

AVONAC SR TABLET

Diclofenac Sodium (100mg)

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What Avonac is Used For

Avonac Tablets contain diclofenac and belong to a group of medicines called non-steroid anti-inflammatory drugs (NSAIDs).

Avonac Tablets are used to treat rheumatoid Arthritis (systemic inflammatory disorder that affects joints) & ankylosing spondylitis (chronic inflammatory disease of the skeleton); osteoarthritis (degenerative joint disease) & spondylarthritis (inflammation of the joint); non-articular rheumatism (musculoskeletal aches and pains which do not arise from joints); painful, post-operative & post-traumatic inflammation & swelling; painful inflammatory conditions in gynecology (medical science that deals with the health maintenance and diseases of women, especially of the reproductive organs).

How Avonac Works

Diclofenac Sodium slow release works by reducing hormones that cause inflammation and pain in the body.

Before you use Avonac

- When you must not use it

- You know that you are allergic to Diclofenac Sodium or any of the ingredients in this medicine.
- You have or previously have had a peptic ulcer bleeding or ruptured bowel (hole) in your stomach, or intestines.
- You show any signs of allergy (such as asthma, hay fever or skin rash) to aspirin, ibuprofen or other NSAIDs (anti-inflammatory medicine)
- You have heart disease, kidney or liver failure or bleeding in your brain
- You have had stomach or bowel problems after taking other NSAIDs
- You are in your last three months of pregnancy.

- Before you start to use it

Be careful and check with doctor or pharmacist if:

- You have had an ulcer or some other problem affecting your stomach, or intestines (ulcerative colitis, Crohn's disease)
- You have asthma or wheezing attacks (or if you have had asthma in the past)
- You have any heart, liver or kidney problems
- You are elderly
- You have experienced stomach discomfort, had heartburn or felt nauseous after taking aspirin or any other nonsteroidal anti-inflammatory drugs
- You have a bleeding/blood disorder.

If, at any time while taking Avonac you experience any signs or symptoms of problems with your heart or blood vessels such as chest pain, shortness of breath, weakness, or slurring of speech, contact your doctor immediately.

Tell your doctor if you recently had or you are going to have a surgery of the stomach or intestinal tract before receiving/taking/using Avonac, as Avonac can sometimes worsen wound healing in your gut after surgery.

- Taking other medicines

Please tell your doctor or pharmacist if you are taking or having recently taken any other medicines, including medicines obtained without a prescription.

Avonac Tablets may affect or be affected by the following medicines:

- Anticoagulant tablets (to prevent blood clots, e.g. warfarin)
- Medicines for the treatment of high blood pressure (e.g. beta-blockers)
- Diuretics (to make you pass more water)
- Lithium (for depression)
- Methotrexate (used to treat cancer)
- anti-hypertensive, for high blood pressure
- antidiabetic agents, for diabetes
- captopril, for high blood pressure, heart failure and kidney problem
- triamterene, for the treatment of hypertension and swelling

How to Use Avonac

Make sure you take your tablets exactly as directed by your doctor. The instructions will be written on the label. You should check with your doctor or pharmacist if you are not sure.

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- How much to use

The recommended initial daily dosage is 100mg.

- When to use it

Avonac Tablets should be taken with or after food.

The tablets should be swallowed whole with a glass of water.

- How long to use it

Continue taking Avonac for as long as your doctor recommends.

- If you forget to use it

If you miss a dose, leave it out and take the next dose whenever it is due. After that, just carry on as before. Do not take double the dose. If you have any further questions about these tablets, ask your doctor or pharmacist.

- If you use too much (overdose)

If you (or someone else) take too many of these tablets, contact your doctor, or hospital immediately for advice. Bring the pack with any remaining tablets with you.

While you are using Avonac Tablets

- Things you must do

- You should take the lowest dose of Avonac Tablets for the shortest possible time, particularly if you are underweight or elderly
- There is a small increased risk of heart attack or stroke when you are taking any medicine like Avonac Tablets. The risk is higher if you are taking high doses for a long time. Always follow the doctor's instructions on how much to take and how long to take it for

• While you are taking these medicines your doctor may want to give you a check-up from time to time

• If you have a history of stomach problems when you are taking NSAIDs, particularly if you are elderly, you must tell your doctor straight away if you notice any unusual symptoms

• Because it is an anti-inflammatory medicine, Avonac Tablets may reduce the symptoms of infection, for example, headache and high temperature. If you feel unwell and need to see a doctor, remember to tell him or her that you are taking Avonac Tablets.

• Discontinue Avonac Tablets immediately if rash occurs and tell your doctor straight away.

- Things you must not do

Pregnancy, breast feeding and fertility

• Do not take Avonac Tablets if you are pregnant (or think you may be), or breast feeding unless your doctor has decided that it is in your best interests.

• If used, the lowest effective dose should be used. You should NOT take these tablets during the last three months of pregnancy as they may affect the baby.

• Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines:

• If you feel visual disturbances, headaches, dizziness or drowsiness when you start to use Avonac Tablets, do not drive or use machines until the effect has worn off.

- Things to be careful of

- Severe liver or kidney damage
- Peptic ulceration or gastrointestinal bleeding
- Asthma
- Unusual narrowing or constriction of the airways
- Heart disease
- Elderly

Side Effects

- Abdominal pain, belching.
- Slight dizziness or headache.
- Allergy, mild skin rash, swelling in the feet and ankles.
- Depression.
- Drowsiness.
- Insomnia & blurred vision. Impairment of liver & kidney function.
- Reduction in the number of white blood cells

Uncommon: Myocardial infarction, cardiac failure, palpitations, chest pain.

Cases of hair loss, bullous eruptions, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), and photosensitivity reactions have been reported.

Frequency "not known": Chest pain, which can be a sign of a potentially serious allergic reaction called Kounis syndrome.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

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Storage and disposal of Avonac

- Storage

- Store below 30°C and protect from moisture.
- Keep out of reach of children.
- The shelf life is 3 years.

- Disposal

- Do not throw away any medicines via wastewater or household waste.
- Ask your pharmacist how to throw away medicines you no longer use.
- These measures will help protect the environment.

Product Description

- What it looks like

Avonac Tablets are pink to pink-orange, round, biconvex, film-coated tablets.

- Ingredients

-Active ingredient

Diclofenac sodium

-Inactive ingredients

Methylene Chloride, Hydroxypropyl Methylcellulose, Povidone K-30, Alcohol 95%, Titanium Dioxide, Sucrose Powder, Iron Sesquioxide Red, Colloidal Silicon Dioxide, Cetyl Alcohol, Polysorbate 80, Magnesium Stearate, Talc.

- MAL number:

MAL10053668ACZ

Manufacturer

Synmosa Biopharma Corporation, Synmosa Plant No. 6, Kuang Yeh 1st Road, Hu-Kuo Hsiang, Hsin-Chu Ind. Park, Hsin Chu Hsien, Taiwan, R.O.C.

Product Registration Holder

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