

PACKAGE LEAFLET: INFORMATION FOR THE USER

RANTUDIL F

60mg capsules

ACEMETACIN

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 or pharmacist • 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 or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What RANTUDIL F is and what it is used for
2. Before you take RANTUDIL F
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1. WHAT RANTUDIL F IS AND WHAT IS IT USED FOR

RANTUDIL F contains 60mg of the active ingredient acemetacin, which is a non-steroidal anti-inflammatory drug (NSAID).

NSAIDs are used to relieve the pain, stiffness and inflammation of painful conditions, particularly those affecting the muscles, bones and joints.

NSAIDs work by blocking the production of chemicals called 'prostaglandins', which are released at the sites of injury and cause symptoms of pain and inflammation, RANTUDIL F capsules are therefore used in the treatment of rheumatoid arthritis, osteoarthritis, low back pain, and pain following surgery because they reduce inflammation and relieve pain and swelling.

2. BEFORE YOU TAKE RANTUDIL F

Do not take RANTUDIL F

- if you are allergic to acemetacin, indomethacin or any of the other ingredients of RANTUDIL F.
- if you have a peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach, or have had two or more episodes of peptic ulcers, stomach bleeding or perforation of the intestine

- if you are allergic to ibuprofen, aspirin, or other NSAIDs. Hypersensitivity reactions include asthma, rhinitis (swelling and irritation inside the nose), angioedema (a serious allergic reaction which causes swelling of the face or throat), or urticaria (skin rash)
- if you have a serious heart condition, liver failure or kidney failure
- if you are more than 6 months pregnant
- if you have had a history of peptic ulcers, stomach bleeding or perforation of the intestine which were caused by taking NSAIDs.
- if you have nasal polyps (growths in the nose) caused by angioedema.
- if you have any blood disorders of unknown cause

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking RANTUDIL F

As with all medicines side effects can occur, and your doctor will make sure that these are minimised. Your doctor may carry out blood tests to monitor how you are responding to your treatment. You can help by making sure that the doctor treating you knows if you:

- suffer from or have previously had asthma, as NSAIDs can cause an asthma attack. If you have a history of asthma, hay fever or breathing disorders, you may also be more likely to experience an allergic reaction.
- have a liver problem, kidney problem, are taking diuretics or are elderly, as taking NSAIDs can cause kidney failure. Anyone with these conditions should be monitored by their doctor to make sure their kidneys are working properly.
- have high blood pressure or have congestive heart failure, because taking NSAIDs may cause fluid retention which results in swollen joints especially in the feet and ankles.
- 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, high cholesterol or are a smoker). Medicines such as RANTUDIL F 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.
- have a peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach, or have
- had two or more episodes of peptic ulcers, stomach bleeding or perforation.
- suffer from stomach ulcers as your doctor may prescribe additional protective medication for your stomach to lower the amount of acid that it produces. This is more likely if you are elderly or if you are also taking other medicines like corticosteroids or certain drugs for depression (for example selective serotonin reuptake inhibitors, SSRIs), or medicines to prevent blood clotting such as warfarin and aspirin.
- have had diseases affecting the intestines such as ulcerative colitis or Crohn’s disease.
- have systemic lupus erythematosus (also called SLE or Lupus) – a long-term disease involving the body’s immune system or mixed connective tissue disease (another long term inherited disease involving the body’s immune system which causes painful joints, and muscles).
- are trying to get pregnant. RANTUDIL F 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.
- have any psychiatric disorders, or suffer from epilepsy or parkinsonism.
- are suffering from chicken pox or herpes zoster, as you may be at increased risk of severe skin reactions. Your doctor should monitor you closely.

You should have your eyes tested regularly, as changes can occur in chronic rheumatoid disease. Signs and symptoms of infection may be hidden during treatment with RANTUDIL F.

Under long-term treatment with RANTUDIL F, regular monitoring of your blood levels and blood clotting status by your doctor is recommended.

Special note for elderly people taking RANTUDIL F

Elderly people are more likely to get side effects when they are taking NSAIDs - see section 4 "Possible side effects". These side effects include stomach bleeding or intestinal bleeding or perforation of the intestine which can be very serious in elderly people.

