

Package leaflet: Information for the user

Itrakonazol Actavis 100 mg, hard capsules

itraconazole

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

1. What /.../ is and what it is used for

/.../ contains itraconazole which is an anti-fungal agent. It prevents the fungus from building up a normal cell wall. Without a functional cell wall the fungus will die.

/.../ is used to treat fungal infections in the vagina, mouth, skin and nails.

2. What you need to know before you take /.../

Do not take /.../

- if you are allergic to itraconazole or any of the other ingredients of this medicine (listed in section 6).
- if you are pregnant or think you may be pregnant or are planning to have a baby (see “Pregnancy and breast-feeding”).
- if you are a woman of childbearing age and you may become pregnant, you should use effective contraception to make sure that you do not become pregnant when taking this medicine. As the medicine in /.../ stays in your body for some time after you have stopped taking them, you should continue to take adequate contraceptive measures until your next menstrual period (menstrual bleed) following after the end of treatment.
- when you have evidence of a severe heart failure (ventricular dysfunction such as congestive heart failure), a history of heart failure (congestive heart failure) except for the treatment of life-threatening or other serious infections (see also section “warnings and precautions”).

Tell your doctor if you are taking any medicines, before you use /.../.

Do not use /.../ if you are taking certain medicines. Also do not use such medicines within 2 weeks of stopping /.../. The following list contains examples of medicines you must not take with /.../, or within 2 weeks of stopping /.../:

- Medicines to treat problems with the heart, blood or circulation
 - aliskiren, eplerenone, lercanidipine or nisoldipine (for high blood pressure)
 - bepridil, ivabradine or ranolazine – (for angina)
 - dabigatran or ticagrelor (for blood clots)
 - disopyramide, dofetilide, dronedarone or quinidine (for irregular heart beat rhythms)
 - finerenone (for kidney problems in patients with type 2 diabetes)
 - lomitapide, lovastatin or simvastatin (to lower cholesterol)
 - sildenafil (for pulmonary arterial hypertension)
- Medicines to treat stomach problems or constipation
 - cisapride (for stomach upsets)
 - domperidone (for nausea and vomiting)
 - naloxegol (for constipation caused by taking opioid painkillers)
- Medicines to treat headaches, sleep or mental health problems
 - dihydroergotamine or ergotamine (ergot alkaloids used for migraine headaches)
 - midazolam (taken by mouth) or triazolam (for sedation or to help you sleep)
 - lurasidone, pimozide, quetiapine or sertindole (for schizophrenia, bipolar disorder or other mental health problems)
- Medicines to treat urinary problems
 - darifenacin (for urinary incontinence)
 - fesoterodine or solifenacin (for irritated urinary bladder) when used in patients with certain kidney or liver problems
- Medicines to treat allergies
 - astemizole, mizolastine or terfenadine (for allergies)
- Medicines to treat erection and ejaculation problems
 - avanafil (for erectile dysfunction)
 - dapoxetine (for premature ejaculation)
 - vardenafil (for erectile dysfunction) when used in men older than 75 years of age
- Other medicines containing:
 - colchicine (for gout) when used in patients with kidney or liver problems
 - ergometrine (ergonovine) or methylergometrine (methylergonovine), ergot alkaloids used after giving birth
 - eliglustat (for Gaucher's disease) when used in patients that cannot break down certain medicines in the body
 - halofantrine (for malaria)
 - irinotecan (for cancer)
 - isavuconazole (for fungal infections)
 - ombitasvir/paritaprevir/ritonavir with or without dasabuvir – (to treat hepatitis C)
 - venetoclax (for chronic lymphocytic leukaemia) when you newly start venetoclax or take increasing doses at beginning of treatment
 - voclosporin (to treat lupus-related kidney problems)

Remember – do not take any of the medicines above for 2 weeks after your last treatment with /.../.

This is not a complete list, so tell your doctor if you are taking or planning to take any of these medicines, or any other medicines.

Warnings and precautions

Talk to your doctor or pharmacist before taking /.../.

Stop taking /.../ and see your doctor immediately if any of the following symptoms of severe liver problems appear during your course of treatment:

- Severe lack of appetite, feeling sick, being sick, unusual tiredness, abdominal (stomach) pain, unusually dark urine or pale stools.

