

FEBUTON FILM COATED TABLET 80MG

Febuxostat (80mg)

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What *Febuton* is used for

Treatment of excess uric acid in the body where urate deposition has already occurred (including a history, or presence of, tophus and/or gouty arthritis).

Febuton is indicated in adults.

How *Febuton* works

Febuton works by reducing uric acid levels. Keeping uric acid levels low by taking *Febuton* 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.

Before you use *Febuton*

- When you must not use it

Do not take *Febuton*:

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

If you are under 18 years old.

Pregnancy and lactation

Do not take *Febuton* if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take *Febuton* if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

Talk to your doctor before taking *Febuton*:

- 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 Lesch-Nyhan syndrome (a rare inherited condition in which there is too much uric acid in the blood)
- If you have thyroid problems.
- If you have received organ transplant.
- If you intolerant to lactose

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

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 *Febuton* and your doctor may wish to consider necessary measures:

- Mercaptopurine (used to treat cancer)
- Azathioprine (used to reduce immune response)

How to use *Febuton*

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking *Febuton* 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.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed 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.

While you are using it

- 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 *Febuton*.

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

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

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

- Things to be careful of

Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

Like all medicines, *Febuton* can cause side effects, although not everybody gets them.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Common side effects include:

- Gout flares
- Headache
- Diarrhea, nausea
- Abnormal liver function
- Rash
- Localized swelling due to retention of fluids in tissues (oedema)

Uncommon side effects:

- decreased appetite, diabetes, increased blood fat levels, weight increase
- loss of sex drive, difficulty in sleeping
- dizziness, numbness, tingling, reduced or altered sensation, altered taste, sleepiness
- increase blood pressure, flushing, hot flush
- abnormal ECG, irregular or rapid heartbeats
- cough, shortness of breath, inflammation of nasal passage and/or throat (upper respiratory tract infection), bronchitis
- dry mouth, abdominal pain/discomfort or heartburn/indigestion, constipation, more frequent passing of stools, vomiting
- itching, rash, skin inflammation, skin discoloration
- muscle cramp, muscle weakness, pain/ache in muscles/joints, inflammation of joints, 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

- changes in blood chemistry or amount of blood cells or platelets (abnormal blood test results)
- erectile difficulties

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npdra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of *Febuton***- Storage**

Keep out of the reach and sight of children.

Store below 30 °C.

- 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.

Product Description**- What it looks like**

An off-yellow to yellow, capsule shaped film-coated tablet, engraved with “980” on one surface and “S D” on the other side having a splitting line between S and D.

- Ingredients

- Active ingredient
Febuxostat 80mg

- Inactive ingredients
Microcrystalline Cellulose, Lactose, Magnesium Stearate, Hydroxypropylmethyl Cellulose-L, Sodium Croscarmellose, Opadrt 03B82459, Purified water

- MAL number:

MAL19056004AZ

Manufacturer

STANDARD CHEM & PHARM CO., LTD.

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Product Registration Holder

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