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 tablet 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 bioavaibility.

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 Sydrome. 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 administer 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.

- 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 poisoning. You may need urgent medical attention.

Taking too many tablets 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 heart beat), minor hearing disorders, blood (Thrombocytopenia and disorder eosinophilia).
- Skin disorder: rashes or skin eruptions
- Cases of hair loss, bullous eruption, multiforme, Stevens erythema Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), and photosensitivity reactions have been reported.

Like all medicines, VOREN can cause side effects, although not everybody gets them.

your doctor or pharmacist Visit 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 calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

Storage and Disposal of VOREN

Storage

Keep in a tight container. 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 hard gelatin of red cap and transparent body containing milkywhite pellets.

- Ingredients

Active ingredient: Diclofenac sodium

- MAL number:

MAL19987985A

Manufacturer & Product Registration Holder

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