

Package leaflet: Information for the user

Febuxostat Clonmel 80 mg film-coated tablets
Febuxostat Clonmel 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 Clonmel is and what it is used for
2. What you need to know before you take Febuxostat Clonmel
3. How to take Febuxostat Clonmel
4. Possible side effects
5. How to store Febuxostat Clonmel
6. Contents of the pack and other information

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

Febuxostat Clonmel 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 Clonmel works by reducing uric acid levels. Keeping uric acid levels low by taking Febuxostat Clonmel 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 Clonmel 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 Clonmel is for adults.

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

DO NOT take Febuxostat Clonmel

- 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 Clonmel:

- 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 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 Clonmel, stop taking this medicine (see also section 4). Possible symptoms of allergic reactions might be:

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

Your doctor might decide to permanently stop treatment with Febuxostat Clonmel.

Stevens-Johnson syndrome

There have been rare reports of potentially life-threatening skin rashes (Stevens-Johnson syndrome) with the use of Febuxostat Clonmel. These appear on the trunk, initially as reddish target-like spots or circular patches often with a central blister. 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 Clonmel at any time. If you developed a rash or these skin symptoms, seek immediate advice from a doctor and tell them 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 Clonmel.

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

Your doctor will often prescribe other medicines, if they are needed, to help prevent or treat the symptoms of flare ups (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 Clonmel for tumour 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; the safety and efficacy have not been established.

Other medicines and Febuxostat Clonmel

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

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 Clonmel 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 Clonmel may harm your unborn child. Febuxostat Clonmel should not be used during pregnancy. It is not known if Febuxostat Clonmel may pass into human breast milk. You should not use Febuxostat Clonmel 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 Clonmel contains sodium

Febuxostat Clonmel 80 mg film-coated tablets:

This medicine contains 1.2 mg sodium (less than 1 mmol sodium (23 mg)) per tablet, that is to say essentially 'sodium-free'.

Febuxostat Clonmel 120 mg film-coated tablets:

This medicine contains 1.8 mg sodium (less than 1 mmol sodium (23 mg)) per tablet, that is to say essentially 'sodium-free'.

3. How to take Febuxostat Clonmel

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

Dosage

The usual dose is one tablet daily.

Gout

Febuxostat Clonmel 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 Clonmel every day even when you are not experiencing gout flare up or attack.

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

Febuxostat Clonmel is available as a 120 mg tablet.

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

Method of administration

The tablets should be taken by mouth and can be taken with or without food.

The 80 mg tablet can be divided into equal doses.

If you take more Febuxostat Clonmel than you should

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

Commented [JCB1]: Applicant's comment: The information presented here is related to the indication that is only valid for the 120mg strength according to SmPC. Therefore, the applicant proposes to introduce grey shading here to clarify this.

If you forget to take Febuxostat Clonmel

If you miss a dose of Febuxostat Clonmel 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 Clonmel

Do not stop taking Febuxostat Clonmel without the advice of your doctor even if you feel better. If you stop taking Febuxostat Clonmel 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 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

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)
- 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 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, 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
- itching 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 type 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
- 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
- decrease 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, vomiting
- urgent need to urinate
- pain
- malaise
- prolonged blood clotting time (INR increased)
- bruising (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 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)
- rash of various types (e.g. itchy, with white spots, with blisters, with blisters containing pus, with shedding of the skin, measles-like rash), widespread reddening, tissue death, and bullous detachment of the epidermis and mucous membranes, resulting in sloughing

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 count (anaemia)
- depression
- sleep disturbance
- loss of sense of taste
- burning sensation
- a feeling of dizziness or "spinning" (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 HPRC 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 Clonmel

- 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 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 Clonmel contains

The active substance is febuxostat.

Febuxostat Clonmel 80 mg film-coated tablets:

Each film-coated tablet contains 80 mg of febuxostat (as hemihydrate).

Febuxostat Clonmel 120 mg film-coated tablets:

Each film-coated tablet contains 120 mg of febuxostat (as hemihydrate).

The other ingredients are:

Tablet core:

microcrystalline cellulose,
sodium starch glycolate,
colloidal anhydrous silica,
magnesium stearate,
copovidone

Film-coating:

Opadry II yellow, 85F42129 containing:
polyvinyl alcohol,
titanium dioxide (E171),
macrogol,
talc,
iron oxide yellow (E172)

What Febuxostat Clonmel looks like and contents of the pack

Febuxostat Clonmel 80 mg are yellow, oblong, biconvex, 16 mm x 5 mm, film-coated tablets with score line on both sides.

Febuxostat Clonmel 120 mg are yellow, oblong, biconvex, 18 mm x 8 mm film-coated tablets.

Febuxostat Clonmel 80 mg film-coated tablets is supplied in PVC/PVDC/Al blisters of 14, 28, 84 and 98 film-coated tablets.

Febuxostat Clonmel 120 mg film-coated tablets is supplied in PVC/PVDC/Al blisters of 14, 28, 84 and 98 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer

STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany

STADA Arzneimittel GmbH, Muthgasse 36/2, 1190 Wien, Austria

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

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

AT	Febuxostat STADA 80 mg Filmtabletten Febuxostat STADA 120 mg Filmtabletten
BE	Febuxostat EG 80mg filmomhulde tabletten Febuxostat EG 120mg filmomhulde tabletten
DE	Febuxostat AL 80 mg Filmtabletten Febuxostat AL 120 mg Filmtabletten
ES	Febuxostat STADA 80 mg comprimidos recubiertos con película EFG Febuxostat STADA 120 mg comprimidos recubiertos con película EFG
FR	Febuxostat EG 80 mg, comprimé pelliculé Febuxostat EG 120 mg, comprimé pelliculé
HR	Febuksostat STADA 80 mg filmom obložene tablete Febuksostat STADA 120 mg filmom obložene tablete
HU	Febuxostat STADA 80 mg filmtableta Febuxostat STADA 120 mg filmtableta
IE	Febuxostat Clonmel 80 mg Film-coated tablets Febuxostat Clonmel 120 mg Film-coated tablets
IT	Febuxostat EG

LU	Febuxostat EG 80 mg comprimés pelliculés Febuxostat EG 120 mg comprimés pelliculés
UK	Febuxostat STADA 80 mg film coated tablets Febuxostat STADA 120 mg film coated tablets

This leaflet was last revised in October 2023.