



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.

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1 What Lozanoc is and what it is used for

Lozanoc belongs to a group of medicines called antimycotics for systemic use, also called **anti-fungal** medicines.

Lozanoc is used to treat fungal infections, including those caused by yeasts. These infections may affect:

- the skin
- the lungs
- the nails
- internal organs

2 What you need to know before you take Lozanoc

⚠ Don't take Lozanoc:

- if you are allergic (*hypersensitive*) to itraconazole or any of the other ingredients of Lozanoc (*listed in Section 6*)
 - if you are taking any of the medicines in the first list under 'Other medicines and Lozanoc', below.
- Check with your doctor if you think either of these applies to you.

Warnings and precautions

Tell your doctor before you start to take Lozanoc:

- if you have, or have had, a problem with your **liver**. If your doctor decides to prescribe Lozanoc, your dose may need to be adjusted. You will also need to look out for symptoms that may appear while you're taking Lozanoc. **Read Section 4, 'Possible side effects'**, for more information. If you take Lozanoc for more than one month continuously, your doctor may ask you to have regular blood tests.
- if you have, or have had, a problem with your **heart**. If your doctor decides to prescribe Lozanoc, you will need to look out for symptoms that may appear while you're taking it. **Read Section 4, 'Possible side effects'**, for more information.
- if you have, or have had, a problem with your **kidneys**. If your doctor decides to prescribe Lozanoc, your dose may need to be adjusted.
- if you are HIV-positive, or have acquired immune deficiency syndrome (AIDS), or any condition which means your immune system isn't working as well as it should be.
- if you have ever had an **allergic reaction** to any other anti-fungal medicine.

Lozanoc can, very rarely, cause hearing loss, which usually gets better when you stop taking it, but can be permanent.

Other medicines and Lozanoc

Tell your doctor or pharmacist before taking Lozanoc if you're taking, have recently taken, or might take any other medicines, including herbal medicines or other medicines you bought without a prescription.

⚠ Don't take Lozanoc if you are taking any of the following medicines:

- antihistamines for hay fever or allergies, containing terfenadine, astemizole or mizolastine
 - some medicines to treat **angina or high blood pressure**, such as bepridil or nisoldipine
 - some medicines (statins) to **lower cholesterol**, such as lovastatin or simvastatin
 - some medicines to treat **anxiety** or to **help you sleep** (tranquilisers), such as midazolam (by mouth) or triazolam
 - eletriptan, to treat **migraine**
 - some medicines (*ergot alkaloids*) to treat **migraine**, such as ergotamine and dihydroergotamine
 - some medicines (*ergot alkaloids*) given **after childbirth**, such as asergotamine (*ergonovine*) and methylergometrine (*methylergonovine*)
 - some medicines to treat **mental health problems**, such as pimozide and sertindole
 - some medicines to treat **irregular heart rhythms**, such as quinidine, dofetilide and dronedarone
 - levacetylmethadol, to treat **drug addiction** (*opioid dependency*)
 - cisapride, to treat some **digestive problems**.
- Tell your doctor and don't take Lozanoc, if you are taking any of these or if you are not sure.

Some medicines may make Lozanoc work less effectively:

- some medicines to treat **epilepsy**, such as carbamazepine, phenytoin and phenobarbital
- some medicines to treat **tuberculosis (TB)**, such as rifampicin, rifabutin and isoniazid

- Tell your doctor if you are taking any of these, as your dose of Lozanoc may need to be adjusted.

With some medicines and Lozanoc, your dose may need to be adjusted:

If you take Lozanoc at the same time as some medicines, either your dose of Lozanoc or your dose of the other medicine may need to be adjusted. These medicines include:

