FEBUSTAD FILM-COATED TABLETS

Febuxostat 40 mg, 80 mg

What is in this leaflet

1. What FEBUSTAD is used for

FEBUSTAD tablets contain the febuxostat 40mg or 80 mg 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.

FEBUSTAD works by reducing uric acid levels. Keeping uric acid levels low by taking FEBUSTAD 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.

FEBUSTAD is for adults.

2. How FEBUSTAD works

Febuxostat in FEBUSTAD reduces the formation of uric acid. It works by blocking an enzyme called xanthine oxidase, which is needed to make uric acid in the body. By reducing the production of uric acid, FEBUSTAD 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.

3. Before you use FEBUSTAD

- *When you must not use it*

Do not take FEBUSTAD if you are allergic to febuxostat or any of the other ingredients of this medicine.

Children and adolescents

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

Pregnancy and breast-feeding

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

FEBUSTAD contains lactose

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

- *Before you start to use it* Talk to your doctor before taking FEBUSTAD:

- If you have or have had heart failure or heart problem
- 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 the blood)
- If you have thyroid problems.

Should you experience allergic reactions to FEBUSTAD, 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 FEBUSTAD.

There have been rare reports of potentially life-threatening skin rashes (Stevens-Johnson Syndrome) with the use of FEBUSTAD, 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 FEBUSTAD 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 FEBUSTAD.

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

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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.

- *Taking other medicines*

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 FEBUSTAD 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)

4. How to use FEBUSTAD

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

- *How much to use*

FEBUSTAD is available as either a 40 mg tablet or a 80 mg tablet. The usual dose is 40 mg or 80 mg daily. A starting dose of 40 mg 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 once daily. Your doctor will have prescribed FEBUSTAD 40 mg or 80 mg for you.

- *How to take it*

40 mg dose:
Take one whole 40mg tablet with a full glass of water. Otherwise, you will need to break 80mg 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.

80mg:
Take one whole 80mg tablet with a full glass of water.

- *When to use it*

FEBUSTAD is for oral use and can be taken with or without food. Try to take your daily dose at about the same time each day.

- *How long to use it*

Continue taking FEBUSTAD for as long as your doctor recommends.

- *If you forget to use it*

Consult your doctor or pharmacist on what you should do if you forget to use it.

If you miss a dose of FEBUSTAD 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 use too much (overdose)*

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

5. While you are using FEBUSTAD

- *Things you must do*

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking FEBUSTAD.

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

- *Things you must not do*

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

Do not take any new medicines without consulting your doctor.

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

- *Things to be careful of*

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.

6. 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 3 "Before you use FEBUSTAD")
- 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 3 "Before you use FEBUSTAD")
- generalised skin rashes

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

- abnormal liver test results
- diarrhoea
- headache

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- 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 (hypoaesthesia, hemiparesis or paraesthesia), altered or reduced sense of taste (hyposmia)
- abnormal ECG heart tracing, irregular heartbeats, feeling your heart beat
- 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 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)

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)]

7. Storage and Disposal of FEBUSTAD

- *Storage*

Keep out of the reach and sight of children.
Store at or below 30°C.
Do not use FEBUSTAD after the expiry date which is stated on the carton and on the blister after EXP.

- *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.

8. Product description

- *What it looks like*

FEBUSTAD FILM-COATED TABLETS 40MG:
Tablets are yellow, round-shaped film-coated, biconvex, plain on both sides.

FEBUSTAD FILM-COATED TABLETS 80MG:
Tablets are yellow, caplet-shaped, film-coated, biconvex, engraved with "80" on one side, break line on the other side.

FEBUSTAD is packed in Alu-PVC/PE/PVDC blister of 10 tablets.

Ingredients

FEBUSTAD FILM-COATED TABLETS 40MG:

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Active ingredient:
Each film-coated tablet contains 40 mg of febuxostat
Inactive ingredient(s):
Lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, hydroxypropyl cellulose, sodium lauryl sulfate, colloidal anhydrous silica, magnesium stearate, Opadry® II complete film coating system 85F42129 yellow containing polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, iron oxide yellow
FEBUSTAD FILM-COATED TABLETS 80MG:
Active ingredient:
Each film-coated tablet contains 80 mg of febuxostat
Inactive ingredient(s):
Lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, hydroxypropyl cellulose, sodium lauryl sulfate, colloidal anhydrous silica, magnesium stearate, Opadry® II complete film coating system 85F42129 yellow containing polyvinyl alcohol, titanium dioxide, polyethylene glycol, talc, iron oxide yellow

MAL No.:

FEBUSTAD FILM-COATED TABLETS 40MG:

FEBUSTAD FILM-COATED TABLETS 80MG:

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9. Manufacturer:

STELLAPHARM J.V. CO., LTD. - BRANCH 1

(A Joint Venture Company of Auxilto GmbH, Germany)

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