PACKAGE LEAFLET

Package leaflet: Information for the user

Azurifin 250 mg tablets

terbinafine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Azurifin is and what it is used for

Azurifin belongs to a group of medicines called antifungal drugs. Azurifin is used for the treatment of fungal infections of:
- The groin area.
- The skin (ring worm).
- Toe and finger nails (yellow, opaque and thickened nails).
- The feet (athlete's foot).

2. What you need to know before you take Azurifin

Do not take Azurifin:
- if you are allergic to terbinafine or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from severely impaired **liver** or **kidney** function.

Warnings and precautions
Talk to your doctor or pharmacist before taking Azurifin if:
- You suffer from **liver** disease.
- You suffer from **kidney** disease.
- You suffer from **psoriasis** (scaling skin disease) or **lupus erythematosus** (auto-immune disorder, affecting the skin, joints, kidneys & brain), as it may worsen whilst you are taking Azurifin.

Children and adolescents
Use in children is not recommended.

Other medicines and Azurifin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. It is especially important to tell your doctor about the following:
- Rifampicin (an antibiotic).
- Cimetidine (used to treat stomach ulcers).
- Tricyclic antidepressants, selective serotonin reuptake inhibitors and monoamine oxidase inhibitors (medicines for depression).
- Amiodarone, beta blockers, other antiarrhythmic drugs (heart medicines).
- Ciclosporin (used to prevent and treat the rejection of transplants and also used in immune diseases).
- Tolbutamine (used for diabetes).
- Terfenadine (an antihistamine).
- Triazolam (a sedative).
- Oral contraceptives. Break-through bleeding and irregular periods may occur when Azurifin tablets are taken with oral contraceptives.
- Fluconazole, ketoconazole (used to treat fungal infections)
- Caffeine

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are breast-feeding, you should not take Azurifin. If you are pregnant or planning to become pregnant, you should not take Azurifin unless your doctor decides it is necessary. You must only take Azurifin according to your doctor's instructions.

Driving and using machines
Azurifin may affect your ability to drive or operate machines.

Azurifin contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'

3. How to take Azurifin

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Swallow the tablets **with water**.

The recommended dose is:
Adults (including the elderly):
Duration of treatment depends on the type of fungal infection and the severity of the infection.

Fungal infection of the groin area, skin and feet:
250 mg (one 250 mg Azurifin tablet) once a day for 2-4 weeks. Some cases of athlete's foot may require treatment for up to 6 weeks.

Complete healing of the infection may not occur until several weeks after completing the course of treatment.

Fungal infection of the nails:
Fingernails: 250mg (one 250 mg Azurifin tablet) once a day for 6 weeks.

Toenails: 250mg (one 250mg Azurifin tablet) once a day for 12 weeks. Some cases may require treatment for up to 6 months.

Complete healing of the infection may not occur until several weeks after completing the course of treatment. A healthy nail may take several months to grow back.

If you take more Azurifin than you should
If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any contact your nearest hospital casualty department or tell your doctor immediately. Symptoms of an overdose include headache, feeling sick, pain in the upper part of the stomach (epigastric pain) and dizziness.

If you forget to take Azurifin
Do not take a double dose to make up for a forgotten dose. If you forget to take a dose take it as soon as you remember it and then take the next dose at the right time.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You must contact your doctor immediately if you notice any of the following:
- **Impaired liver function or liver failure** including reduction in liver enzymes (seen in tests), yellowing of the skin or whites of the eyes (jaundice), inflammation of the liver (hepatitis) and blocked bile flow (cholestasis). Symptoms include itching, constantly feeling sick, loss of appetite, tiredness, being sick, fatigue, stomach pain, dark urine or pale stools.
- **An allergic (hypersensitivity) reaction** with swelling of the face, lips, tongue or throat, difficulty breathing or swallowing (anaphylaxis) or skin reactions such as a rash or pale or red irregular raised patches with severe itching (hives).
- **A skin reaction** such as a severe form of skin rash with flushing, fever, blisters or ulcers (Stevens-Johnson syndrome), severe rash involving reddening, peeling and swelling of the skin that resembles severe burns (toxic epidermal necrolysis), circular, irregular red patched on the skin of the hands and arms (erythema multiforme), sensitivity to sunlight or artificial light (e.g. sun beds).
- **Fever or sore throat.**

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

Very common (may affect more than 1 in 10 people)
Stomach problem (such us feeling bloated, loss of appetite, feeling of fullness, indigestion, feeling sick, mild stomach pain, diarrhoea, acid regurgitation). Joint pain and muscle pain.Headache.

Common (may affect up to 1 in 10 people)
Symptoms of depression due to taste changes. Dizziness. Impaired vision. Feeling tired.
Uncommon (may affect up to 1 in 100 people)
Taste disturbances and loss of taste sense, which usually normalizes sometime after the end of treatment. This has led to anxiety and loss of appetite and weight loss in some isolated patients. Tell your doctor if the taste change lasts more than a few days. Anemia. Decreased skin sensitivity, tingling and numbness. Noises (e.g. hissing) in ears. Fever. Increased skin sensitivity to sun exposure. Weight loss due to taste changes.

Rare (may affect up to 1 in 1,000 people)
Liver problems.

Very rare (may affect up to 1 in 10,000 people)
Severe skin reactions, allergic reactions and severe allergic reactions. Swelling of the face, lips, tongue or throat, sometimes with shortness of breath or difficulty swallowing. Decreased levels of different types of blood cells. Exacerbation or outbreak of psoriasis, loss of hair. SLE (systemic lupus erythematosus) (an autoimmune disease).
Not known (frequency cannot be estimated from the available data)
Reduced ability to smell, including permanent loss of sense of smell. Impaired hearing. Inflammation of the blood vessels. Inflammation of the pancreas. Inflammation of the liver. Yellow eyes or skin (liver problems) and abnormal liver function test results. Flu-like symptoms (e.g., tiredness, chills, sore throat, joint or muscle aches). Increased levels of a muscle enzyme shown in the blood tests. Blurred vision, decreased sharpness of vision. Skin rash with increased amount of a certain type of white blood cell. Skin rash with systemic symptoms.
Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Azurifin

Keep this medicine out of the sight and reach of children.
This medicine does not require any special storage conditions.
Do not use this medicine after the expiry date which is stated on the label/carton/bottle. The expiry date refers to the last day of that month.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer required. These measures will help protect the environment.

6. Further information

What Azurifin contains
- The active substance is terbinafine, as terbinafine hydrochloride. Each tablet contains 250mg of the active substance.
- The other ingredients are microcrystalline cellulose, croscarmellose sodium, anhydrous colloidal silica, hypromellose and magnesium stearate.

What Azurifin looks like and contents of the pack
White, round, flat tablets, scored on both sides with side scores and marked with ‘T’ above and ‘1’ below the score on one side.
Azurifin is available in the following blister pack sizes: 7, 14, 20, 28, 30 ,42, 50, 60, 84, 90, 98, 100, 50 x 1 tablets.
Azurifin is available in the following bottle pack sizes: 14, 28, 500 tablets.

Not all container types or pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<[To be completed nationally]>

<This medicinal product is authorised in the Member States of the EEA under the following names:>

<{Name of the Member State}> <{Name of the medicinal product}>
<{Name of the Member State}> <{Name of the medicinal product}>

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