

RETACID 80mg Film Coated Tablets

Febuxostat 80mg

What is in this leaflet

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

What RETACID is used for

RETACID tablets contain the active substance febuxostat and are used to treat gout, which is associated with an excess of a chemical called uric acid (urate) in the body. In some people, the amount of uric acid builds up in the blood and may become too high to remain soluble. When this happens, urate crystals may form in and around the joints and kidneys. These crystals can cause sudden, severe pain, redness, warmth and swelling in a joint (known as a gout attack). Left untreated, larger deposits called tophi may form in and around joints. These tophi may cause joint and bone damage.

RETACID works by reducing uric acid levels. Keeping uric acid levels low by taking RETACID once every day stops crystals building up, and over time it reduces symptoms. Keeping uric acid levels sufficiently low for a long enough period can also shrink tophi.

RETACID is for adults.

How RETACID works

The active substance in RETACID, febuxostat reduces the formation of uric acid. It works by blocking enzyme called xanthine oxidase, which is needed to make uric acid in the body. By reducing the production of uric acid, RETACID can reduce levels of uric acid in the blood and keep them low, stopping crystals from building up. This can reduce the symptoms of gout. Keeping uric acid levels low for long enough can also shrink tophi.

Before you use RETACID

- When you must not use it

Do not take this medicine if:

- you are allergic to active ingredients Febuxostat or any other ingredients of this medicine (listed in Product Description).

Children and adolescents

Do not give this medicine to children under the age of 18 because the safety and efficacy have not been established.

RETACID contains lactose

RETACID tablets contain lactose (a type of sugar). If you have been told that you have an intolerance to some sugars contact your doctor before taking this medicine.

- Before you start to use it

Check with your doctor or pharmacist before taking RETACID if you:

- If you have or have had heart failure or heart problems.
- If you have or have had renal disease and/or serious allergic reaction to Allopurinol (a medication used for the treatment of Gout)
- If you have or have had liver disease or liver function test abnormalities
- If you are being treated for high uric acid levels as a result of cancer disease or Lesch-Nyhan syndrome (a rare inherited condition in which there is too much uric acid in blood)
- If you have thyroid problems.

Should you experience allergic reactions to RETACID, stop taking this medicine (see also section 6 "Side Effects"). Possible symptoms of allergic reactions might be:

- rash including severe forms (e.g. blisters, nodules, itchy-, exfoliative rash), itchiness
- swelling of limbs or face
- difficulties in breathing
- fever with enlarged lymph nodes
- but also serious life threatening allergic conditions with cardiac and circulatory arrest

Your doctor might decide to permanently stop treatment with RETACID.

There have been rare reports of potentially life-threatening skin rashes (Stevens-Johnson Syndrome) with the use of RETACID, appearing initially as reddish target-like spots or circular patches often with central blister on the trunk. It may also include ulcers in the mouth, throat, nose, genitals and conjunctivitis (red and swollen eyes). The rash may progress to widespread blistering or peeling of the skin.

If you have developed Stevens-Johnson Syndrome with the use of febuxostat, you must not be re-started on RETACID at any time. If you developed a rash or these skin symptoms, seek immediate advice from a doctor and tell that you are taking this medicine.

If you are having a gout attack at the moment (a sudden onset of severe pain, tenderness, redness, warmth and swelling in a joint), wait for the gout attack to subside before first starting treatment with RETACID.

For some people, gout attacks may flare up when starting certain medicines that control uric acid levels. Not everyone gets flares, but you could get a flare-up even if you are taking RETACID, and especially during the first weeks or months of treatment. It is important to keep taking RETACID even if you have a flare, as RETACID is still working to lower uric acid. Over time, gout flares will occur less often and be less painful if you keep taking RETACID every day.

Your doctor will often prescribe other medicines, if they are needed, to help prevent or treat the symptoms of flares (such as pain and swelling in a joint).

Your doctor may ask you to have blood tests to check that your liver is working normally.

Pregnancy and lactation

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using any medicine.

- 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.

Inform your doctor or pharmacist if you are taking:

- Mercaptopurine (used to treat cancer)
- Azathioprine (used to reduce immune response)
- Theophylline (used to treat asthma)

How to use RETACID

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- How much to use

RETACID is available as an 80 mg tablet. The usual dose is 40 mg or 80 mg daily. A starting dose of 40 mg (half a tablet) is recommended and if your serum uric acid is > 6 mg/dL (357 μmol/L) after 2-4 weeks, the dose may be increased to 80mg (1 whole tablet) once daily. Your doctor will have prescribed the strength most suitable for you.

40 mg dose:

You will need to break a tablet in half. To break the tablet, hold the tablet between your thumbs and index fingers close to the score line. Then, with the score line facing you, apply enough pressure to snap the tablet apart. Swallow one half of the tablet with a full glass of water. Keep the other half of the tablet for your next dose.

80 mg dose:

Take one whole tablet with a full glass of water.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Use this medicine for the duration that your doctor recommends.

- If you forget to use it

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you or anyone else may have use too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using RETACID

- Things you must do

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using RETACID.

Tell your doctor immediately if you become pregnant while using this medication.

Take RETACID only with a doctor's prescription.

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

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

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If this medicine makes you feel dizziness, sleepiness,

blurred vision and numbness or tingling sensation, do not drive or use machines and contact your doctor immediately.

