

VOREN SUPPOSITORIES

Consumer Medication Information Leaflet (RiMUP)

Diclofenac sodium (12.5mg, 25mg, 50mg)

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What VOREN SUPPOSITORIES is used for

VOREN SUPPOSITORIES is indicated for chronic rheumatic arthritis (systemic inflammatory disorder that affects joints), degenerative osteoarthritis (degenerative joint disease) and painful post-operative inflammation.

How VOREN SUPPOSITORIES works

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

Rectally administered Diclofenac Sodium is rapidly and almost completely absorbed and distributed to blood, liver and kidneys.

Before you use VOREN SUPPOSITORIES

-When you must not use it

Do not use VOREN SUPPOSITORIES:

1. If you allergy or hypersensitivity to Diclofenac Sodium or any other ingredients listed at the end of this leaflet
2. If you have or have had any inflammatory lesions of the rectum or anus
3. If you are under 12 months of age
4. If you have active or suspected stomach ulcer or stomach and intestinal bleeding.
5. If you have had asthma, rhinitis (Inflammation of the nasal mucous membrane), urticaria (itching or

hives) and the symptoms become worsen caused by Aspirin or NSAIDs.

-Before you start to use it

Please kindly inform your doctor:

1. If you have blood disorder
2. If you have heart disease or stroke
3. If you have hypertension
4. If you have fluid retention or oedema
5. If you have infection
6. If you have liver, or kidney problem
7. If you are elderly
8. If you have or have had ulceration, bleeding and perforation of the stomach and intestinal
9. If you suffering from dyspepsia (discomfort at the epigastric region due to digestion problem).
10. If you have liver porphyria
11. VOREN SUPPOSITORIES 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.

-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 SUPPOSITORIES may interfere with each other. These include:

1. Potassium sparing diuretic, water pills
2. Aspirin, a medicine used to prevent blood clot
3. Warfarin, a blood thinning agent
4. Digoxin, a heart medicine
5. Methotrexate, a medicine used to treat rheumatoid arthritis, as well as some types of cancers
6. Cyclosporin, a medicine used in organ transplant
7. Oral hypoglycemic agents, medicines used in diabetes

How to use VOREN SUPPOSITORIES

-How much to use

Adult: 100mg, usually to be used at night.

Maximum total daily dose is 150mg.

Children: 0.5 - 2mg/kg body weight daily, in 2 - 3 divided doses.

To be inserted deep into the rectum.

Your doctor will prescribe the lowest effective dose for the shortest possible duration for you.

Please refer to your doctor or pharmacist for the method of suppository insertion into the rectum.

-When to use it

Please refer to doctor or pharmacist.

-How long to use it

Please refer to doctor or pharmacist.

-If you forget to use it

If you miss a dose of VOREN SUPPOSITORIES, 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 may cause kidney and central nervous system toxicities, kidney failure, fit 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 SUPPOSITORIES

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 SUPPOSITORIES 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 SUPPOSITORIES affects you.

Side effects

Local irritation; Itching, burning and increased bowel movement.

Central nervous system: Dizziness, headache, insomnia, drowsiness.

Hematologic system (blood): Hemolytic anemia.

Dermatologic system (skin): Rash, pruritis, skin eruptions, eczema, urticaria and erythema.

Hepatic (liver): Jaundice, hepatitis.

Ophthalmological (eyes): Blurred vision.

Allergic: Hypersensitivity reaction.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell. Other side effects not listed above may occur in some people.

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 SUPPOSITORIES

- Storage

Store below 25°C, protect from light & moisture.

- Disposal

If your doctor or pharmacist tells you to stop using VOREN SUPPOSITORIES or the batch has passed the expiry date, ask your doctor or pharmacist what to do with any that is left over.

Product Description

- What it looks like

Voren Suppositories 12.5mg

A white to pale yellow colour spindle suppositories

Voren Suppositories 25mg

A white to pale yellow colour spindle suppositories

Voren Suppositories 50mg

A white to pale yellow colour spindle suppositories

- Ingredients

- Active ingredient
Diclofenac sodium

- Inactive ingredients
Witepsol

- MAL number:

Voren Suppositories 12.5mg:

MAL19987004A

Voren Suppositories 25mg:

MAL19985559A

Voren Suppositories 50mg:

MAL19985560A

Manufacturer and 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 D.E., Malaysia.

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