Febuxostat 80 mg Film-Coated Tablets

Febuxostat 120 mg Film-Coated Tablets

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 this medicine?

This medicine is for adults.

Febuxostat 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).

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 is for adults.

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 (see section 4).

Warnings and precautions

Talk to your doctor before taking Febuxostat:
- 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 Lesh-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, itchiness, exfoliative rashes), itching, 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, genitalia 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 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.

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.

You 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.

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)
- Thiotepa (used to treat asthma)

Pregnancy and breastfeeding

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 breastfeeding, 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 tablets contain lactose. If you are lactose intolerant then you may be affected by taking this medicine.

Febuxostat tablets contain lactose. If you are lactose intolerant then you may be affected by taking this medicine.

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.

Once a day dose to gout

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

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 and around your joints and kidneys.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.
1. What Febuxostat is and what it is used for

Febuxostat is a medicine prescribed to lower the uric acid level in the blood of patients with gout. Febuxostat works by reducing uric acid in the body and preventing the formation of crystals of uric acid in the body.

2. Before you use Febuxostat

If you are having a gout attack or an acute gout flare (a sudden, severe pain, redness, warmth and swelling in a joint (known as a gout attack). If you are having a gout attack at the start of treatment, your doctor may wish to consider necessary precautions (see also section 4). Possible symptoms of gout may be:

- feeling thirsty
- ringing in the ears
- blurred vision, change in vision
- hair loss
- mouth ulcération
- 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 indication of muscle damage)

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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 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.

3. How to take your medicine

Toxic epidermal necrolysis

Red and swollen eyes. The rash may progress to the trunk. It may also include ulcers in the mouth, throat, nose, genitals and conjunctivitis (see also section 4). Possible symptoms of Stevens-Johnson syndrome may be:

- widespread erythema, necrosis, and bullae detachment of the epidermis and mucous membranes, resulting in exfoliation and possible sepsis (Stevens-Johnson Syndrome/ Toxic epidermal necrolysis)

- 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 indication of muscle damage)

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

4. Possible side effects

5. How to store Febuxostat

6. Contents of the pack and other information

What Febuxostat tablets contain

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

- The other ingredients are: Appendix A: Other information

- Do not use this medicine after the expiry date which is stated on the carton and blister after Expiry. 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.

Appendix A: Other information

- Theophylline (used to treat asthma)
- Azathioprine (used to reduce immune system attacks on transplanted organs)
- Methotrexate (used to treat rheumatoid arthritis, psoriasis, Crohn’s disease, certain types of cancer)
- Other medicines that may interact with Febuxostat

Appendix B: Interaction with other medicines

Appendix C: Other information

Appendix D: Interaction with other medicines

Appendix E: Other information