

Package leaflet: Information for the user

Febuxostat Rowex 80 mg Film-coated tablets Febuxostat Rowex 120 mg Film-coated tablets

febuxostat

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. See section 4.

What is in this leaflet

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

1. What Febuxostat Rowex is and what it is used for

Febuxostat Rowex 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.

Febuxostat Rowex works by reducing uric acid levels. Keeping uric acid levels low by taking Febuxostat Rowex 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.

Febuxostat Rowex 120 mg:

Febuxostat Rowex 120 mg Film-coated tablets are also used to treat and prevent high blood levels of uric acid that may occur when you start to receive chemotherapy for blood cancers.

When chemotherapy is given, cancer cells are destroyed, and uric acid levels increase in the blood accordingly, unless the formation of uric acid is prevented.

Febuxostat Rowex is for adults.

2. What you need to know before you take Febuxostat Rowex

Do not take Febuxostat Rowex

- If you are allergic to febuxostat or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor before taking Febuxostat Rowex:

- If you have or have had heart failure, heart problems or stroke
- If you have or have had renal disease and/or serious allergic reaction to allopurinol (a medicine 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 Lesch-Nyhan syndrome (a rare inherited condition in which there is too much uric acid in the blood)
- If you have thyroid problems.

Should you experience allergic reactions to Febuxostat Rowex, stop taking this medicine (see also section 4). 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 Febuxostat Rowex.

There have been rare reports of potentially life-threatening skin rashes (Stevens-Johnson Syndrome) with the use of febuxostat, 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 Febuxostat Rowex at any time. If you develop a rash or these skin symptoms, seek immediate advice from a doctor and tell him/her 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 Febuxostat Rowex.

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 Febuxostat Rowex, and especially during the first weeks or months of treatment. It is important to keep taking Febuxostat Rowex even if you have a flare, as Febuxostat Rowex is still working to lower uric acid. Over time, gout flares will occur less often and be less painful if you keep taking Febuxostat Rowex 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).

In patients with very high urate levels (e.g. those undergoing cancer chemotherapy), treatment with uric acid-lowering medicines could lead to the build-up of xanthine in the urinary tract, with possible stones, even though this has not been observed in patients being treated with febuxostat for Tumor Lysis Syndrome.

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

Children and adolescents

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

Other medicines and Febuxostat Rowex

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

It is especially important to tell your doctor or pharmacist if you are taking medicines containing any of the following substances as they may interact with Febuxostat Rowex and your doctor may wish to consider necessary measures:

- Mercaptopurine (used to treat cancer)

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

Pregnancy and breast-feeding

It is not known if Febuxostat Rowex may harm your unborn child. Febuxostat Rowex should not be used during pregnancy. It is not known if Febuxostat Rowex may pass into human breast milk. You should not use Febuxostat Rowex if you are breast-feeding, or if you are planning to breast-feed.

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.

Driving and using machines

Be aware that you may experience dizziness, sleepiness, blurred vision and numbness or tingling sensation during treatment and should not drive or operate machines if affected.

Febuxostat Rowex contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Febuxostat Rowex contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Febuxostat Rowex

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

- The recommended dose is one tablet daily. The back of the blister pack is marked with the days of the week to help you check that you have taken a dose each day. [Not for pack size 30]
- The tablets should be taken by mouth and can be taken with or without food.

Gout

Febuxostat Rowex is available as either an 80 mg tablet or a 120 mg tablet. Your doctor will have prescribed the strength most suitable for you.

Continue to take Febuxostat Rowex every day even when you are not experiencing gout flare or attack.

Febuxostat Rowex 120 mg:

For prevention and treatment of high uric acid levels in patients undergoing cancer chemotherapy

Febuxostat Rowex is available as a 120 mg tablet.

Start taking Febuxostat Rowex two days before chemotherapy and continue its use according to your doctor's advice. Usually treatment is short-term.

If you take more Febuxostat Rowex than you should

In the event of an accidental overdose ask your doctor what to do, or contact your nearest accident and emergency department.

If you forget to take Febuxostat Rowex

If you miss a dose of Febuxostat Rowex take it as soon as you remember unless it is almost time for your next dose, in which case miss out the forgotten dose and take your next dose at the normal time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Febuxostat Rowex

Do not stop taking Febuxostat Rowex without the advice of your doctor even if you feel better. If you stop taking Febuxostat Rowex your uric acid levels may begin to rise and your symptoms may worsen due to the formation of new crystals of urate in and around your joints and kidneys.

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.

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 (see also section 2 “Warnings and precautions”)
- potentially life-threatening skin rashes characterized by formation of blisters and shedding of the skin and inner surfaces of body cavities, e.g. 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) (see section 2)
- generalised skin rashes.

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

- abnormal liver test results
- diarrhoea
- 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)
- dizziness
- shortness of breath
- itching
- pain in extremity, pain/ache in muscles/joints
- fatigue.

