiting blood, bleeding from the back passage, black sticky stools or bloody diarrhoea
- Persistent nausea, loss of appetite, unusual tiredness, vomiting, abdominal pain
- Liver function disorders, including hepatitis and jaundice (yellowing of the skin or eyes, dark urine)
- Presence of protein and blood in the urine, frequent need to urinate
- Signs of frequent infections such as fever, sore throat or mouth ulcers
- Bleeding or bruising more easily than normal; reddish or purplish blotches under the skin
- Signs of anaemia such as tiredness and looking pale
- Difficulty breathing, swelling of the feet or legs (signs of cardiac failure)
- Wheezing, troubled breathing or feelings of tightness in the chest (signs of asthma)
- Chest pains which may be a sign of a heart attack
- Rash, itching on the skin, swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, low blood pressure (hypotension), fainting, shortness of breath (possible allergic reaction)

The above list includes rare and serious 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®150 ID

- 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®150 ID 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®150 ID 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®150 ID or the expiry date has passed.

Product Description

- What it looks like

Diclac®150 ID Modified Release Tablet is a round, bi-layer tablet with white-pink coloured, flat with facet and plain surface.

- Ingredients

- Active ingredient

Each tablet contains 150mg of diclofenac sodium: 25mg diclofenac sodium, immediate release, and 125mg diclofenac sodium, slow release.

- Inactive ingredients

Lactose monohydrate, magnesium stearate, methylhydroxypropylcellulose, maize starch, calcium hydrogen phosphate dihydrate, microcrystalline cellulose, colloidal anhydrous silica, sodium starch glycollate and red ferric oxide E172.

- Packing

It comes in strip of 10 tablets which is supplied in the boxes of 10, 20, 50 and 100 tablets.

- MAL Number

MAL07050894AZ

Manufacturer

Salutas Pharma GmbH
Barleben, Germany.
(A wholly owned subsidiary of HEXAL AG)

For

HEXAL AG
83607 Holzkirchen, Germany.

Product Registration Holder

IMEKS Pharma Sdn Bhd.
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