PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

This medicine is to be supplied upon a doctor's prescription only

Feburic® 80 mg
Film-coated tablets

Active ingredient and its quantity:
Each film-coated tablet contains:
Febuxostat 80 mg

For the excipients in this product, please see section 6: "Additional information" and section 2: "Important information regarding some of the ingredients of this medicine".

Read all of this leaflet carefully before you start taking this medicine. This leaflet contains concise information about the medicine. 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 you think that their illness is the same as yours.

Do not give this medicine to children under 18 years of age since the safety and efficacy have not been proven.

1. What is the medicine intended for?

The medicine is intended for the treatment of gout in adults, which is characterized by chronic increase of uric acid in the blood (chronic hyperuricemia) and is accompanied with urate deposition (including formation of crystals and/or gouty arthritis).

Therapeutic group:
Medicines which inhibit production of uric acid.

2. Before you take the medicine:

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient (Febuxostat) or to any of the other ingredients of this medicine (listed in section 6).

! Special warnings regarding the use of this medicine:
Talk to your doctor before taking Feburic if:

- you have or have had heart failure, heart problems or stroke.
- you have or have had renal disease and/or serious allergic reaction to Allopurinol (a medication used for the treatment of Gout).
- you have or have had liver disease or liver function test abnormalities.
- 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).
- you have thyroid problems.
- you are sensitive to any kind of food or medicine.

Should you experience allergic reactions to Feburic, **stop taking this medicine** (see also section 4).
Possible symptoms of allergic reactions might be:
- Rash including severe forms [such as blisters, nodules, itchy-, exfoliative rash], itchiness
- Swelling of the limbs or face
- difficulties in breathing
- Fever with enlarged lymph nodes
- serious life threatening allergic reactions with cardiac and circulatory arrest

The doctor might decide to permanently stop treatment with Feburic.

There have been rare reports of potentially life-threatening skin rashes (Stevens-Johnson Syndrome) with the use of Feburic, appearing initially as reddish target-like spots or circular patches often with central blister on the trunk. The rash 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 Feburic at any time. If you develop a rash or these skin symptoms, refer to the doctor immediately and inform him/her 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 attack to subside before first starting treatment with Feburic.

For some people, gout attacks may flare up when starting certain medicines that control uric acid levels. This phenomenon does not occur in everyone, but you could suffer from gout attacks even if you are taking Feburic, and especially during the first weeks or months of treatment. It is important to keep taking the medicine even if you suffer from attacks, as Feburic is still working to lower uric acid. Over time, if you continue taking the medicine every day, the gout attacks (gout flares) will occur less often and be less painful.

The doctor will often prescribe other medicines, if they are needed, to help prevent or treat the gout attack symptoms (such as pain and swelling in a joint).

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

Tests and follow up:
The doctor may ask you to have blood tests in order to check that your liver is working normally.

Other medicines and Feburic
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including non-prescription drugs and nutrition supplements.
It is especially important to tell your doctor or pharmacist if you are taking a medicine containing one of the following active ingredients, as they may interact with Feburic 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)

Use of this medicine and food:

The tablets can be swallowed with or without food.

Pregnancy and breast-feeding:
It is not known if Feburic may harm your unborn child. Feburic should not be used during pregnancy.
It is not known if Feburic may pass into human breast milk. Do not use Feburic if you are breast feeding or if you are planning to breastfeed.

If you are pregnant, think you may be pregnant, planning to have a baby or breast-feeding consult your doctor or pharmacist before using this medicine.

Driving and using machines:
The medicine may cause dizziness, sleepiness, blurred vision, numbness or tingling sensation during treatment and you should not drive or operate machines if affected.

Important information regarding some of the ingredients of this medicine:
This medicine contains lactose monohydrate (80 mg tablet contains 76.50 mg). If you suffer from intolerance to some sugars consult your doctor before starting treatment with this medicine.

3. How to use this medicine

Always use according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure.

The dosage and administration will be determined by the doctor only. The usual recommended dosage is:
One tablet daily.

Continue to take Feburic every day even if you are not experiencing gout flare or attack.

Do not exceed the recommended dose.