Tell your doctor immediately:

- If you have any unusual feelings of tingling, numbness or weakness in your hands or feet whilst taking /.../.
- If you experience any hearing loss symptoms. In very rare cases patients taking /.../ have reported temporary or permanent hearing loss.

You must tell your doctor before taking /.../ if you suffer or have suffered in the past from:

- an allergic reaction to any other antifungal medicines
- a heart problem, including heart failure (also called congestive heart failure or CHF), this medicine could make it worse. If your doctor decides to give you /.../, you should be told about the symptoms listed below to watch out for. If you get any of the following stop taking this medicine and tell your doctor straight away. These may be signs of heart failure:
 - shortness of breath
 - unexpected weight gain
 - swelling of your legs or stomach
 - feel unusually tired
 - wake up short of breath at night
- a liver problem, such as jaundice (yellowing of the skin) as your dose of /.../ may have to be changed. Your doctor should give you instructions on symptoms to watch out for. These include: lack of appetite, feeling sick, being sick, unusual tiredness, abdominal (stomach) pain, unusually dark urine. If you have to take this medicine continuously for more than one month, your doctor may want to check your liver by doing blood tests. In addition, there may be specific medication you may not be able to take.
- a kidney disorder as your dose of /.../ may have to be changed. In addition, there may be specific medication you may not be able to take.
- cystic fibrosis (a genetic disease affecting the lungs, pancreas, liver, kidneys and intestines).
- if your immune system is not working as well as it should, e.g. neutropenia (reduced number of white blood cells), AIDS or after an organ transplant. The dose of /.../ may then have to be increased.
- if you are an AIDS patient and have a fungal disease of the organs (e.g. sporotrichosis, blastomycosis, histoplasmosis, cryptococcosis [with and without meningitis]), your doctor will check whether you need to perform a so-called maintenance therapy.
- if your stomach acid content is low as this will impair the absorption of itraconazole. Patients who are also receiving medicines to neutralise the stomach acid (e.g. aluminium hydroxide), should take these at least 1 hour before or 2 hours after taking /.../. In patients who have an absence of hydrochloric acid in the gastric juice (achlorhydria), as in some AIDS patients and patients who are taking medicines to suppress hydrochloric acid (H₂-antagonists, proton-pump inhibitors), it is advisable to take this medicine with a non-diet cola beverage. Your doctor may check whether the dosage of /.../ needs to be increased.

Children and adolescents

So far there is limited experience on the use of itraconazole in children and adolescents. /.../ should therefore only be used in children and adolescents after the doctor has carefully considered the benefits and risks.

Other medicines and /.../

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. There are some medicines that **you should not take** whilst taking /.../. These are listed above under the heading “Do not take /.../”

Certain medicines are not recommended for use with /.../.

Your doctor may decide that you **should not take some medicines at the same time as, or within 2 weeks of stopping** /.../.

Examples of these medicines are:

- Medicines to treat problems with the heart, blood or circulation
 - apixaban, edoxaban, rivaroxaban or vorapaxar (for blood clots)
 - atorvastatin (to lower cholesterol)
 - felodipine (for high blood pressure)
 - riociguat or tadalafil (for pulmonary hypertension)
- Medicines to treat epilepsy, headaches or mental health problems
 - phenytoin, carbamazepine or phenobarbital (anti-epileptics)
 - eletriptan (for migraine headaches)
 - St. John’s Wort (*Hypericum perforatum*) (a herbal medicine used for mental health problems)
- Medicines to treat urinary problems
 - tamsulosin (for male urinary incontinence)
 - tolterodine (for irritated urinary bladder)
- Medicines to treat cancer
 - axitinib, bosutinib, cabazitaxel, cabozantinib, ceritinib, cobimetinib, crizotinib, dabrafenib, dasatinib, docetaxel, entrectinib, glasdegib, ibrutinib, lapatinib, nilotinib, olaparib, pazopanib, regorafenib, sunitinib, talazoparib, trabectedin, trastuzumab emtansine, venetoclax (when you are on a stable dose of venetoclax for chronic lymphocytic leukaemia, or at any time of treatment for acute myeloid leukaemia) or vinca alkaloids (e.g., vinflunine, vinorelbine)
- Medicines to treat tuberculosis
 - bedaquiline, isoniazid, rifabutin or rifampicin (for tuberculosis)
- Medicines to treat human immunodeficiency virus (HIV) or hepatitis
 - efavirenz or nevirapine (for HIV/AIDS)
 - elbasvir/grazoprevir, tenofovir alafenamide fumarate (TAF), tenofovir disoproxil fumarate (TDF) (for HIV or hepatitis)
- Medicines used after organ transplant
 - everolimus, rapamycin (also known as sirolimus), temsirolimus
- Medicines to treat benign prostatic enlargement
 - alfuzosin, silodosin
- Medicines to treat lung problems or allergies
 - ciclesonide (for inflammation, asthma and allergies)
 - ebastine (for allergies)
 - salmeterol (for asthma or chronic obstructive pulmonary disease -COPD)
- Medicines to treat erection and ejaculation problems
 - tadalafil or vardenafil (when used in men 75 years of age and younger) (for