- **antibiotics** for bacterial infections called clarithromycin or erythromycin
 - some drugs that act on the **heart and blood vessels** (digoxin, disopyramide and some calcium channel blockers such as dihydropyridines, verapamil and cilostazol)
 - medicines that **thin the blood** (reduce blood clotting), such as warfarin and dabigatran
 - some medicines given by mouth or injection to treat **inflammation, asthma and allergies**, such as methylprednisolone, budesonide, fluticasone and dexamethasone
 - medicines given **after an organ transplant**, to prevent rejection, such as ciclosporin, tacrolimus and rapamycin (also named sirolimus)
 - some medicines to treat **viral infections**, such as ritonavir, indinavir and saquinavir
 - some medicines to treat **cancer**, such as busulphan, docetaxel and trimetrexate and vinca alkaloids
 - some medicines to treat **anxiety** or to **help you sleep** (tranquilisers), such as buspirone, alprazolam and brotizolam
 - fentanyl, a **strong painkiller**
 - alfentanil, a **painkiller**
 - atorvastatin, to **lower cholesterol**
 - halofantrine, to treat **malaria**
 - repaglinide, to treat **diabetes**
 - ebastine, to treat **allergies**
 - reboxetine, to treat **depression**
 - midazolam, to treat **anxiety** or to **help you sleep** (tranquiliser), when given by intravenous injection.
- Tell your doctor if you are taking any of these or if you are not sure.

Lozanoc with food and drink

Lozanoc capsules may be taken with or without food (although you may have previously been told you should take other anti-fungal medicines after a full meal).

Pregnancy and breast-feeding

Don't take Lozanoc if you are pregnant

⚠ Tell your doctor and don't take Lozanoc if you are pregnant, if you think you may be pregnant or if you are planning to have a baby.

⚠ If you could become pregnant, use reliable contraception (birth control) while you are taking Lozanoc. After you have finished your course of Lozanoc, carry on using reliable contraception until after your next menstrual period.

If you are breast-feeding

- Ask your doctor before you take Lozanoc. Small amounts of the medicine can pass into breast milk.

Children and older people

Lozanoc is not recommended for children or older people unless the potential benefits outweigh the risks.

Driving and using machines

Taking Lozanoc will not usually affect your ability to drive or use machines. But, very rarely, Lozanoc can cause dizziness, ringing in the ears (*tinnitus*) and hearing loss. Don't drive or use machines unless you are feeling well.

3 How to take Lozanoc

Always take Lozanoc exactly as your doctor has told you to. Check with your doctor or pharmacist if you are not sure. Swallow the capsules with water. Lozanoc can be taken with or without food.

How much to take

Lozanoc capsules give you twice as much of the active medicine, itraconazole, as other anti-fungal capsules you may have taken before. So a 50 mg capsule of Lozanoc gives you as much medicine as other brands of 100 mg itraconazole capsules.

⚠️ Only take as many Lozanoc capsules as you have been prescribed, and ask your doctor or pharmacist if you are not sure.

The usual dose of Lozanoc depends on the type of fungal infection you have: see the table below.

Your doctor may prescribe different doses for different lengths of time, depending on your condition. **It is important to take the full course your doctor has prescribed.**

What to expect from Lozanoc treatment

Don't worry if you don't see an immediate improvement after your treatment.

- With **skin infections**, the marks or spots (*lesions*) typically disappear a few weeks after you finish the course. Although the medicine kills the fungus, the marks don't disappear until after new skin has grown.
- With **nail infections**, marks on the nail may take 6 to 9 months to disappear, because new nail needs to grow.
- **Ask your doctor or pharmacist** if you're not sure whether the treatment is working.

If you take more Lozanoc than you should

⚠️ Contact your nearest hospital Emergency department or your doctor immediately:

- if you (or someone else) swallow a lot of Lozanoc capsules
- if you think a **child** has swallowed any Lozanoc capsules.

Take this leaflet, any remaining capsules and the container with you to the hospital or doctor, so they know what medicine was swallowed.

If you forget to take Lozanoc

If you forget to take a dose, take the next dose as usual. Then continue with the course until all the capsules are finished. Don't take a double dose to make up for a missed dose.

If you stop taking Lozanoc

If you stop taking Lozanoc before you have finished all the capsules in your course, your infection may not be fully treated and may come back.

Don't stop until you have finished the course, even if you feel better.

