PACKAGE LEAFLET

Package leaflet: Information for the patient

Febuxostat 80mg film-coated tablets

Febuxostat 120mg film-coated tablets

febuxostat

Read all of this leaflet carefully before you start using 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 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 or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Febuxostat is and what it is used for

Febuxostat film-coated 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 works by reducing uric acid levels. Keeping uric acid levels low by taking Febuxostat 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 120 mg tablets is 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 is for adults.

2. What you need to know before you take Febuxostat

Do not take Febuxostat

- 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:

- If you have or have had heart failure or heart problems or stroke.
- 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 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, 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.
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 at any time. If you develop 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 febuxostat.

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, and especially during the first weeks or months of treatment. It is important to keep taking febuxostat even if you have a flare, as febuxostat is still working to lower uric acid. Over time, gout flares will occur less often and be less painful if you keep taking febuxostat 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
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 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 may harm your unborn child. Febuxostat should not be used during pregnancy. It is not known if febuxostat may pass into human breast milk. You should not use febuxostat if you are breast feeding, or if you are planning to breastfeed.
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 contains lactose

Febuxostat 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.

Febuxostat contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablets, that is to say essentially ‘sodium-free’

3. How to take Febuxostat

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

- The usual dose is one tablet daily.
- The tablets should be taken by mouth and can be taken with or without food.

Gout
febuxostat 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 every day even when you are not experiencing gout flare or attack.

Prevention and treatment of high uric acid levels in patients undergoing cancer chemotherapy
Febuxostat is available as a 120 mg tablet.
Start taking febuxostat two days before chemotherapy and continue its use according to your doctor's advice. Usually treatment is short-term.

If you take more Febuxostat 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

If you miss a dose of febuxostat 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
Do not stop taking febuxostat without the advice of your doctor even if you feel better. If you stop taking febuxostat 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

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 characterised 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
- localised 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 (hypoaesthesia, hemiparesis or paraesthesia), altered sense of taste, diminished sense of smell (hyposmia)
- abnormal ECG heart tracing, irregular or rapid heartbeats, feeling your heart beat (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, 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 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, 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 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 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)
- sudden cardiac death

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 Yellow Card Scheme

Website: 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 Febuxostat

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

This medicinal product 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 contains

The active substance is febuxostat.
Each tablet contains 80 mg or 120 mg of febuxostat (as febuxostat hemihydrate).
The other ingredients are:
Tablet core: Lactose monohydrate, Pregelatinized starch, Croscarmellose sodium, Microcrystalline sodium, Silica colloidal anhydrous, Magnesium stearate,
Film-coating: Opadry II Yellow 85F42129 containing: Polyvinyl alcohol-partially hydrolyzed, Macrogol, Titanium dioxide(E171), Talc, Iron oxide yellow(E172).

What Febuxostat looks like and contents of the pack
Febuxostat 80 mg film-coated tablets: Pale yellow to yellow, oval shaped, film-coated tablet debossed with “HP” on one side and “242” on other side.

Febuxostat 120 mg film-coated tablets: Pale yellow to yellow, capsule shaped, film coated tablet debossed with “EM 48” on one side and plain on other side.

Febuxostat are supplied in ALU-PVC/ACLAR clear Blister Packs of 28 & 84 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Tillomed Laboratories Ltd
220 Butterfield Great Marlings,

Luton LU2 8DL,
UK

Manufacturer[1]

Tillomed Laboratories Ltd
220 Butterfield Great Marlings,
Luton LU2 8DL,
UK

Tillomed Pharma GmbH
Mittelstraße 5/5a,
12529 Schönefeld
Germany

This medicinal product is authorised in the Member States of the EEA under the following names:

Country	Product Name
United Kingdom:	Febuxostat Tillomed 80mg, 120mg Film-coated Tablets
Ireland	Febuxostat Tillomed 80mg, 120mg Film-coated Tablets
Spain	Febuxostat Tillomed 80 mg, 120 mg Comprimido recubierto con película EFG
Italy	Febuxostat Tillomed
Germany	Febuxostat Tillomed 80 mg, 120 mg Filmtabletten
Netherland	Febuxostat Tillomed 80 mg, 120mg filmomhulde tabletten

This leaflet was last revised in 05/2020.

[1] Only actual site will be listed on printed leaflet