Other medicines and RANTUDIL F

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Medicines can sometimes interfere with each other. Your doctor may limit your use of acemetacin or other medicines, or you may need to take a different medicine. It's especially important to mention if you are taking the following medicines:

- Two or more **pain killers**, such as **aspirin** or **other NSAIDs** including **COX-2 selective NSAIDs**, for pain relief as this may increase the risk of side effects.
- **Corticosteroids**, which are drugs given to treat a variety of conditions such as allergies and hormone imbalances as this could increase risk of gastrointestinal ulceration or bleeding when taken with NSAIDs.
- **Anticoagulants**, such as **warfarin**, to prevent blood clots and this can increase the effects of the anticoagulant when taken with NSAIDs. Your doctor should regularly monitor your blood clotting status.
- **Selective serotonin reuptake inhibitors (SSRI)**, which are used to treat depression as use with NSAIDs can increase the risk of gastrointestinal bleeding. NSAIDs may also reduce the effect of SSRIs.
- Medicines such as **acetylsalicylic acid (aspirin)** to prevent platelet clumping as use with NSAIDs can also increase the risk of gastrointestinal ulceration or bleeding. (Platelet clumping results in blood clots and these drugs are used to prevent the formation of blood clots in order to help prevention of heart attacks and strokes).
- **Antihypertensive medicines** to lower blood pressure, as NSAIDs can reduce the effectiveness of the antihypertensive medicine.
- **Diuretics** (water tablets), as the diuretic tablet or the NSAID may not work as well when taken together, and may also increase the toxicity of acemetacin on the kidney. Potassium concentration should be monitored frequently, as high blood concentration can occur when acemetacin is taken with potassium-sparing diuretics.
- **Diuretics and antihypertensives** taken in combination, as use with NSAIDs could lead to deterioration of your kidney function if you have kidney problems. It is important you drink plenty fluids – your kidney function should also be checked regularly by your doctor in this case.
- **Cardiac glycosides**, such as **digoxin** for a heart condition, as use of NSAIDs at the same time could increase the possibility of heart failure.
- **Lithium based drugs**, which are used in the treatment of depression, as NSAIDs can cause a build up of these lithium drugs in the body with increases in their toxic effects.
- **Methotrexate**, which is used in cancer treatments. NSAIDs can slow down the removal of methotrexate by the kidneys leading to a build up of methotrexate in the body.
- **Ciclosporin**, which is used as an anti-rejection drug. NSAIDs can increase the toxicity of Ciclosporin to the kidney following organ transplants.
- **Mifepristone**, which is used in the early stages of pregnancy for terminations. NSAIDs should not be used for 8-12 days after taking mifepristone as they can reduce the effect of mifepristone.
- **Quinolone antibiotics**, such as **ciprofloxacin**, when taken with NSAIDs can increase the risk of convulsions that sometimes happen with quinolone antibiotics.
- **Tacrolimus**, which is used as an antirejection drug in organ transplantation. There is a possible increased risk of damage to the kidney when NSAIDs are given with tacrolimus.
- **Zidovudine**, which is used in the treatment of HIV. There is an increased risk of internal bleeding in HIV positive haemophiliacs who have received concurrent treatment with zidovudine and ibuprofen.
- **Probenecid** or **sulphinpyrazone**, which are used to treat gout, can decrease the elimination of NSAIDs from the body.

- **Antacids** may slow down the elimination of acetaminophen from the body.
- **Haloperidol**, an anti-psychotic, can cause drowsiness if taken with NSAIDs.
- **Penicillin** antibiotics. Acetaminophen can slow down the elimination of the antibiotic from the body.
- **Phenytoin**, which is used to treat epilepsy. Acetaminophen can increase the blood concentration of phenytoin.

RANTUDIL F with food and drink

Take with or after food. There are no specific foods that need to be avoided.

You should be very cautious if you drink any alcohol while you are taking RANTUDIL F. Side effects may be more likely, particularly those related to bleeding from the stomach or intestines.