Type of infection	How many capsules? (see the note above)	How long to take Lozanoc
Pityriasis versicolor (<i>tinea versicolor</i> , a skin infection, usually on the chest and back)	2 capsules once a day	7 days
Skin infection in the groin, arms or legs	1 capsule once a day	2 weeks
Athlete's foot Skin infection on the hand	1 capsule once a day	4 weeks
Infections of the nails	2 capsules once a day	12 weeks
Internal infections	1 to 2 capsules once or twice a day	Depends on how the infection responds. Your doctor will advise.

4 Possible side effects

Like all medicines, Lozanoc can cause side effects, although not everyone gets them.

Symptoms that need immediate attention

⚠️ Stop taking Lozanoc and contact a doctor immediately, or go to your nearest hospital's Emergency department if you get:

- swelling of the lips, face or neck
- severe difficulty in breathing
- itchy, lumpy skin rash (hives)

These can be signs of a very rare but very serious allergic reaction. You might need to be treated in hospital.

⚠️ Stop taking Lozanoc and contact a doctor immediately if you get:

- yellowing of the skin or eyes (*jaundice*)
- loss of appetite, feeling sick (*nausea*), being sick (*vomiting*)
- abdominal (stomach) pain
- tiredness, muscle weakness
- darker urine or paler stools (poo) than normal
- hair loss
- a tingling sensation, numbness or weakness in the arms or legs
- a severe skin rash
- shortness of breath
- rapid, unexpected weight gain
- swelling of the legs or abdomen
- unusual tiredness
- waking up more than usual during the night

These could be signs of very rare effects on your liver or your heart.

It is especially important to look out for these symptoms if **you have already had problems with your liver or your heart.**

Common side effects

These may affect **up to 1 in 10 people:**

- stomach ache, feeling sick (*nausea*)

Uncommon side effects

These may affect **up to 1 in 100 people:**

- problems with periods
- headache, dizziness
- constipation, diarrhoea, wind, being sick (*vomiting*), indigestion, change in taste.
- swelling due to fluid under the skin
- unusual hair loss or thinning (*alopecia*)

Rare side effects

These may affect **up to 1 in 1000 people:**

- increases in liver function tests (shown by blood tests)
- unexpected passing of urine or need to urinate (pass water) more often
- problems with sight including blurred vision and double vision

- certain blood disorders which may increase the risk of bleeding, bruising or infections

- ringing in your ears
- severe upper stomach pain, often with nausea and vomiting
- fever or high temperature

The following side effects have been reported, however the precise frequency cannot be estimated from the available data and is classed as unknown:

- high levels of triglycerides in the blood (shown by blood tests)
- muscle pain, painful joints
- red, itchy, flaking or peeling skin
- erection difficulties
- sensitivity of the skin to light hearing loss (may be permanent)
- lower levels of potassium in your blood (shown by blood tests)

If you get any side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

5 How to store Lozanoc

Keep Lozanoc out of the sight and reach of children.

HDPE Bottles and Soft Temper Aluminium foil blisters:

This medicinal product does not require any special temperature storage conditions.

Store in the original package in order to protect from light and moisture.

Triplex blister:

Do not store above 25°C.

Store in the original package in order to protect from light and moisture.

Don't take Lozanoc after the expiry date which is stated on the outer packaging. 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 use. These measures will help protect the environment.

6 Further information

What Lozanoc contains

The active substance is itraconazole. Each hard capsule contains 50 mg itraconazole.

The other ingredients are hypromellose phthalate, sodium starch glycolate (Type A), silica colloidal anhydrous, magnesium stearate.

The capsule is made from gelatin and the colours FD&C Blue FC (E133), titanium dioxide (E171).

The capsule is printed with black Ink (SW-9008), consisting of shellac, potassium hydroxide, black iron oxide (E172), and purified water.

What Lozanoc looks like and contents of the pack

Lozanoc 50 mg hard capsules are hard gelatin light-blue capsules (size 1) with i-50 printed in black ink.

Lozanoc is available in blister pack sizes of 4, 6, 7, 8, 14, 15, 18, 28, 30 and 60 capsules.

Lozanoc is available in bottle pack sizes of 15, 30, 60 and 90 capsules.

Not all pack sizes and container types may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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Manufacturer

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LOZANOC: United Kingdom

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