Side effects

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

Stop taking this medicine and contact your doctor immediately or go to an emergency department nearby if the following rare (may affect up to 1 in 1,000 people) side effects occur, because a serious allergic reaction might follow:

- anaphylactic reactions, drug hypersensitivity
- potentially life-threatening skin rashes characterized by formation of blisters and shedding of the skin and inner surfaces of body cavities, eg. mouth and genitals, painful ulcers in the mouth and/or genital areas, accompanied by fever, sore throat and fatigue (Stevens-Johnson Syndrome/ Toxic Epidermal Necrolysis), or by enlarged lymph nodes, liver enlargement, hepatitis (up to liver failure), raising of the white-cells count in the blood (drug reaction with eosinophilia and systemic symptoms-DRESS)
- generalised skin rashes

The common side effects (may affect up to 1 in 10 people) are:

- abnormal liver test results
- diarrhea
- headache
- rash (including various types of rash, please see below under "uncommon" and "rare" sections)
- nausea
- increase in gout symptoms
- localized swelling due to retention of fluids in tissues (oedema)

Other side effects which are not mentioned above are listed below.

Uncommon side effects (may affect up to 1 in 100 people) are:

- decreased appetite, change in blood sugar levels (diabetes) of

which a symptom may be excessive thirst, increased blood fat levels, weight increase

- loss of sex drive
- difficulty in sleeping, sleepiness, dizziness, numbness, tingling, reduced or altered sensation (hypoesthesia, hemiparesis or paraesthesia), altered or reduced sense of taste (hyposmia)
- abnormal ECG heart tracing, irregular heartbeats
- hot flushes or flushing (e.g. redness of the face or neck), increased blood pressure
- cough, shortness of breath, chest discomfort or pain, inflammation of nasal passage and/or throat (upper respiratory tract infection), bronchitis
- dry mouth, abdominal pain/discomfort or wind, heartburn/indigestion, constipation, more frequent passing of stools, vomiting, stomach discomfort
- itching, hives, skin inflammation, skin discoloration, small red or purple spot on the skin, small, flat red spots on the skin, flat, red area on the skin that is covered with small confluent bumps, rash, areas of redness and spots on the skin, other type of skin conditions
- muscle cramp, muscle weakness, pain/ache in muscles/joints, bursitis or arthritis (inflammation of joints usually accompanied by pain, swelling and/or stiffness), pain in extremity, back pain, muscle spasm
- blood in the urine, abnormal frequent urination, abnormal urine tests (increased level of proteins in the urine), a reduction in the ability of the kidneys to function properly
- fatigue, chest pain, chest discomfort
- stones in the gallbladder or in bile ducts (cholelithiasis)
- increase in blood thyroid stimulating hormone (TSH) level
- changes in blood chemistry or amount of blood cells or platelets (abnormal blood test results)
- kidney stones
- erectile difficulties

Rare side effects (may affect up to 1 in 1,000 people) are:

- muscle damage, a condition which on rare occasions can be serious. It may cause muscle problems and particularly, if at the same time, you feel unwell or have a high temperature it maybe caused by an abnormal muscle breakdown. Contact your doctor immediately if you experience muscle pain, tenderness or weakness
- severe swelling of the deeper layers of the skin, especially around the lips, eyes, genitals, hands, feet or tongue, with possible sudden difficult breathing
- high fever in combination with measles-like skin rash, enlarged lymph nodes, liver enlargement, hepatitis (up to liver failure), raising of the white-cells count in the blood (leukocytosis, with or without eosinophilia)
- reddening of the skin (erythema), rash in various types (e.g. itchy, with white spots, with blisters, with blisters containing pus, with shedding of the skin, measles-like rash), widespread erythema, necrosis, and bullous detachment of the epidermis and mucous membranes, resulting in exfoliation and possible sepsis (Stevens-Johnson Syndrome/Toxic epidermal necrolysis)
- nervousness
- feeling thirsty
- ringing in the ears
- blurred vision, change in vision
- hair loss
- mouth ulceration
- inflammation of the pancreas: common symptoms are abdominal pain, nausea and vomiting
- increased sweating
- weight decrease, increased appetite, uncontrolled loss of appetite (anorexia)
- muscle and/or joint stiffness
- abnormally low blood cell counts (white or red blood cells or platelets)
- urgent need to urinate
- changes or decrease in urine amount due to inflammation in the kidneys (tubulointerstitial nephritis)

- inflammation of the liver (hepatitis)
- yellowing of the skin (jaundice)
- liver damage
- increased level of creatine phosphokinase in blood (an indicator of muscle damage)

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of RETACID

- Storage

Keep out of the reach and sight of children.
Store below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

RETACID tablets are yellow, oval-shape film coated, engraved "574" on one side and "NK" on the other side with a score line.

- Ingredients

- Active ingredient(s)

- Febuxostat

- Inactive ingredients

- Lactose monohydrate
- Microcrystalline cellulose,
- Hydroxypropyl cellulose
- Croscarmellose Sodium
- Colloidal Silicon Dioxide,
- Magnesium Stearate,
- Alcohol Polyvinyl,
- Polyethylene Glycol,
- Talc,
- Titanium Dioxide,
- Yellow Iron Oxide,
- Alcohol 95%
- Purified Water.

- MAL number(s):

MAL*****

Manufacturer

NangKuang Pharmaceutical Co., Ltd
No.1001, 1001-1, Zhongshan Rd.,
Xinhua Dist., Tainan City, Taiwan
R.O.C

Product Registration Holder

Nano Medic Care Sdn Bhd
No.1-6 & 1-12, 1st Floor,
Jalan Indah 2, Taman Indah,
84000 Muar Johor,
Malaysia.

Date of revision

11/02/2026

Serial Number

NPRA (R2) 24/176