Pregnancy and breast-feeding

Pregnancy

Tell your doctor if you are or think you may be pregnant or if you are planning to become pregnant. RANTUDIL F should not be used during the first 6 months of pregnancy unless your doctor believes that the benefits outweigh any risks. RANTUDIL F should not be used during labour.

Breast-feeding

If you are breast-feeding, RANTUDIL F can reach your baby in very small amounts through your breast milk, so it is best to avoid taking RANTUDIL F when breast-feeding.

Driving and using machines

Some NSAIDs can cause dizziness, drowsiness, fatigue and visual disturbances. If this happens when you take RANTUDIL F do not drive, use any tools, power tools or machinery. These effects will be enhanced if you also drink alcohol.

RANTUDIL F contains, lactose

As RANTUDIL F contains lactose, if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking RANTUDIL F.

The full ingredient list is shown in section 6 "Contents of the pack and other information"

3. HOW TO TAKE RANTUDIL F

Dosage

- The normal adult dose is 1 to 2 drops in one or both eyes as often as directed by your doctor.
- The dose for children will be decided by the doctor or eye specialist.

Method of administration

If you are putting the eye drops in yourself, then follow these instructions carefully:

1. Wash your hands.
2. Use a mirror, this will help you to see what you are doing.
3. Carefully dry your eyes using a tissue, and twist off the cap from the RANTUDIL F body of the unit.
4. Pull your lower eyelid down gently, and then carefully place 1 or 2 drops inside your lower eyelid.

Make sure the dropper does not touch any parts of your eye.

5. Close your eye and blink a few times to make sure your eye is covered by the liquid.
6. Close the eyelids. It is advisable to press gently on the inner corner of your eyelid for 3 minutes. This will help stop the solution draining into your nose and throat. This is especially advisable in children, the elderly and population at risk.
7. Repeat steps 4, 5 and 6 for the other eye if necessary.

If your eyes get worse or are not better after a few weeks of using the eye drops, see your doctor or eye specialist or pharmacist.

This medicine should not be used for long term and frequent use without talking to your doctor or pharmacist.

If you use more RANTUDIL F than you should, an overdose is very unlikely to occur. If you suddenly feel unwell after using the drops, tell your doctor or eye specialist or contact the nearest emergency department immediately.

If you forget to use RANTUDIL F, you should take the missed dose as soon as you remember, unless it is nearly time for the next dose, but you should not take a double dose to make up for a missed dose.

4. POSSIBLE SIDE EFFECTS

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

- **If any of the side effects mentioned in this leaflet gets serious, please tell your doctor or pharmacist.**

The frequency of possible side effects listed below is defined using the following:

- Very common (affects more than 1 patient in 10)
- Common (affects 1 to 10 patients in 100)
- Uncommon (affects 1 to 10 patients in 1,000)
- Rare (affects 1 to 10 patients in 10,000)
- Very rare (affects less than 1 patient in 10,000)
- Frequency not known

Serious side effects

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

- Severe abdominal pain
- Passing blood in your faeces (stools/motions)
- Passing black tarry stools
- Vomiting any blood or dark particles that look like coffee grounds.

These may be signs of gastro-intestinal bleeding. In exceptional cases, this bleeding can cause anaemia. This is a decrease in the number of red blood cells, typically causing a lack of iron in the body (very rare). You might feel extremely tired, have fever, a sore throat, mouth lesions, flu-like symptoms, nosebleeds or bruising. Other blood problems can also occur, such as aplastic anaemia (where bone marrow stops producing new cells), neutropenia, leucopenia and agranulocytosis (low number of white blood cells) or thrombocytopenia (low number of platelets in the blood). Platelets may stick together which could cause an increased tendency to bleed.

Your doctor may want to carry out regular blood tests to check your blood cells for these conditions. Do not exceed the recommended dose or duration of treatment.

Self-medication with painkillers and anti-fever medications such as paracetamol and ibuprofen is not recommended.

