

Patient Information Leaflet (PIL)

Divido® 75 mg Dual Release Capsules
Diclofenac Sodium

Read all of this leaflet carefully before you start taking this medicine

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. Serious side effects

Cardiovascular Risk

The risk of heart attack or stroke can occur as early as the first weeks of using an NSAID.

The risk may increase with longer use of the NSAID.

The risk for heart attack or stroke is similar for all NSAIDs.

NSAIDs can increase the risk of heart attack or stroke in patients with or without heart disease or risk factors for heart disease. A large number of studies support this finding, with varying estimates of how much the risk is increased, depending on the drugs and the doses studied.

In general, patients with heart disease or risk factors for it have a greater likelihood of heart attack or stroke following NSAID use than patients without these risk factors because they have a higher risk at baseline.

Patients treated with NSAIDs following a first heart attack were more likely to die in the first year after the heart attack compared to patients who were not treated with NSAIDs after their first heart attack.

There is an increased risk of heart failure with NSAID use.

Divido is contraindicated for the treatment of perioperative pain in the setting of coronary artery bypass graft (CABG) surgery.

Gastrointestinal Risk

NSAIDs cause an increased risk of serious gastrointestinal adverse events including inflammation, bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients are at greater risk for serious gastrointestinal events.

2. What **Divido** is and what it is used for

Diclofenac sodium, the active ingredient in **Divido** 75 mg capsules, is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs) and is used to reduce pain and inflammation. Some of the pellets inside the **Divido** capsule shell release diclofenac quickly to give a rapid effect (gastro-resistant pellets). The remainder of the pellets dissolve more slowly to produce a longer lasting effect (prolonged release pellets).

Divido can be used for the treatment of pain and inflammation due to:

- Acute attacks of gout.
- Acute musculo-skeletal disorders (for example frozen shoulder, inflamed tendons).
- Dental or other minor surgery.
- Joint disorders (such as ankylosing spondylitis, osteoarthritis, rheumatoid arthritis).
- Traumatic conditions (including sprains, strains, dislocations, fractures).
- Low back pain.

3. Before you take **Divido**

Do not take **Divido**

- If you have had an allergic reaction to any of the ingredients in **Divido** 75 mg capsules.
- If you have had an allergic reaction to ibuprofen, aspirin or other NSAIDs.
- If you have **severe** liver, kidney or heart failure.
- If you have ischemic heart disease
- If you have peripheral arterial disease.
- If you have cerebrovascular disease.
- If you have congestive heart failure (New York Heart Association (NYHA) classification II-IV)
- If you are in the last three months of pregnancy.
- If you have a peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach (for example, passed black tarry or bloody stools or vomited blood or dark particles that look like coffee grounds), or have had two or more episodes of peptic ulcers, stomach bleeding or perforation.

- If your child is under 14 years old.

If you think any of these apply to you, or you are unsure, do not take the capsules. Talk to your doctor first and follow the advice given.

Take special care with **Divido**

Talk to your doctor before taking **Divido** if you are also taking other NSAIDs, as **Divido** should not be used at the same time as other NSAIDs.

If you have any of the following health problems, you may need to take special care while taking the medicine as your condition could get worse:

- Asthma, hayfever or other allergies, polyps in your nose, difficulty breathing (COPD), long term respiratory infections.
- Crohn's disease or ulcerative colitis.
- SLE (Systemic Lupus Erythematosus), an inflammation of the connective tissue.
- Heart, kidney or liver problems (your doctor may want to carry out some tests while you are taking the capsules).
- High blood pressure.
- Acute porphyria.
- Blood clotting problems.

Tell your doctor if you are about to have major surgery.

Because **Divido** is a NSAID, it can make the symptoms of an infection (such as fever, pain) less noticeable.

Medicines such as **Divido** may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

If you have heart problems, previously had a stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. You may still be able to take **Divido** if you are taking these medicines, but you must discuss this matter with your doctor and be advised before taking any of the medicines listed below:

- Other painkillers or anti-inflammatory drugs (NSAIDs), including aspirin, or any other medicines used to prevent platelet clumping.
- Medicines to lower blood pressure (anti-hypertensives).
- Anti-coagulants, such as warfarin (to "thin" the blood).
- Anti-diabetic tablets.
- Certain antibiotics, such as ciprofloxacin.
- Ciclosporin or tacrolimus (immunosuppressive medicines, used to dampen down the body's immune reactions).
- Corticosteroids.
- Mifepristone (for early termination of pregnancy).
- Heart drugs, such as digoxin.
- Diuretics ("water tablets"), including the potassium-sparing type.
- Lithium (a medicine used to treat mood swings and some types of depression).
- Selective serotonin reuptake inhibitors (SSRIs) (medicines used to treat some types of depression).
- Methotrexate (a medicine used to treat arthritis and some types of cancer).
- Zidovudine (a medicine used to treat HIV and AIDs).
- Phenytoin (used to treat epilepsy).
- Colestipol or cholestyramine (medicines used to lower cholesterol levels).
- Voriconazole (used to treat fungal infections).
- Sulfapyrazone (used to treat gout).

