

Voren® Enteric Microencapsulated Capsule

Diclofenac Sodium (50mg)

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What Voren® is used for

It is used for:

1. Inflammatory and degenerative forms of rheumatism
 - 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)
2. Non-articular rheumatism (musculoskeletal aches and pains which do not arise from joints).
3. Post traumatic inflammation and swelling.

How Voren® works

Voren® contains a substance called Diclofenac. It belongs to a group of medicines called non-steroidal anti-inflammatory agents (NSAIDs) which reduces fever, pain and inflammation.

Voren® enteric-coated allow medication to be distributed on a larger surface area which can reduce the risk of damage caused by the dumping of the medication in an area. Moreover, Voren® enteric-coated can also achieve a more stable plasma concentration, releases the medication more slowly, providing better dosage accuracy and increased bioavailability.

Before you use Voren®

- When you must not use it
Do not use Voren®:

- If you are aspirin-sensitive.
- If you have active stomach ulcer or stomach and intestinal bleeding.
- If you have allergy or hypersensitivity to Diclofenac, other NSAIDs or any other ingredients listed at the end of this leaflet
- Before you start to use it
Tell your doctor or pharmacist:
 1. If you have heart disease or stroke
 2. If you have high blood pressure
 3. Diclofenac may cause severe skin reactions, e.g., 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.
 4. If you have or have had ulceration, bleeding and perforation of the stomach and intestinal
 5. If you suffering from dyspepsia (discomfort at the epigastric region due to digestion problem).
 6. If you have bleeding disorder
 7. If you have kidney and liver problem
 8. If you are concomitantly administering anti-inflammatory drugs or other non-steroidal anti-inflammatory drugs including aspirin (blood thinning agent)
 9. If you have fluid retention or heart failure.
 10. If you have infection.
 11. Please consult your doctor before start to use Voren® 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 Voren® against the benefits they expect it will have for you.

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 Voren®, as Voren® can sometimes worsen wound healing in your gut after surgery.

- 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.

Some medicines when taken with Voren® may interfere with each other. These include:

1. Potassium-sparing diuretics, water pills
2. Aspirin, for blood thinning
3. Warfarin, medicine to prevent blood clot
4. Digoxin, medicine for heart
5. Methotrexate, a medicine used to treat rheumatoid arthritis, as well as some types of cancers
6. Cyclosporin medicine used after organ transplant
7. Oral hypoglycemics, for diabetes

How to use Voren®

- How much to use

Adult: 1 capsule twice daily

Please follow the instruction given by your doctor. Your doctor might want to prescribe you the lowest effective dose for the shortest duration.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking Voren® for as long as your doctor recommends.

- If you forget to use it

If you miss a dose of Voren®, take it as soon as possible. If it is approaching time for the next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

- If you use too much (overdose)

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

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poisoning. You may need urgent medical attention.

Taking too many capsules may cause stomach and intestinal, kidney, and brain toxicities, stomach and intestinal bleeding, kidney failure, convulsion and coma.

While you are using it

- 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 Voren[®].

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Voren[®] to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Be careful driving or operating machinery until you know how Voren[®] affects you.

Side effects

Stomach and intestinal side effects are common.

Other side effects are:

- Central nervous system: Headache, insomnia, somnolence (sleepiness) and dizziness
- Kidney toxicity, edema (swelling), palpitation (feel your heartbeat), minor hearing disorders, blood disorder (Thrombocytopenia and eosinophilia).
- Skin disorder: rashes or skin eruptions
- Cases of hair loss, bullous eruption, 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.

Like all medicines, Voren[®] can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking 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 Voren[®]

- Storage

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

A size #4 red cap and transparent body hard gelatin capsule containing milky-white pellets.

- Ingredients

- Active ingredient:

Diclofenac sodium

- Inactive ingredients:

Capsule #4

- MAL number:

MAL 19987985AZ

Manufacturer & Product Registration Holder

Y.S.P. Industries (M) Sdn. Bhd.
(199001001034)

Lot 3, 5, 7 & 12, Jalan P/7, Section 13, Kawasan Perindustrian Bandar Baru Bangi, 43000 Kajang, Selangor, Malaysia.

Ordering Line: 1 800 88 3027

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