erectile dysfunction)

- Other medicines containing:
 - colchicine (for gout)
 - fentanyl (for pain)
 - lumacaftor/ivacaftor (for cystic fibrosis)

Remember - do not take any of the medicines above for 2 weeks after your last treatment with /.../. This is not a complete list, so tell your doctor if you are taking or planning to take any of these medicines, or any other medicines.

Care needs to be taken when using /.../ with certain other medicines.

You may be more likely to get side effects, or the dose of /.../ or the other medicine might need to be changed. Examples of these medicines are:

- Medicines to treat problems with the heart, blood or circulation
 - bosentan (for pulmonary hypertension)
 - calcium channel blockers such as, dihydropyridines such as amlodipine, isradipine, nifedipine, nimodipine or diltiazem (for hypertension)
 - or verapamil (for high blood pressure)
 - cilostazol (for circulatory problems)
 - ‘coumarins’ such as warfarin (for blood clots)
 - digoxin (for atrial fibrillation)
 - nadolol (for pulmonary hypertension or angina)
- Medicines to treat stomach problems or diarrhoea
 - aprepitant or netupitant (for nausea and vomiting during cancer treatment)
 - loperamide (for diarrhoea)
 - antacids such as aluminium, calcium, magnesium, or sodium bicarbonate; H₂-receptor antagonists such as cimetidine, ranitidine and proton pump inhibitors such as lansoprazole, omeprazole, rabeprazole (to treat stomach acid problems)
- Medicines to treat sleep problems or mental health problems
 - alprazolam, brotizolam, buspirone, or midazolam (when injected into a vein) (for anxiety or to help you sleep)
 - zopiclone (to help you sleep)
 - reboxetine or venlafaxine (for depression and anxiety)
 - aripiprazole, cariprazine, haloperidol or risperidone (for schizophrenia, bipolar disorder or other mental health problems)
 - galantamine (for Alzheimer’s disease)
 - guanfacine (for attention deficit hyperactivity disorder)
- Medicines to treat urinary problems
 - imidafenacin, fesoterodine, oxybutynin, solifenacin (for irritated urinary bladder)
- Medicines to treat cancer
 - bortezomib, brentuximab vedotin, busulfan, erlotinib, gefitinib, idelalisib, imatinib, nintedanib, panobinostat, pemigatinib, ponatinib, ruxolitinib, sonidegib or tretinoin (oral)

- Medicines to treat infections
 - ciprofloxacin, clarithromycin, or erythromycin (for bacterial infections)
 - delamanid (for tuberculosis)
 - artemether/lumefantrine or quinine (to treat malaria)
 - praziquantel (for fluke and tapeworms)
- Medicines to treat human immunodeficiency virus (HIV) or hepatitis
 - cobicistat, ritonavir-boosted elvitegravir, maraviroc, ritonavir, boosted darunavir, ritonavir-boosted fosamprenavir, indinavir, ritonavir-boosted saquinavir or saquinavir (for HIV)
 - glecaprevir/pibrentasvir (for hepatitis)
- Medicines used after organ transplant
 - cyclosporine or tacrolimus
- Medicines to treat benign prostatic enlargement
 - dutasteride
- Medicines to treat lung problems, allergies or inflammatory conditions
 - bilastine or rupatadine (for allergy)
 - methylprednisolone or dexamethasone, (medicines given by mouth or injection for asthma, allergies or inflammatory conditions)
 - budesonide or fluticasone (for asthma, allergies)
- Medicines to treat erection and ejaculation problems
 - sildenafil (for erectile dysfunction)
- Medicines to treat pain
 - alfentanil, buprenorphine, oxycodone or sufentanil (for pain)
 - meloxicam (for joint inflammation and pain)
- Other medicines containing:
 - alitretinoin (given by mouth) (for eczema)
 - cabergoline (for Parkinson's disease)
 - cannabis based products including medicines (such as for nausea and vomiting or muscle spasms in patients with multiple sclerosis)
 - cinacalcet (for an over active parathyroid)
 - dienogest or ulipristal (contraceptives)
 - eliglustat (for Gaucher's disease) when used in patients that cannot break down certain medicines in the body
 - ivacaftor; (for cystic fibrosis)
 - methadone (to treat drug addiction)
 - repaglinide or saxagliptin (for diabetes)

