Adenuric®

80 and 120 mg film-coated tablets
Febuxostat

Read all of this leaflet carefully before you start taking this medicine:
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT ADENURIC® IS AND WHAT IT IS USED FOR

Adenuric® containing the active substance febuxostat, is a xanthine oxidase (XO) inhibitor indicated for the chronic management of hyperuricemia in patients with gout.
Adenuric® tablets are used to treat gout, which is associated with an excess of 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.

Adenuric® works by reducing uric acid levels. Keeping uric acid levels low by taking Adenuric® once every day stops crystals building up, and over time it reduces symptoms. Keeping uric acid levels sufficiently low for a long period can also shrink tophi.
Adenuric® 120 mg tablets is also used to treat and prevent high blood levels of uric acid that may occur when you start to receive chemotherapy for blood cancers.
When chemotherapy is given, cancer cells are destroyed, and uric acid levels increase in the blood accordingly, unless the formation of uric acid is prevented.

Adenuric® is indicated in adults.

2. BEFORE YOU TAKE ADENURIC®

Do not take Adenuric®:
If you are allergic (hypersensitive) to febuxostat, or any of the other ingredients of this medicine (listed in section 6).

Take special care with Adenuric®:
Tell your doctor before you start to take this medicine:
- 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

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, 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 Adenuric®.

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

Taking other medicines:
Please tell your doctor or pharmacist if you are taking, or have recently taken, 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 Adenuric® 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 breastfeeding:
It is not known if Adenuric® may harm your unborn child. Tell your doctor if you think you are pregnant or if you are planning to become pregnant as Adenuric® should not be used during pregnancy. It is not known if Adenuric® may pass into human breast milk. You should not use Adenuric® if you are breastfeeding, or if you are planning to breast-feed.

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.

Important information about some of the ingredients of Adenuric®:
Adenuric® tablets 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 ADENURIC®

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.
The usual dose is one tablet daily.
The tablets should be taken by mouth and can be taken with or without food.

• Gout:
Adenuric® is available as either an 80 mg tablet or a 120 mg tablet. Your doctor will have prescribed the strength most suitable for you.
Continue to take Adenuric® every day even when you are not experiencing gout flare or attack.

• Prevention and treatment of high uric acid levels in patients undergoing cancer chemotherapy:
Adenuric® is available as a 120 mg tablet.
Start taking Adenuric® two days before chemotherapy and continue its use according to your doctor's advice. Usually treatment is short-term.

If you take more Adenuric® 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 Adenuric®:
If you miss a dose of Adenuric® 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 Adenuric®:
Do not stop taking Adenuric® without the advice of your doctor even if you feel better. If you stop taking Adenuric® 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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Adenuric® can cause side effects, although not everybody gets them.
Stop taking this medicine and contact your doctor immediately 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)
- potentially life-threatening skin rashes characterized by formation of blisters and shedding of the skin and inner surfaces of body cavities, eg. 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), rise of the white-cells count in the blood (drug reaction with cosinophilia and systemic symptoms-DRESS) (see section 2)
- generalised skin rashes

Common side effects (may affect up to 1 in 10 people) are:
abnormal liver test results, diarrhea, headache, rashes, nausea, increase in gout symptoms and localized swelling due to retention of fluids in tissues (oedema).

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 (hypoesthesia, hemiparesis or paraesthesia), altered or reduced sense of taste
- abnormal ECG heart tracing, irregular or rapid heartbeats, feeling your heart beat (palpitation)
- hot flushes or flushing (e.g. redness of the face or neck), increased blood pressure, bleeding (hemorrhage, seen only in patients taking chemotherapy for blood disorders)
- 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, heartburn/indigestion, constipation, more frequent passing of stools, vomiting, stomach discomfort
- itching, hives, skin inflammation or discolouration, 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), rise 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

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ADENURIC®

Keep out of reach and sight of children.
Do not store above 30°C.
Do not use after the expiry date which is stated on the carton and the tablet blister foil. The expiry date refers to the last day of that month.

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.

6. FURTHER INFORMATION

What Adenuric® contains
The active substance is febuxostat.
Each tablet contains 80 mg or 120 mg of febuxostat.
The other ingredients are:
Tablet core: lactose monohydrate, microcrystalline cellulose, magnesium stearate, hydroxypropylcellulose, croscarmellose sodium and colloidal hydrated silica.
Film-coating: Opadry II yellow, 85F42129 containing: polyvinyl alcohol, titanium dioxide (E171), macrogols 3350, talc and iron oxide yellow (E172).

What Adenuric® looks like and contents of the pack
Adenuric® film-coated tablets are pale yellow to yellow in colour and capsule shaped.
The 80 mg film-coated tablets are marked on one side with '80', with a break line on the other side. The 120 mg film-coated tablets are marked on one side with '120'.
Adenuric® is supplied in 2 blisters of 14 tablets (28 tablet pack).
Not all presentations may be marketed.

This is a medicament
- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists

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