There is no information regarding dividing, grinding or crushing the tablet.

If you have accidentally taken a higher dosage or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

If you forget to take this medicine at the specified time, take a dose as soon as you remember, unless the next dose is soon, in which case skip the forgotten dose and take the next dose at the normal time. Do not take a double dose to make up for a forgotten dose.

Continue with the treatment as recommended by your doctor.
Even if there is an improvement in your health, do not stop taking this medicine without consulting your doctor.

If you stop taking this medicine
Do not stop taking Feburic without the advice of your doctor even if you feel better. If you stop taking Feburic 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 the joints and kidneys.

- Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

If you have any further questions on the use of this medicine, consult your doctor or pharmacist.

4. Side effects:

Like all medicines, the use of Feburic may cause side effects in some users. Do not be alarmed while reading the list of side effects, you may not suffer from any of them.

Stop use of this medicine and contact your doctor immediately or go to an emergency room 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 "Special warnings regarding the use of this medicine").
- potentially life-threatening skin rashes characterised by formation of blisters and peeling of the skin and inner surfaces of body cavities such as: 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 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 " Special warnings regarding the use of this medicine").
- generalised skin rashes.

Refer to your doctor immediately if:

- You suffer from pain, tenderness or weakness of the muscles. These effects can indicate muscle damage, a condition which on rare occasions can be serious. This condition 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.

Additional side effects:

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

- abnormal liver function test results
- diarrhoea
- headache
- rash (including various types of rash, see below "uncommon" and "rare" sections)
- nausea
- increase in gout symptoms
- localised swelling due to retention of fluids in tissues (oedema)

Uncommon side effects (may affect up to 1 in 100 people) are**:**

- decreased appetite, changes in blood sugar levels (diabetes) of which symptoms 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 (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 flashes or flushing (such as 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 or 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 types of skin problems
- muscle cramps, 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 spasms
- 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) levels
- 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 deep 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 blood cells count (leukocytosis, with or without eosinophilia)
- reddening of the skin (erythema)**,** various types of rash (such as: 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, changes 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 joints 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

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If a side effect appears, if any of the side effects worsens, or if you experience side effects not mentioned in this leaflet, consult your doctor.

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" that appears on the homepage of the Ministry of Health's website (www.health.gov.il) which links to an online form for reporting side effects, or by the following link:
https://sideeffects.health.gov.il/
In addition you can report by emailing the Registration Holder's Patient Safety Unit at : drugsafety@neopharmgroup.com

5. How to store the medicine

- Avoid poisoning! This medicine, and any other medicine, must be stored in a safe place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by your doctor!
- Do not use this medicine after the expiry date (exp. date) which is stated on the carton package and the tablet blister foil. The expiry date refers to the last day of that month.
- This medicine does not require any special storage conditions, yet it is recommended to store it in a cool, dry place, in room temperature.
- 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. Additional information

In addition to the active ingredient, this medicine also contains:

Tablet core:
Microcrystalline cellulose (Avicel PH101 & PH102), lactose monohydrate, croscarmellose sodium, hydroxypropylcellulose, magnesium stearate, colloidal hydrated silica.

Film-coating:
Opadry II yellow, 85F42129 containing: polyvinyl alcohol, titanium dioxide, macrogols 3350, talc, iron oxide yellow.

What the medicine looks like and contents of the pack:
Feburic film-coated tablets are pale yellow to yellow in colour and capsule shaped.
Feburic 80 mg film-coated tablets are marked on one side with the digits '80'.
The tablets are packed in clear (Aclar/PVC/Aluminium) blister of 14 tablets.
The pack contains 28 film-coated tablets.

Registration Holder's name and address:
Neopharm Ltd., 6 Hashiloach St., P.O.B. 7063, Petach Tikva 4917001.

Manufacturer's name and address: Patheon France, 40 boulevard de Champaret, 38300 Bourgoin Jallieu, France.

Drug registration number at the national medicines registry of the Ministry of Health:
Feburic 80 mg**:** 151-81-34037

This leaflet has been checked and approved by the Ministry of Health in 04/2017 and updated according to the guidelines of the Ministry of Health in 09/2019.