

Package leaflet: Information for the user

GOUTGESIC™- 80

Febuxostat Tablets 80 mg

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.

What is in this leaflet

1. What **GOUTGESIC 80** is and what it is used for
2. What you need to know before you take **GOUTGESIC 80**
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1 What GOUTGESIC 80 is and what it is used for

Goutgesic 80 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.

Goutgesic 80 work by reducing uric acid levels. Keeping uric acid levels low by taking Goutgesic 80 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. Goutgesic 80 are for adults.

2. What you need to know before you take GOUTGESIC 80

Do not take GOUTGESIC 80:

- if you are allergic to febuxostat or any of the other ingredients of this medicine.

Warnings and precautions

Talk to your doctor before taking Goutgesic 80:

- 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 have thyroid problems.

Should you experience allergic reactions to Goutgesic 80, stop taking this medicine. 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 Goutgesic 80.

There have been rare reports of potentially life-threatening skin rashes 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 restarted on Goutgesic 80 at any time. If you develop 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 Goutgesic 80.

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 Goutgesic 80, and especially during the first weeks or months of treatment. It is important to keep taking Goutgesic 80 even if you have a flare, as Goutgesic 80 are still working to lower uric acid. Over time, gout flares will occur less often and be less painful if you keep taking Goutgesic 80 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 Goutgesic 80

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 Goutgesic 80 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 Goutgesic 80 may harm your unborn child. Goutgesic 80 should not be taken during pregnancy.

It is not known if Goutgesic 80 may pass into human breast milk. You should not take Goutgesic 80 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.

Goutgesic 80 contain lactose

Goutgesic 80 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.

3 How to take Goutgesic 80

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

For treatment of hyperuricemia in patients with gout, Goutgesic is recommended at 40 mg or 80 mg once daily.

One tablet of Goutgesic-40 daily is recommended as starting dose.

For patients who do not achieve a serum uric acid (sUA) less than 6 mg/dL after two weeks with 40 mg, Goutgesic-80 is recommended.

Goutgesic can be taken without regard to food or antacid use. Or as directed by the Physician.

If you take more Goutgesic 80 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 Goutgesic 80

If you miss a dose of Goutgesic 80, 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 Goutgesic 80

Do not stop taking Goutgesic 80 without the advice of your doctor even if you feel better. If you stop taking Goutgesic 80, 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:

Common reactions to febuxostat include nausea, rash, joint pain, gout flares, and liver problems. Less common side effects include stroke, heart attack, anemia, hepatitis, hypersensitivity, and weight loss.

5. How to store Goutgesic 80

Keep out of the reach and sight of children

Store in a dry, well-ventilated place at a temperature not exceeding 30⁰C.

Do not use Goutgesic 80 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.

Do not use Goutgesic 80 if you notice the visible signs of deterioration.

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) FURTHER INFORMATION

Contents of the pack and other information

What Goutgesic 80 contain

- The active ingredient is febuxostat.

Each tablet contains 80mg of febuxostat.

- The other ingredients are

Tablet core: Lactose, Microcrystalline cellulose, Low substituted hydroxypropyl cellulose, Crosscarmellose sodium, Colloidal silicon dioxide, Magnesium stearate, Win coat WT-1001 (White)/ Instacoat IC-U-A05R01962, Isopropyl Alcohol, Methylene chloride

What Goutgesic 80 look like and contents of the pack

Goutgesic 80: Film-coated Tablets

White to off white coloured, circular biconvex film coated tablets plain on both sides

1 Alu-Alu Blister of 10 Tablets packed in Carton with printed insert. (1×10's Blisters pack)

Pack sizes:

Cartons containing 10 film-coated tablets.

Marketing Authorisation Holder

Galaxy Pharmaceuticals

Regd. Off.: B.No:37, Gala No.1, Bhiwandi, Thane (Mumbai) M.S .India

Manufacturer

Skybiotech Life Sciences Private Limited

Factory: Gut No.05, Gevrai Tanda, Paithan Road, Aurangabad-431 002 (M.S.) India

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