

RHEMOFENAX CAPSULE/TABLET

Diclofenac Sodium (25mg, 50mg)

What is in the leaflet

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

What RHEMOFENAX is used for

RHEMOFENAX is used to treat:

- Inflammatory and degenerative forms of rheumatism (joint and muscle disease)
- rheumatoid arthritis (systemic inflammatory disorder that affects joints), ankylosing spondylitis (chronic inflammatory disease of the skeleton)
- osteoarthritis (degenerative joint disease) and spondylarthritis (inflammation of the joint).
- painful syndromes of the vertebral column (spine)
- non-articular rheumatism (musculoskeletal aches and pains which do not arise from joints)
- painful after trauma and after operation inflammation and swelling.

How RHEMOFENAX works

RHEMOFENAX contains the active ingredient diclofenac sodium.

RHEMOFENAX belongs to a group of medicines called Non-Steroidal Anti-Inflammatory Drugs (or NSAIDs) which reduces the inflammation and pain

Before you use RHEMOFENAX

- When you must not use it

Do not take this medicine if you have an allergy to:

- diclofenac sodium, the active ingredient
- any of the other ingredients listed at the end of this leaflet

Do not take RHEMOFENAC if:

- you have or have had peptic ulcer
- 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.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

- Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- heart problem
- you have a peptic ulcer (ie stomach or duodenal ulcer), a recent history of one, or have had peptic ulcers before.
- you have or have had inflammation and/or ulceration of the lining of the stomach or bowel.
- a tendency to bleed or other blood problems
- swellings on the skin, itching, hives or any other skin rash
- kidney disease
- liver disease
- high blood pressure
- elderly
- suffering from dyspepsia (discomfort at the epigastric region due to digestion problem).

Diclofenac 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.

Tell your doctor if you are pregnant, plan to become pregnant or breastfeeding. Your doctor will discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking RHEMOFENAX.

- Taking other medicines

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

Some medicines and RHEMOFENAX may interfere with each other.

These include:

- other NSAIDs
- warfarin or other medicines used to prevent blood clotting
- lithium, a medicine used to treat some types of depression
- digoxin, a medicine for heart problem
- diuretics, medicines used to increase amount of urine
- medicines used to treat diabetes
- methotrexate, a medicine used to treat some cancers
- cyclosporine, a medicine used in patients who have received organ transplants

These medicines may be affected by RHEMOFENAX or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use RHEMOFENAX

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

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

- How much to use

The dosage of RHEMOFENAX depends on the condition it is being used to treat.

Take RHEMOFENAX as directed by your doctor or pharmacist.

The usual starting dose of RHEMOFENAX is 100mg to 150mg.

If you are elderly, doctor may prescribe a lower dosage for you.

Do not take more tablets than your doctor has recommended.

Ask your doctor or pharmacist if you are unsure of the correct dose for you. They will tell you exactly how much to take.

- When to use it

Take RHEMOFENAX with with a full glass of water.

This may help reduce the possibility of stomach upset.

- How long to use it

Do not use RHEMOFENAX for longer than your doctor says.

- If you forget to use it

Take your dose as soon as you remember, and continue to take it as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

- If you use too much (overdose)

Immediately telephone your doctor for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much RHEMOFENAX.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Taking too much RHEMOFENAX may cause hypotension (low blood pressure), kidney failure, fit, stomach and intestinal irritation and respiratory depression.

While you are using it

- Things you must do

If you become pregnant while taking RHEMOFENAX tell your doctor immediately.

If you are about to start taking any new medicine tell your doctor and pharmacist that you are taking RHEMOFENAX.

Tell all of the doctors, dentists, and pharmacists that are treating you that you are taking RHEMOFENAX.

- Things you must not do

Do not give RHEMOFENAX to anyone else, even if they have the same condition as you.

Do not use RHEMOFENAX to treat any other complaints unless your doctor tells you to.

- Things to be careful of

Be careful driving or operating machinery until you know how RHEMOFENAX affects you.

