

VOTAN SR F.C. TABLETS

Diclofenac Sodium (100mg)

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What Votan SR F.C. Tablets is used for

It is used for:

- joint and bone problems such as arthritis (rheumatoid arthritis, osteoarthritis, ankylosing spondylitis).
- back pain.
- muscle or tissue pain not related to the joints.
- pain, swelling, or inflammation after injury or surgery.
- period pain (menstrual cramps).

How Votan SR F.C. Tablets works

Votan SR F.C. Tablets contains active ingredient called diclofenac sodium. It belongs to a group of medicines called non-steroidal anti-inflammatory agents (NSAIDs) which reduces fever, pain and inflammation.

Before you use Votan SR F.C. Tablets

- When you must not use it

Do not use Votan SR F.C. Tablets if you:

- are allergic to diclofenac sodium or any other ingredients of this medicine (listed in Product Description).
- have stomach ulcer.
- history of asthma, skin rash (hives), or severe nose allergy (rhinitis) triggered by aspirin or similar painkillers.
- suffer from severe heart, kidney or liver problems.
- are in the last three months of pregnancy.

- Before you start to use it

You should check with your doctor before taking this medicine if you:

- have heart disease, high blood pressure, diabetes, high cholesterol, or if you smoke.
- have or had ulceration, bleeding and perforation of the stomach and intestinal, or at risks of getting stomach problems like elderly, frequently drink alcohol, or smoking.
- have bleeding disorder.

- have kidney, liver or heart problem.
- not recommended for children and use in caution in elderly people.

Pregnancy and lactation

You should check with your doctor if you are or think you may be pregnant, planning for pregnancy or if you are breastfeeding before taking any medication.

You should not take diclofenac during the last 3 months of pregnancy as it could harm your unborn child and cause problems during delivery.

Diclofenac passes into breast milk in small amounts. Therefore, it should not be used during breastfeeding in order to avoid undesirable effects in the baby.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

You should talk to your doctor or pharmacist if you are taking:

- Lithium, medicine for depression.
- Digoxin, medicine for heart problem.
- Diuretic, potassium sparing diuretic, water pills.
- Other NSAIDs, medicine for pain.
- Anticoagulants, medicines for blood thinning effect.
- Antidiabetes, medicines for diabetes.
- Methotrexate, a medicine used to treat rheumatoid arthritis, as well as some types of cancers.

How to use Votan SR F.C. Tablets

Follow all directions given to you by your doctors and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor and pharmacist for help.

- How much to use

Oral administration.

1 tablet daily, preferably to be taken in the evening with liquid during mealtimes.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Swallow the tablet whole with a glass of water. Do not break, crush, or chew the tablet.

Your doctor may adjust the dose according to your condition. Always take the lowest effective dose for the shortest time needed to control your symptoms.

Important:

- This medicine is not usually recommended for patients with heart disease (heart failure, heart attack, stroke, circulation problems) or uncontrolled high blood pressure.
- If you have heart problems, high blood pressure, diabetes, high cholesterol, or if you smoke, your doctor will carefully decide if this medicine is suitable for you.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Use this medicine for the duration that your doctor recommends.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

Consult your doctor or pharmacist on what you should do if you forget to use it.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too much tablets may cause low blood pressure, kidney failure, convulsions, stomach irritation and difficulty in breathing.

While you are using Votan SR F.C. Tablets

- Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists treating you that you are taking Votan SR F.C. Tablets.
- Tell your doctor immediately if you become pregnant while taking this medication.
- Take Votan SR F.C. Tablets only with a doctor's prescription.

- Things you must not do

- Do not take any new medicines without consulting your doctor.
- Do not give Votan SR F.C. Tablets to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of**Driving and using machines**

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side Effects

Like all medicines, Votan SR F.C. Tablets can cause side effects, although not everybody gets them. The side effects are;

Gastro-intestinal tract:

- Occasional: gastric pain, nausea, vomiting, diarrhoea.
- Rare: gastrointestinal tract bleeding.
- Very rare: stomach ulcer with obstruction or perforation, disturbances in lower gut.

Central nervous system:

- Occasional: headache, dizziness or vertigo
- Rare: drowsiness
- Very rare: blurred vision, double vision, ringing in the ear, difficulty to sleep, irritability, seizure.

Skin

- Occasional: rashes or skin eruptions (peel off)
- Rare: hives.
- Very rare: severe skin reactions with blisters, peeling, or redness (including serious conditions like Stevens-Johnson syndrome or toxic skin reactions), eczema, hair loss, or skin becoming sensitive to sunlight.

Kidney

- Very rare: sudden kidney failure or damage, blood in the urine.

Liver

- Rare: liver inflammation (hepatitis) with or without jaundice (yellowing of the skin and whites of your eye).
- Very rare: sudden liver damage.

Blood

- Very rare: low platelet, reduction in the number of white blood cells, abnormal breakdown of red blood cells, aplastic anaemia (body stops producing enough new blood cells), atherothrombotic events.

Heart:

Not common: heart attack, heart failure, strong pounding of heartbeat, chest pain and acute heart problem.

Not known: Kounis syndrome.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

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)].

Storage and disposal of Votan SR F.C. Tablets**- Storage**

Keep out of the reach and sight of children.

Store below 30 °C. Protect from light and moisture.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description**- What it looks like**

Pale sunset yellow, biconvex film-coated tablet.

- Ingredient(s)

- Active Ingredient

- Diclofenac Sodium

- Inactive Ingredients

- Lactose
- Cetyl Alcohol
- Silicon Dioxide
- Polyvinylpyrrolidone
- Magnesium Stearate
- 95% Alcohol
- Hydroxypropyl Methylcellulose
- Opaspray White (50%)
- Sunset Yellow FCF

- MAL number

MAL10070587AZ

Manufacturer

Taiwan Biotech Co., Ltd.
22, Chieh Shou Road, Taoyuan,
Taiwan R.O.C

Product Registration Holder

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