

Package leaflet: Information for the user

Tolfenamic Acid 200mg Tablets (Tolfenamic Acid)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Tolfenamic Acid 200mg Tablets is and what it is used for
2. What you need to know before you take Tolfenamic Acid 200mg Tablets
3. How to take Tolfenamic Acid 200mg Tablets
4. Possible side effects
5. How to store Tolfenamic Acid 200mg Tablets
6. Contents of the pack and other information

1. What Tolfenamic Acid 200mg Tablets is and what it is used for

Tolfenamic acid is one of a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs reduce pain.

Tolfenamic Acid 200mg Tablets are effective in treating the pain associated with an acute attack of migraine in adults.

2. What you need to know before you take Tolfenamic Acid 200mg Tablets

Do not take Tolfenamic Acid 200mg Tablets if you

- are allergic to tolfenamic acid or any of the other ingredients (listed in section 6)
- have previously experienced allergic reactions (e.g. asthma, nasal discharge, nettle rash or swelling of the face, lips, tongue or throat) when taking ibuprofen, aspirin or other NSAIDs
- have severe liver, kidney or heart failure
- are in your last three months of pregnancy
- have or have a history of recurrent peptic ulcer or peptic bleeding (ulcer or bleeding in your stomach or duodenum)
- have ever had bleeding or perforation in your digestive tract due to NSAID treatment

Warnings and precautions

Talk to your doctor or pharmacist before taking Tolfenamic Acid 200mg Tablets.

Take special care with Tolfenamic Acid 200mg Tablets if you

- are taking other NSAIDs including NSAIDs known as COX-2 inhibitors
- are elderly

- have or have had asthma
- have decreased heart, liver or kidney function
- have or have had high blood pressure
- have had a gastrointestinal disease (Crohn's disease or inflammation of the colon and rectum)
- have a connective tissue disease such as systemic lupus erythematosus (SLE)
- have cardiovascular disease, peripheral arterial disease and/or cerebrovascular disease
- have had a peptic ulcer, intestinal bleeding or perforation

Medicines such as Tolfenamic Acid 200mg Tablets 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, previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes, raised cholesterol, raised triglycerides or are a smoker) you should discuss your treatment with your doctor or pharmacist.

Children

Use in children is not recommended

Other medicines and Tolfenamic Acid 200mg Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

- Any other NSAIDs (including aspirin), as Tolfenamic Acid 200mg Tablets may increase the risk of undesirable effects
- Cardiac glycosides (heart medicines), as Tolfenamic Acid 200mg Tablets may increase the risk of undesirable effects and aggravate heart failure
- Corticosteroids (used to treat various inflammatory conditions), as Tolfenamic Acid 200mg Tablets may increase the risk of gastrointestinal undesirable effects
- Quinolones (antibiotics), as Tolfenamic Acid 200mg Tablets may increase the risk of developing convulsions
- Tacrolimus, ciclosporin (medicines used to suppress the immune system), as Tolfenamic Acid 200mg Tablets may increase the risk of kidney problems
- Water tablets (diuretic medicine), as Tolfenamic Acid 200mg Tablets may increase the risk of kidney problems
- Medicines used to treat anxiety and depression known as selective serotonin re-uptake inhibitors (SSRIs)
- Medicines used to treat high blood pressure
- Mifepristone (abortion pill)
- Lithium (used to treat certain mental conditions)
- Methotrexate (used to treat e.g. cancer, psoriasis and rheumatism)
- Blood thinners such as warfarin or aspirin
- Zidovudine (used in cases of HIV infection)

Tolfenamic Acid 200mg Tablets with food, drink and alcohol

Tolfenamic Acid 200mg Tablets should be taken with or after food. Drink a glass of water with your medicine.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Abnormalities have been reported in babies whose mothers have taken NSAIDs during pregnancy. Do not take tolfenamic acid if you are in the last three months of pregnancy as it could harm your unborn child or cause problems at delivery. It can cause kidney and heart problems in your unborn baby. It may affect your and your baby's tendency to bleed and cause labour to be later or longer than expected. You should not take tolfenamic acid during the first 6 months of pregnancy unless absolutely necessary and advised by your doctor. If you need treatment during this period or while you are trying to get pregnant, the lowest dose for the shortest time possible should be used. If taken for more than a few days from 20 weeks of pregnancy onward, tolfenamic acid can cause kidney problems in your unborn baby that may lead to low levels of amniotic fluid that surrounds the baby (oligohydramnios) or narrowing of a blood vessel (ductus arteriosus) in the heart of the baby. If you need treatment for longer than a few days, your doctor may recommend additional monitoring.

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

Tolfenamic Acid 200mg Tablets 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.

Driving and using machines

Tolfenamic Acid 200mg Tablets may cause dizziness, drowsiness, exhaustion and visual disturbances. If you are affected by these, do not drive or use machines.