Side effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- Gastrointestinal tract: Epigastric pain, other gastrointestinal symptoms, eg. nausea, vomiting, diarrhoea, abdominal cramps, dyspepsia, flatulence, gastrointestinal bleeding, haematemesis (bleeding vomiting), melaena (bleeding stools), peptic ulcer with or without bleeding or perforation, bloody diarrhoea, constipation.
- Central (and peripheral) nervous system: Headache, dizziness or vertigo,

tiredness, sensory disturbances, including paraesthesia, memory disturbances, disorientation, disturbances of vision (blurred vision, diplopia), impaired hearing, tinnitus (ringing in the ear), insomnia, irritability, convulsions, depression, anxiety, nightmares, tremor, psychotic reactions, taste disturbances.

- Skin: Skin rash, urticarial, bullous eruptions, eczema, erythema multiforme (dermatology infection), Stevens-Johnson syndrome, Lyell's syndrome (acute toxic epidermolysis), erythroderma (exfoliative dermatitis), loss of hair, photosensitivity reactions, purpura (including allergic purpura).
- Kidney: Acute renal failure, haematuria (blood in urine), proteinuria (protein in urine), interstitial nephritis, papillary necrosis (kidney problem).
- Liver: Hepatitis with or without jaundice, fulminant hepatitis.
- Blood: Thrombocytopenia (deficiency of platelets in the blood), leucopenia (decrease in the number of white blood cells), agranulocytosis, anaemia, haemolytic anaemia, aplastic anaemia.
- Hypersensitivity reactions: eg. asthma, systemic anaphylactic / anaphylactoid reactions (including hypotension).

These are the more common side effects of RHEMOFENAX.

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and disposal of RHEMOFENAX

- Storage

Keep your medicine in the original container. If you take it out of its original container it may not keep well.

Keep your medicine in a place where the temperature stays below 25°C. Protect from light.

Do not store RHEMOFENAX or any other medicine in the bathroom or near a sink. Do

not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

- Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product Description

- What it looks like

RHEMOFENAX CAPSULE 25MG

- light brown/grey capsule with 'DUO 861' marking.

RHEMOFENAX CAPSULE 50MG

- maroon/maroon capsule with 'DUO 861' marking.

RHEMOFENAX TABLET
25MG

- A light blue caplet with 'DUO' on one side and scored 'DUO' on another side.

RHEMOFENAX TABLET
50MG

- A blue, round caplet with 'd 861' marking on one side.

- Ingredients

Active ingredient

RHEMOFENAX
CAPSULE 25MG

- Each capsule contains 25mg diclofenac sodium

RHEMOFENAX
CAPSULE 50MG

- Each capsule contains 50mg diclofenac sodium

RHEMOFENAX TABLET
25MG

- Each tablet contains 25mg diclofenac sodium

RHEMOFENAX TABLET
50MG

- Each tablet contains 50mg diclofenac sodium

Inactive ingredients:

RHEMOFENAX
CAPSULE 25MG

- Magnesium stearate
- Lactose

RHEMOFENAX
CAPSULE 50MG

- Magnesium stearate
- Lactose

RHEMOFENAX TABLET
25MG

- Aerosil
- Avicel
- Cornstarch
- Lactose
- Brilliant blue
- Tween 80
- Talcum

- Promigel
- Magnesium stearate

RHEMOFENAX TABLET
50MG

- Talcum
- Promigel
- Brilliant blue
- Lactose
- Aerosil
- Avicel
- Cornstarch
- Magnesium stearate

- MAL number

RHEMOFENAX
CAPSULE 25MG
MAL19880389AZ

RHEMOFENAX
CAPSULE 50MG
MAL19880388AZ

RHEMOFENAX TABLET
25MG
MAL19890255AZ

RHEMOFENAX TABLET
50MG
MAL19890256AZ

Manufacturer

Duopharma (M) Sdn. Bhd.
(42491-M)
Lot. 2599, Jalan Seruling 59,
Kawasan 3, Taman Klang Jaya,
41200 Klang, Selangor Darul
Ehsan, Malaysia.

Product Registration Holder

Duopharma (M) Sdn Bhd. Bhd.
(42491-M)
Lot. 2599, Jalan Seruling 59,
Kawasan 3, Taman Klang Jaya,
41200 Klang, Selangor Darul
Ehsan, Malaysia.

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