PATIENT INFORMATION LEAFLET

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SCHEDULING STATUS **S3**

ZORIKOS 100 and 300

Allopurinol

Tablets

ZORIKOS 100 contains sugar (lactose monohydrate, 37,26 mg per tablet).

ZORIKOS 300 contains sugar (lactose monohydrate, 111,80 mg per tablet).

Read all of this leaflet carefully before you start taking ZORIKOS

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ZORIKOS has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ZORIKOS is and what is it used for
2. What you need to know before you take ZORIKOS
3. How to take ZORIKOS
4. Possible side effects
5. How to store ZORIKOS
6. Contents of the pack and other information

1. What ZORIKOS is and what it is used for

Zorikos contains contain a medicine called allopurinol. It works by slowing down the speed of certain chemical reactions in your body to lower the level of uric acid in your blood and urine.

ZORIKOS is used to treat high amounts of uric acid in the blood associated with the following conditions and therapy:

- Gout. The uric acid builds up in your joints and tendons as crystals causing a tender inflammatory reaction, which leads to the skin around your joints becoming swollen and sore when only slightly touched. You may also get severe pain when the joint is moved.
- Kidney stone formation and other types of kidney disease.
- Cancer (such as leukaemia).
- Anti-cancer medicines (such as 6-mercaptopurine) and radiation therapy for cancer.
- Diuretic (water tablet) therapy (for example, hydrochlorothiazide).

2. What you need to know before you take ZORIKOS

Do not take ZORIKOS:

- If you are hypersensitive (allergic) to allopurinol or any of the other ingredients of ZORIKOS listed in section 6.
- If you are breastfeeding your baby (see Pregnancy and breastfeeding).
- If you are lactose intolerant, because ZORIKOS contains lactose monohydrate (see WHAT ZORIKOS CONTAINS).
- In children, except those that have cancer.

Take special care with ZORIKOS:

- If you develop serious skin rashes, discontinue the use of ZORIKOS immediately and consult your doctor. These skin reactions include hypersensitivity reactions, Stevens-Johnson syndrome and toxic epidermal necrolysis (which may be life-threatening). Signs and symptoms of these skin reactions may be blisters, fever, peeling of the skin, joint pain, swollen glands (throat and/or under arms). These skin rashes are more common in

patients with chronic renal impairment and in people of Han Chinese Origin.

- If you have liver or kidney damage, your doctor will need to reduce the dose, or request that you take ZORIKOS less often. Caution is advised if you are using medicines to treat a heart disease or high blood pressure, such as water tablets or ACE inhibitors (for example, enalapril), because these medicines may decrease the functioning of your kidneys.
- ZORIKOS should not be started until the gout attack has cleared, because allopurinol may. worsen this condition
- If you are diagnosed with high levels of uric acid in the blood, but you are not experiencing any symptoms of gout (painful and swollen joints), your doctor may adjust your diet and advise that you increase your water intake, before starting therapy with **ZORIKOS**.
- If you have a condition that may increase the levels of urate in the body (for example, Lesch-Nyhan syndrome), this may lead to the formation of crystals in the urinary tract. It is advised that you increase your water intake, to prevent the crystal formation.
- If you have high levels of uric acid in the blood, you may be at risk of kidney stones (uric acid crystals forming in the tubes, which lead from the kidneys to the bladder). Therapy with ZORIKOS may dissolve these crystals.
- Caution is advised if you have any thyroid problems (gland at the base of the neck).

Use in Children:

ZORIKOS should not be used in children, unless they have been diagnosed with:

- Cancer (for example, leukaemia) or
- A metabolic (enzyme) disease (for example, Lesch-Nyhan syndrome).

Other medicines and ZORIKOS

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Please discuss the use of the following medicines or substances in combination with ZORIKOS with your doctor or pharmacist:

- Immuno-suppressants (medicines used to reduce your immune response), such as azathioprine, ciclosporin and 6-mercaptopurine.
- Antibiotics, such as ampicillin and amoxicillin.
- Medicines used to treat diabetes, such as chlorpropamide.
- Medicines used to thin your blood (anticoagulants), such as warfarin.
- Medicines for cancer, such as bleomycin, cyclophosphamide, doxorubicin, mechlorethamine procarbazine, alkyl halogenides.
- Didanosine, a medicine used to treat HIV infection.
- Medicines used to treat epilepsy (fits), such as phenytoin.
- Other medicine to treat gout, such as aspirin and probenecid.
- Theophylline, a medicine used to treat breathing problems.
- Medicines used to treat heartburn, upset stomach, sour stomach, or acid indigestion, such as aluminium hydroxide. There should be at least a 3 hour waiting period between taking these medicines and taking ZORIKOS.
- Medicines for heart problems or high blood pressure such as ACE inhibitors (such as enalapril) or water tablets (diuretics) (e.g. furosemide).
- Vidarabine, an anti-viral medicine used to treat herpes infections.

Taking ZORIKOS with food and drink:

ZORIKOS can be taken with food.

It is important to drink sufficient water (2 litres) everyday, to prevent uric acid crystal formation.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking ZORIKOS.

Pregnancy

Do not use Zorikos if you are pregnant (see “Do not take Zorikos”).

Breastfeeding

Do not use ZORIKOS if you are breastfeeding your baby (see “Do not take ZORIKOS”).

Driving and using machinery:

ZORIKOS commonly causes disturbance in eyesight, drowsiness and dizziness.
Therefore, you should not drive, operate complex machinery or engage in other potentially hazardous activities until it is known whether ZORIKOS affects your ability to perform such tasks.