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

- Severe, but very rare, allergic reactions. The types of effects that can happen are anaphylaxis (a severe allergic reaction which can affect the whole body), asthma, shortness of breath, wheezing/difficulty breathing, skin rashes, exfoliative dermatitis (intense reddening of skin with skin peeling off in scales or layers), epidermal necrolysis (a disease with blistering and peeling of the top layer of skin), erythema multiforme (red spots sometimes with purple or blistered areas in the centre affecting the skin mouth, eyes and other moist surfaces), itchiness, angioedema (a serious allergic reaction which causes swelling of the face, tongue or throat), blisters and mouth ulcers, tachycardia (fast heart beat) or low blood pressure leading to life-threatening shock.

- Other, very rare, skin reactions: Bullous reactions including Stevens Johnson Syndrome (a condition with red blistered, eroded, bloody or crusted skin), Toxic Epidermal Necrolysis (a very rare side effect which causes blistering and peeling of the top layer of skin), and photosensitivity.
- Worsening of inflammation associated with an infection (very rare).

Clinical trials using high doses over prolonged periods have suggested that medicines such as RANTUDIL F may be associated with a small increased risk of heart attack (“myocardial infarction”) or stroke. Do not exceed the recommended dose or duration of treatment.

Other side effects

Very Common:

- Gastrointestinal disorders such as nausea, vomiting, abdominal pain, diarrhoea, and minor bleeding from the stomach and intestines which in some cases can cause anaemia.

Common:

- Indigestion, flatulence (wind), abdominal cramps, loss of appetite, and stomach ulcers (sometimes with bleeding).
- General allergic reactions causing itching or rash
- Feeling agitated
- Headache; feeling tired; dizziness; drowsiness
- Increased liver enzymes

Uncommon:

- Blood in vomit, faeces or diarrhoea
- Hives
- Eye disorders: blurred or double vision may be a typical symptom.
- Liver problems which can cause hepatitis or jaundice (a yellow tinge to the whites of your eyes or skin)
- Hair loss
- Oedema (fluid retention) which can cause swollen legs and ankles, especially in patients with high blood pressure and kidney problems.
- “Pins and needles”

Rare:

- High blood potassium levels
- Irritability, confusion

Very rare:

- High blood sugar; sugar in the urine
- Inflamed blood vessels or inflamed lung tissue (normally related to an allergic reaction)
- Mental disorders; disorientation; anxiety; nightmares; tremor; psychosis; hallucinations; depression; temporary loss of consciousness which may lead to coma.
- Worsening of any psychiatric conditions that are already present
- Sensibility disorders; muscle weakness; increased sweating; loss of taste; memory loss; sleep disorders; seizures
- Worsening of the symptoms of epilepsy or Parkinson’s disease
- Meningitis. This is more common in persons suffering from diseases like systemic lupus erythematosus (SLE or lupus - a long-term disease involving the body’s immune system), and mixed connective tissue disease (another long term inherited disease involving the body’s immune system which causes painful joints, and muscles). Symptoms of meningitis that have been caused by NSAIDs will include stiff neck, headache, nausea, vomiting, fever, disorientation, depression, confusion, hallucinations, tinnitus, vertigo, dizziness, malaise, fatigue, irritability, sleep problems and drowsiness
- Ringing in the ears; temporary hearing loss
- Feeling your heartbeat; chest pain (angina); heart failure; high blood pressure
- Inflammation of the mouth or tongue; injuries in the food pipe; complaints in the lower abdomen (e.g bleeding or inflammation of the colon); worsening of Crohn’s disease and ulcerative colitis (inflammatory conditions of the bowel) and constipation.
- Inflammation of the liver leading to acute liver failure – your doctor should regularly check your liver function

- Difficulties in passing water; increased blood urea (a chemical normally found in urine); kidney problems; kidney damage; protein in the urine; blood in the urine – your doctor should regularly check your kidney function
- Vaginal bleeding
- Eczema, Redness of the skin, Sensitivity to light, minor or widespread bleeding from the skin, Dermatitis, Rash with fluidfilled blisters which may develop into Steven-Johnson syndrome and Lyell's syndrome

Frequency not known:

Failure of the circulatory system

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.

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

5. HOW TO STORE RANTUDIL F

Store below 25°C. They should be kept in the original container supplied to you by your pharmacist. You should keep the container tightly closed.

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 and bottle after 'EXP'. 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 protect the environment.