Children

These capsules are not suitable for children under 14 years old.

Elderly patients

If you are elderly, your doctor may want to monitor you carefully while you are taking **Divido**.

Pregnancy and breast feeding

Tell your doctor before taking **Divido** if you are pregnant or breast feeding. As with other non-steroidal anti-inflammatory drugs, **Divido** may make it more difficult to become pregnant. You should inform your doctor if you are planning to become pregnant or if you have problems becoming pregnant.

Divido must not be taken during the last three months of pregnancy.

It is not usually recommended at other stages of pregnancy, but you may be able to take it if your doctor advises that it is necessary for you.

Divido should be avoided if you are breast feeding, as small amounts of the medicine may pass into breast milk.

Driving and using machines

These capsules can cause some people to feel dizzy or giddy, drowsy or sleepy, tired or have problems with their vision. If you are affected, do NOT drive or operate machinery.

4. How to take **Divido**

Divido 75 mg capsules must be swallowed whole with a drink of water (about half a glass). Do not chew or break open the capsules. The capsules are best taken with or after food. It may help you to remember to take your capsules if you take them at the same time every day, perhaps with breakfast or an evening meal.

Dosage

The usual dose is **ONE capsule of Divido, ONCE or TWICE a day as prescribed.**

It is important that the second dose is taken 8-12 hours after the first dose and that no more than two **Divido** 75 mg capsules are taken in any 24 hour period.

Tell your doctor if you have any concerns about your treatment.

If you take more Divido than you should

If you take more capsules than you should or if a child accidentally swallows some, go to your doctor or nearest emergency department immediately and take your medicine pack with you.

If you forget to take Divido.

If it is a little more than 12 hours since your previous dose, take the missed dose and then adjust the timing of your next dose to 8-12 hours later. Do not take a double dose to make up for the one you forgot and do not take more than two capsules in 24 hours.

5. Possible side effects

Like all medicines, **Divido** can cause side effects, although not everybody gets them. Taking the lowest effective dose for the shortest possible time will minimise side effects.

Some side effects can be serious. STOP taking **Divido** 75 mg capsules and tell your doctor immediately if you notice any of the following symptoms:

- Stomach ulcer or duodenal ulcer.
- Passing blood in your feces (stools/motions).
- Bleeding from the stomach or intestines (e.g. passing black 'tarry' stools).
- Vomiting blood or dark particles that look like coffee grounds.
- Stomach pains or other abnormal stomach symptoms.
- Indigestion or heartburn.
- Worsening of Crohn's disease or of ulcerative colitis.
- Allergic reactions, which can include sudden wheeziness, difficulty in breathing, swelling of the face, lips, hands or fingers, skin rash, itching, bruising, painful red areas, peeling or blistering.

You should tell your doctor or pharmacist if you notice any of the side effects listed below or any others not mentioned. You will be advised if you need to stop the medicine. (If any of them is **severe** stop the medicine and then tell your doctor.)

Other common side effects include:

Sickness, feeling sick, flatulence, diarrhea, constipation (including blockages), problems swallowing, loss of appetite, swelling of the tongue.

Other less common side effects include:

Kidney problems, urinary problems (e.g. any change in the usual amount or colour of the urine), liver problems, jaundice (yellowing of the skin or whites of the eyes), blurred vision, double vision, headache, pins and needles, stiff neck, depression, confusion, hallucinations, tinnitus (ringing in the ears), dizziness or giddiness, feeling unwell, tiredness, sleepiness, sensitivity to light, rashes and spots, flaky skin, changes in blood test results.

Reports of isolated cases include:

Memory problems, disorientation, impaired hearing, insomnia, irritability, fits, anxiety, nightmares, tremor, mood changes, changes in taste, hair loss, eczema and unusual bruising.

Very rare reports include:

Skin rashes, blisters on the skin and sore mouth/eyes, inflammation of the pancreas.

Other effects:

Medicines such as **Divido** may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

Other side effects reported in association with non-steroidal anti-inflammatory drugs include swelling caused by a build-up of fluid (known as 'oedema'), high blood pressure, palpitations, chest pain and heart failure.

Your doctor may require you to have occasional check-ups while you are taking **Divido** 75 mg capsules.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

6. How to store **Divido**

Keep out of reach of children.

Store below 30°C.

Do not use beyond the expiry date or if the product shows any signs of deterioration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away the medicines you no longer use. These measures will help to protect the environment.

7. Further information

What **Divido contains:**

Divido 75 mg: Each 75 mg dual release capsule contains: 25 mg Diclofenac Sodium in enteric coated pellets and 50 mg Diclofenac Sodium in sustained release pellets.

Excipients: Talc, cellulose, povidone, silicon dioxide, propylene glycol, polymethacrylic acid derivatives, triethyl citrate, gelatin, coloring agents E132, E171.

Presentations:

Packs of 20 Capsules.

® is a trademark.

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Strictly follow the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicament out of reach of children.

Council of Arab Health Ministers & Union of Arab Pharmacists.



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