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
- numbness, tingling, reduced or altered sensation (hypoesthesia, hemiparesis or paraesthesia), altered sense of taste, diminished sense of smell (hyposmia)
- abnormal ECG heart tracing, irregular or rapid heartbeats, feeling your heartbeat (palpitation)
- hot flushes or flushing (e.g. redness of the face or neck), increased blood pressure, bleeding (haemorrhage, seen only in patients taking chemotherapy for blood disorders)
- cough, chest discomfort or pain, inflammation of nasal passage and/or throat (upper respiratory tract infection), bronchitis, lower respiratory tract infection
- dry mouth, abdominal pain/discomfort or wind, abdominal pain upper, heartburn/indigestion, constipation, more frequent passing of stools, vomiting, stomach discomfort
- itchy rash, hives, skin inflammation, skin discolouration, small red or purple spots 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, increased sweating, night sweating, alopecia, reddening of the skin (erythema), psoriasis, eczema, other types of skin conditions

- muscle cramp, muscle weakness, bursitis or arthritis (inflammation of joints usually accompanied by pain, swelling and/or stiffness), back pain, muscle spasm, muscle and/or joint stiffness
- 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, urinary tract infection
- 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
- decreased activity of thyroid gland, blurred vision, change in vision
- ringing in the ears
- runny nose
- mouth ulceration
- inflammation of the pancreas: common symptoms are abdominal pain, nausea and vomiting
- urgent need to urinate
- pain
- malaise
- INR increased
- contusion
- lip swelling.

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 may be 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 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)
- rash in various types (e.g. 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
- weight decrease, increased appetite, uncontrolled loss of appetite (anorexia)
- abnormally low blood cell counts (white or red blood cells or platelets)
- changes or decrease in urine amount due to inflammation in the kidneys (tubulointerstitial nephritis)
- inflammation of the liver (hepatitis)
- yellowing of the skin (jaundice)
- infection of the bladder
- liver damage
- increased level of creatine phosphokinase in blood (an indicator of muscle damage)
- sudden cardiac death
- low red blood cell counts (anaemia)
- depression
- sleep disturbance
- loss of sense of taste
- burning sensation
- vertigo
- circulatory failure

- lung infection (pneumonia)
- mouth sores; inflammation of the mouth
- gastrointestinal perforation
- rotator cuff syndrome
- polymyalgia rheumatic
- feeling hot
- sudden vision loss due to blockage of an artery in the eye.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: HPRA Pharmacovigilance; website: www.hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Febuxostat Rowex

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 blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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.

6. Contents of the pack and other information

What Febuxostat Rowex contains

- The active substance is febuxostat.
Febuxostat Rowex 80 mg film-coated tablet:
Each film-coated tablet contains 80 mg febuxostat (as hemihydrate).
Febuxostat Rowex 120 mg film-coated tablet:
Each film-coated tablet contains 120 mg febuxostat (as hemihydrate).

- The other ingredients are:
Tablet core:
lactose monohydrate, cellulose, microcrystalline (E460), hydroxypropylcellulose (E463), croscarmellose sodium, silica, colloidal anhydrous (E551), magnesium stearate (E470b).

Film-coating:
poly (vinyl alcohol) (E1203), talc (E553b), titanium dioxide (E171), macrogol 3350 (E1521), methacrylic acid - ethyl acrylate copolymer (1:1) (Type A), iron oxide yellow (E172), sodium hydrogen carbonate (E500(ii)).

What Febuxostat Rowex looks like and contents of the pack

Febuxostat Rowex 80 mg film-coated tablet:
Pale yellow to yellow, film-coated, capsule shaped tablets, engraved with “80” on one side and plain on the other, with dimensions 16.5 mm x 7.0 mm

Febuxostat Rowex 120 mg film-coated tablet:
Pale yellow to yellow, film-coated, capsule shaped tablets, engraved with “120” on one side and plain on the other, with dimensions 18.5 mm x 9.0 mm

Febuxostat Rowex 80 mg and 120 mg film-coated tablets are packed in Aluminium-OPA/Alu/PVC or Aluminium-PVC/PE/PVDC blisters.

Febuxostat Rowex 80 mg and 120 mg is available in packs containing 14, 28, 30, 42, 56, 84 and 98 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturers

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Rontis Hellas Medical and Pharmaceutical Products S.A., P.O. Box 3012 Larisa Industrial Area, Larisa 41004, Greece.

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, Sachsen-Anhalt, Barleben 39179, Germany.

Lek Pharmaceuticals d.d., Verovškova ulica 57, 1526 Ljubljana, Slovenia.

This medicine is authorised in the Member States of the European Economic Area under the following names:

Austria	Febuxostat Sandoz 80 mg – Filmtabletten Febuxostat Sandoz 120 mg - Filmtabletten
Belgium	Febuxostat Sandoz 80 mg filmomhulde tabletten Febuxostat Sandoz 120 mg filmomhulde tabletten
Czech Republic	Febuxostat Sandoz
France	FEBUXOSTAT SANDOZ 80 mg, comprimé pelliculé FEBUXOSTAT SANDOZ 120 mg, comprimé pelliculé
Germany	Febuxostat HEXAL 80 mg Filmtabletten Febuxostat HEXAL 120 mg Filmtabletten
Greece	Febuxostat/Sandoz
Hungary	Febuxostat Sandoz 80 mg filmtabletta Febuxostat Sandoz 120 mg filmtabletta
Ireland	Febuxostat Rowex 80 mg Film-coated tablets Febuxostat Rowex 120 mg Film-coated tablets
Italy	Febuxostat Sandoz
The Netherlands	Febuxostat Sandoz 80 mg, filmomhulde tabletten Febuxostat Sandoz 120 mg, filmomhulde tabletten
Spain	Febuxostat Sandoz 80 mg comprimidos recubiertos con película EFG Febuxostat Sandoz 120 mg comprimidos recubiertos con película EFG
Slovakia	Febuxostat Sandoz 80 mg Febuxostat Sandoz 120 mg

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