

# Agout<sup>®</sup>

Agout  
Agout 40 mg  
Agout 80 mg  
Agout 120 mg  
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 get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## In this leaflet:

1. What Agout is and what it is used for.
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3. How to take Agout.
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### 1. What Agout is and what it is used for.

Agout tablets 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 (TOE-FI) may form in and around joints. These tophi may cause joint and bone damage.

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

Agout 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. **Agout is for adults.**

### 2. Before you take Agout.

#### Do not take Agout if you are:

- If you are allergic (hypersensitive) to Febuxostat, the active ingredient of Agout, or any of the other ingredients in these tablets.

#### Take special care with Agout:

##### 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 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 Agout, 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 Agout.

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

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 Agout, and especially during the first weeks or months of treatment. It is important to keep taking Agout even if you have a flare, as Agout is still working to lower uric acid. Over time, gout flares will occur less often and be less painful if you keep taking Agout 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). Your doctor may ask you to have blood tests to check that your **liver is working normally.**

### Children and Adolescents

Do not give the medicine to children under 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 Agout 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).

### Taking Agout with food and drink:

The tablets should be taken by mouth and can be taken with or without food.

### Pregnancy and breast-feeding:

It is not known if Febuxostat may harm your unborn child.

Tell your doctor if you think you are pregnant or if you are planning to become pregnant as Agout should not be used during pregnancy.

It is not known if Febuxostat may pass into human breast milk.

You should not use Agout if you are breast feeding, or if you are planning to breastfeed.

### Driving and using machines

No studies on the effects of Febuxostat on the ability to drive and use machines have been performed. However, you should be aware that you may experience dizziness, sleepiness and numbness or tingling sensation during treatment and should not drive or operate machines if affected.

### Important information about some of the ingredients of Agout:

Agout 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.

### 3. How to take Agout.

Always take Agout exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Agout is available as 40mg, 80 mg tablet or a 120 mg tablet. Your doctor will have prescribed the strength most suitable for you.

- The usual dose is one tablet daily.
- The tablets should be taken by mouth and can be taken with or without food.

#### Gout

Agout is available as 40mg, 80 mg tablet or a 120 mg tablet. Your doctor will have prescribed the strength most suitable for you.

Continue to take Agout 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

#### Agout is available as a 120 mg tablet.

Start taking Agout two days before chemotherapy and continue its use according to your doctor's advice. Usually treatment is short-term.

It is important that you do not stop taking Agout unless your doctor tells you.

Continue to take Agout every day even when you are not experiencing gout flare or attack.

#### If you take more Agout 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 Agout:

If you miss a dose of Agout 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 Agout:

Do not stop taking Agout without the advice of your doctor even if you feel better. If you stop taking Agout 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, Agout 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 2 "Warnings and precautions")
- 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), raising of the white-cells count in the blood (drug reaction with eosinophilia and systemic symptoms-DRESS) (see section 2).
- generalised skin rashes.

#### Common side effects (reported in more than 1 in 100 patients but less than 1 in 10 patients) are:

- Abnormal liver test results.
- Diarrhea.
- Headache.
- Rashes.
- Nausea.
- Increase in gout symptoms.
- Localized swelling due to retention of fluids in tissues (oedema).

#### Uncommon side effects (more than 1 in 1,000 patients but less than 1 in 100 patients) are:

- Decreased appetite, change in blood sugar levels (diabetes) of which a symptom may be excessive thirst, increased blood fat levels.
- Loss of sex drive.
- Difficulty in sleeping, sleepiness.
- Dizziness, numbness, tingling, reduced or altered sensation (hypoaesthesia or paraesthesia), altered or reduced sense of taste.
- Abnormal ECG heart tracing, irregular heartbeats, feeling your heart beat.
- Hot flushes or blushing (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 or discolouration, 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), and a reduction in the ability of the kidneys to function properly.
- Fatigue, localised swelling due to the retention of fluids in the tissues (oedema), chest pain, chest discomfort.
- Stones in the gallbladder or in bile ducts (cholelithiasis).
- Changes in blood chemistry or amount of blood cells or platelets (abnormal blood test results).
- Kidney stones.
- Erectile difficulties

#### Rare side effects (more than 1 in 10,000 patients but less than 1 in 1,000 patients) are:

- Allergic reactions (e.g. skin rash, itching, swelling).
- Generalized skin rashes.

#### Stop taking Agout and contact your doctor immediately if these side effects occur, because a serious allergic reaction might follow.

- Nervousness.
- Feeling thirsty.
- Erectile difficulties.
- Ringing in the ears.
- Hair loss.
- Mouth ulceration.
- Inflammation of the pancreas: common symptoms are abdominal pain, nausea and vomiting
- Increased sweating.
- Weight change (increase/decrease), increased appetite, uncontrolled loss of appetite (anorexia).
- Muscle and/or joint stiffness.
- Abnormally low blood cell counts (white or red blood cells).
- 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 get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

#### 5 How to store Agout.

Store below 30° C.

#### 6. Further information.

##### What Agout contains

The active substance is Febuxostat. Each film coated tablet contains: 40 mg, 80 mg or 120 mg of Febuxostat.

##### The other ingredients are:

Tablet core: lactose fast flow, microcrystalline cellulose, magnesium stearate, hydroxypropylcellulose low-S, croscarmellose sodium, colloidal Silicon Dioxide. Film-coating: Opadry OY-37202 Dark Tan, Purified Water.

##### What Agout looks like and contents of the pack

Agout 40mg film-coated tablets are light brown to brown color, Oblong, biconvex, with "22" debossed on one side and plain surface on the other.

Agout 80mg film-coated tablets are light brown to brown color, Oblong, biconvex, with "23" debossed on one side and plain surface on the other.

Agout 120mg film-coated tablets are light brown to brown color, Oblong, biconvex, with "24" debossed on one side and plain surface on the other. In pack carton of 30 films- coated tablets.

#### Manufactured by SPIMACO

Al-Qassim Pharmaceutical Plant  
Saudi Pharmaceutical Industries &  
Medical Appliances Corporation,  
Saudi Arabia.

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"Agout" is a trade mark  
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#### To report any side effect(s):

- The National Pharmacovigilance and Drug Safety Centre (NPC)
- Fax: +966-11-205-7662
- Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340.
- Toll free phone: 8002490000
- E-mail: npc.drug@sfd.gov.sa
- Website: www.sfd.gov.sa/npc

#### This is a medicament

- A 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 pharmacists who sold the medicament.
- The doctor and the pharmacists are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

#### Keep medicaments out of the reach of children

Council of Arab Health Ministers  
Union of Arab Pharmacists