

VOREN ENTERIC COATED TABLET

Diclofenac sodium (25mg, 50mg)

What is in this leaflet

1. What VOREN ENTERIC COATED TABLET is used for
2. How VOREN ENTERIC COATED TABLET works
3. Before you use VOREN ENTERIC COATED TABLET
4. How to use VOREN ENTERIC COATED TABLET
5. While you are using it
6. Side effects
7. Storage and Disposal of VOREN ENTERIC COATED TABLET
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What VOREN ENTERIC COATED TABLET is used for

VOREN ENTERIC COATED TABLET to relieve

1. Inflammatory and degenerative forms of rheumatism; rheumatoid arthritis (systemic inflammatory disorder that affects joints); ankylosing spondylitis (chronic inflammatory disease of the skeleton) and osteoarthritis (degenerative joint disease).
2. Non-articular rheumatism (musculoskeletal aches and pains which do not arise from joints), inflammation and swelling after traumatic event.

How VOREN ENTERIC COATED TABLET works

VOREN enteric coated tablet contains a substance called Diclofenac. Diclofenac is a non-steroidal anti-inflammatory drugs (NSAIDs) which reduces inflammation, pain and fever.

Before you use VOREN ENTERIC COATED TABLET

- When you must not use it

Do not take VOREN ENTERIC COATED TABLET if you:

- are allergic to Diclofenac or other ingredients of VOREN ENTERIC COATED TABLET.
- Have a history of allergic reactions (swollen eyes or mouth, difficulty breathing, rashes) to similar painkillers such as aspirin, or other NSAIDs.

- Before you start to use it

Tell your doctor if:

1. You have any heart problem or risk of thrombosis (forming blood clot).
2. You have high blood pressure
3. You have or have had ulceration, bleeding and perforation of the stomach and intestinal
4. You have asthma and constriction of the airway
5. VOREN ENTERIC COATED TABLET 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.
6. Please consult your doctor before start to use VOREN ENTERIC COATED TABLET 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 ENTERIC COATED TABLET against the benefits they expect it will have for you.
7. 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 ENTERIC COATED TABLET, as VOREN ENTERIC COATED TABLET can sometimes worsen wound healing in your gut after surgery.

- Taking other medicines

Seek for your doctor or pharmacist advice if you intended to use VOREN ENTERIC COATED TABLET together with other medication. Besides, you must also inform them about all the medicines you are taking, including those without a prescription.

How to use VOREN ENTERIC COATED TABLET

- How much to use

VOREN ENTERIC COATED TABLET should be taken according to prescription by the doctor. Osteoarthritis patients need to take 100 - 150mg a day, Rheumatoid arthritis 150 - 200 mg per day and for patients with ankylosing spondylitis 100 - 125mg a day. It may be given in separate doses in one day.

Follow all directions given to you by your doctor 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 or pharmacist for help.

- When to use it

VOREN ENTERIC COATED TABLET should be taken according to the time advised by your doctor or pharmacist.

- How long to use it

VOREN ENTERIC COATED TABLET should be taken as your doctor advised you to do so.

- If you forget to use it

Consult your doctor or pharmacist on what you should do 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.

- 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 poisoning. You may need urgent medical attention.

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 ENTERIC COATED TABLET.

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 ENTERIC COATED TABLET 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 ENTERIC COATED TABLET affects you.

Side effects

Like all medicines, VOREN ENTERIC COATED TABLET can cause side effects, although not everybody gets them. Possible side effects of VOREN ENTERIC COATED TABLET are gastrointestinal side effects such as nausea & vomiting. Other side effects are rare, which includes insomnia (difficulty to fall asleep), hearing problem, rashes, palpitation (feel your heart beat fast), headache, dizziness, vertigo (spinning), pruritus (itchiness), depression, blurred vision, liver function disorder (jaundice).

Severe skin reaction (rashes or skin eruptions, bullous eruptions, erythema multiforme, Stevens-Johnson Syndrome, toxic epidermal, necrolysis), hair loss, sensitive to light 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)].

Storage and Disposal of VOREN ENTERIC COATED TABLET**- Storage**

Keep out of the reach and sight of children.

Store below 30°C, protect from light & 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**

VOREN ENTERIC COATED TABLET 50mg:

A yellow round color enteric coated tablet

VOREN ENTERIC COATED TABLET 25mg:

A yellow round color enteric coated tablet

- Ingredients

VOREN ENTERIC COATED TABLET 25mg:

- Active Ingredient-
Diclofenac sodium

- Inactive Ingredients-
Titanium dioxide, hydroxypropyl methylcellulose, metacrylic acid copolymer, triethyl citrate, Avicel, magnesium stearate, sodium starch glycolate, polyethylene glycol, dimethylpolysiloxane, sunset yellow, quinoline yellow.

VOREN ENTERIC COATED TABLET 50mg:

- Active Ingredient-
Diclofenac sodium

- Inactive Ingredients-

Povidone isopropyl alcohol, titanium dioxide, hydroxypropyl methylcellulose, metacrylic acid copolymer, riboflavin, triethyl citrate, microcrystalline cellulose, magnesium stearate, colloidal silicon dioxide, sodium starch glycolate, polyethylene glycol, dimethylpolysiloxane and sunset yellow lake.

- MAL number(s):

VOREN ENTERIC COATED TABLET 25mg: MAL 19930606AZ

VOREN ENTERIC COATED TABLET 50mg: MAL 19930605AZ

Manufacturer & Product Registration Holder

Y.S.P Industries (M) Sdn. Bhd.
Lot 3, 5 & 7, Jalan P/7, Section 13,
Kawasan Perindustrian Bandar Baru
Bangi, 43000 Kajang, Selangor Darul
Ehsan, Malaysia.

Date of revision

20/09/2022

Serial Number

BPFK(R4/1)101215/00488