Important information about some of the ingredients of ZORIKOS:

ZORIKOS contains lactose monohydrate. If you are lactose intolerant you should not take ZORIKOS. ~~(see “What Zorikos contains”).~~

3. How to take ZORIKOS

Do not share medicines prescribed for you with any other person.
Always take ZORIKOS exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
Swallow the tablet whole with a glass of water.

ZORIKOS is for oral use.
Take with or just after food.

Adults:

The recommended dose of ZORIKOS ranges from 100 mg to 900 mg per day. You will usually start on a low dose, which will be increased if necessary.

Children (under 15 years):

The dosage for children is calculated based on the child's bodyweight. The normal dose range for ZORIKOS is 100 to 400 mg each day.

Elderly (over 65 years):

Your doctor will prescribe the lowest, appropriate dose of ZORIKOS that will be able to control your condition.

If you have a serious kidney problem:

Your doctor will prescribe a reduced dosage, based on your kidney function.
If you are receiving dialysis two or three times a week, your doctor may prescribe a dose of 300 or 400 mg of ZORIKOS, which must be taken immediately after each dialysis session.
Do not exceed the recommended daily dosage.

If you have a serious liver problem:

Your doctor will prescribe a reduced dosage, based on your liver function.
Do not exceed the recommended daily dosage.

Your doctor will tell you how long your treatment with ZORIKOS will last.
If you have the impression that the effect of ZORIKOS is too strong or too weak, tell your doctor or pharmacist.

If you take more ZORIKOS than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Signs and symptoms of overdosage may include diarrhoea, dizziness, nausea and vomiting.

If you forget to take a dose of ZORIKOS:

Always take ZORIKOS as prescribed (see " How to take ZORIKOS). If you have missed a dose, take it as soon as you remember. Do not take a double dose of ZORIKOS to make up for forgotten individual doses.

4. Possible side effects

ZORIKOS can have side effects.

Not all side effects reported for ZORIKOS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking ZORIKOS, please consult your healthcare provider for advice.

If you have a kidney or liver disorder, you are at a higher risk of experiencing the following side effects.

If any of the following happens, stop taking ZORIKOS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing, build-up of fluid leading to swelling (oedema) particularly of your ankles.
- Skin reaction including boils, blisters, swelling, fever, rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ZORIKOS. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequent side effects:

- Serious skin rashes. These skin reactions include hypersensitivity reactions, Stevens-Johnson syndrome and toxic epidermal necrolysis, accompanied by blisters, fever, peeling of the skin, joint pain, swollen glands (throat and/or under arms). These reactions may involve multiple organs.

Less frequent side effects:

- Diabetes mellitus (signs and symptoms of this condition includes feeling thirsty, tired and losing weight).
- Loss of consciousness (coma).
- Paralysis (unable to move limbs/muscles).
- Angina pectoris (chest pain).
- Irregular slow heartbeat.
- Inflammation of the liver (swelling or pain in the upper right abdomen).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Less frequent side effects:

- Boils.
- Decreased levels of blood components such as white blood cells, red blood cells and platelets.
- High levels of cholesterol in your blood (hyperlipidaemia).

- Feeling depressed.
- Impaired balance or coordination, can be due to damage to brain, nerves or muscles.
- Headache.
- Drowsiness.
- Tingling feeling (“Pins and needles”).
- A change in taste.
- Cataracts (clouding of the lens of the eye).
- Loss of vision.
- Disturbance in vision.
- Vertigo (a feeling of dizziness or “spinning”).
- High blood pressure (symptoms may include severe headache, fatigue or confusion,
- chest pain and difficulty breathing).
- Abdominal pain.
- A change in your normal bowel habit.
- Diarrhoea.
- Gastric irritation.
- Nausea and vomiting, occasionally with blood.
- Fat in the faeces (oily stool).
- Inflamed or sore mouth.
- Increase in liver function test results.
- Hair loss.
- Hair discolouration.
- Blood in urine.
- Urea in the blood.
- Male infertility or erectile dysfunction.
- Enlargement of the breasts (in males and females).
- Feeling weak.

- Fever.
- Feeling tired and unwell.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. How to store ZORIKOS

- Store all medicines out of reach of children.
- Store at or below 30 ºC
- Protect from light and moisture.
- Store in the original packaging.
- Keep the blister strips in the outer carton until required for use.
- Do not take ZORIKOS after the expiry date stated on the package.
- Return all unused ZORIKOS to your pharmacist.
- Do not dispose of unused tablets in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Zorikos contains:

Each tablet of ZORIKOS 100 contains 100 mg allopurinol.

Each tablet of ZORIKOS 300 contains 300 mg allopurinol.

ZORIKOS 100 contains sugar (lactose monohydrate, 37,26 mg per tablet).

ZORIKOS 300 contains sugar (lactose monohydrate, 111,80 mg per tablet).

The other ingredients include lactose monohydrate, magnesium stearate, maize starch, and povidone (K-30).

What Zorikos looks like and contents of the pack

What Zorikos looks like:

ZORIKOS 100: White to off white, scored, flat cylindrical tablet debossed with “I” and “56” on either side of the break line on one side, and plain on other side.

ZORIKOS 300: White to off white, scored, flat cylindrical tablet debossed with “I” and “57” on either side of the break line on one side, and plain on other side.

Contents of the pack:

Aluminium and clear, PVC blister strip containing 10 tablets per blister strip. Blister strips are packed into a cardboard carton.

Pack sizes: 30, 60 and 100 tablets.

Not all pack sizes may be marketed.

Holder of certificate of registration

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