Important information about some of the ingredients of Tolfenamic Acid 200mg Tablets

Tolfenamic Acid 200mg Tablets contain less than 1 mmol sodium (23mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Tolfenamic Acid 200mg Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will prescribe a dose suitable for you. Depending on your response the dose may be repeated **once** after 1-2 hours.

The tablet should be taken orally (by mouth).

The tablet should be swallowed whole. Drink a glass of water with your medicine.

The usual dose is:

Adults:

Migraine – acute attacks: 200mg when the first symptoms of migraine appear. The treatment can be repeated once after 1-2 hours if a satisfactory effect is not obtained.

Use in children:

Use in children is not recommended.

Elderly:

Your doctor will prescribe a suitable dose for you.

If you take more Tolfenamic Acid 200mg Tablets than you should

If you have taken more Tolfenamic Acid 200mg Tablets than you should, contact your doctor or your local hospital immediately.

If you forget to take Tolfenamic Acid 200mg Tablets

Do not take a double dose to make up for a forgotten dose.

If you stop taking Tolfenamic Acid 200mg Tablets

It is very important that you take your medicine as your doctor has told you to. You should not suddenly stop taking Tolfenamic Acid 200mg Tablets, before you have spoken to your doctor about it.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

If you suffer from any of the following side effects at any time during your treatment **STOP TAKING** the medicine and **seek immediate medical help:**

- Pass blood in your faeces (stools/motions)
- Pass black tarry stools
- Vomit any blood or dark particles that look like coffee grounds

STOP TAKING the medicine and tell your doctor if you experience:

- Indigestion or heartburn
- Stomach pain or other abnormal stomach symptoms

If any of the following serious side effects occur, **STOP TAKING** this medicine and contact your doctor immediately or go straight to the emergency department at your nearest hospital.

- Peptic ulcer (belching, discomfort in the stomach, vomiting)
- Gastrointestinal bleeding
- An allergic shock reaction (shortness of breath, rash or wheezing)
- Swelling of the face, lips, tongue or throat
- Serious skin reactions with bullous/blister rash, inflammation of the skin and/or the top layer of the skin peels off e.g Stevens Johnson Syndrome and Toxic Epidermal Necrolysis (very rare)
- Lack of a type of white blood cells (flu-like symptoms, cold, high fever, sore throat)
- Decrease in the number of all blood cells (flu-like symptoms, fatigue, dizziness, spontaneous bleedings)
- Meningitis (stiff neck, headache, fever, nausea, vomiting or disorientation)
- Reddish or purplish spots on the skin
- Hallucinations
- Inflammation of the liver (yellowing of the skin or whites of the eyes)
- Inflammation of the kidney and kidney failure (urination disturbances)
- Bloody stool
- Vomiting of blood
- Allergic reactions such as asthma, aggravated asthma, wheezing, difficulty breathing
- Inflammation of the pancreas (pancreatitis)
- High blood pressure (hypertension)
- Cardiac failure

Other side effects include the following and you should inform your doctor as soon as you notice any of these:

- Swelling
- Nausea
- Vomiting
- Diarrhoea
- Flatulence (wind)
- Constipation
- Indigestion
- Stomach pain
- Inflammation of the mouth or stomach
- Worsening of gastrointestinal diseases (Crohn's disease or inflammation of the colon and rectum)
- Rash
- Itching
- Nettle rash
- Visual disturbances
- Pain in the eye and/or loss of vision
- Headache
- Sensation of pins and needles on the skin
- Depression
- Confusion
- Tinnitus
- Trembling or shaking
- Feeling of elation
- Dizziness
- Vague feeling of weakness
- Exhaustion
- Drowsiness
- Slight pain when passing urine
- Discolouration of urine (little more lemon coloured)
- Decreased liver or kidney function
- Sensitivity to light

Medicines such as Tolfenamic Acid 200mg Tablets may be associated with a small increased risk of heart attack (“myocardial infarction”) or stroke.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tolfenamic Acid 200mg Tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

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

Store below 25°C.

6. Contents of the pack and other information

What Tolfenamic Acid 200mg Tablets contains

- The active substance is tolfenamic acid.
- The other ingredients are: Maize starch, sodium starch glycolate, macrogol, alginic acid, microcrystalline cellulose, croscarmellose sodium, silica colloidal anhydrous and sodium stearyl fumarate.

What Tolfenamic Acid 200mg Tablets look like and contents of the pack

Tolfenamic Acid 200mg Tablets are white, oval, convex, scored tablets, with the markings FM7 and GEA on one side.

Tolfenamic Acid 200mg Tablets are packed in blisters or polyethylene tablet containers and available in packs with 3, 10, and 30 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

A/S GEA Farmaceutisk Fabrik, Edvard Thomsens Vej 14, 2300 Copenhagen S, Denmark.

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This leaflet was last revised in October 2022.