This is not a complete list, so tell your doctor if you are taking or planning to take any of these medicines, or any other medicines.

/.../ with drink

Patients with gastric juice deficiency (achlorhydria), certain AIDS patients or patients taking medicines to reduce gastric secretion (e.g. H₂-antagonists, proton pump inhibitors) should take this medicine with an acidic drink, such as a non-diet cola beverage.

Children, adolescents and elderly patients

/.../ are not normally given to children, adolescents and the elderly. However, your doctor may prescribe them in special cases.

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.

Pregnancy

/.../ must not be taken during pregnancy except for life-threatening cases. For this reason your doctor should carefully weigh up the benefit versus the risk of treatment with /.../ if you are pregnant.

If you are a women of childbearing age and you may become pregnant, talk to your doctor. You should use effective contraception to make sure that you do not become pregnant when taking this medicine. As the medicine in /.../ stays in your body for some time after you have stopped taking them, you should continue to take adequate contraceptive measures until your next menstrual period (menstrual bleed) following after the end of treatment.

If you become pregnant after starting treatment with /.../ capsules, stop taking them and tell your doctor straight away.

There is only limited information on the use of itraconazole during pregnancy. During post-marketing experience, cases of congenital abnormalities have been reported. These cases included skeletal, genitourinary tract, cardiovascular and ophthalmic malformations as well as chromosomal and multiple malformations. A causal relationship with itraconazole has not been established. Epidemiological data on exposure to itraconazole during the first three months of pregnancy - mostly in patients receiving short-term duration of treatment - did not show an increased risk for malformations.

Breast-feeding

Do not breast-feed if you are taking /.../, as small amounts of the medicine could pass into your milk.

Driving and using machines

/.../ can sometimes cause dizziness, blurred/double vision or hearing loss. If you have these symptoms do not drive or use machines.

/.../ contains sucrose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take /.../

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

Take this medicine immediately **after a meal with an adequate amount of liquid** (1 glass of water) so that your body can optimally absorb the medicine. **Swallow the capsules whole unchewed.**

Your doctor will decide which dose you will take, based on your individual needs.

The usual recommended doses are:

Superficial mycoses (skin, mucosal membranes)		
Indication	Dose	Duration of treatment
Fungal diseases of the female reproductive organs (vulvovaginal candidosis)	2 hard capsules in the morning and 2 hard capsules in the evening (equivalent to 200 mg of itraconazole in the morning and 200 mg of itraconazole in the evening) The intake can also be started in the evening and be finished the following morning.	1 day
Fungal diseases of the mouth, oral thrush (oral candidiasis)	1 hard capsule 1 x daily (equivalent to 100 mg of itraconazole per day)	2 weeks
Fungal skin diseases of the body or lower legs (Tinea corporis/cruris)	1 hard capsule 1 x daily (equivalent to 100 mg of itraconazole per day)	2 weeks
Fungal skin diseases of the palms and soles (Tinea pedis/manus)	1 hard capsule 1 x daily (equivalent to 100 mg of itraconazole per day)	4 weeks
Branny fungal eruptions (Pityriasis versicolor)	2 hard capsules 1 x daily (equivalent to 200 mg of itraconazole per day)	7 days

Fungal diseases of the nails									
Interval treatment (intake with interruption)				Dose and duration of treatment					
				Interval treatment entails the following dosing schedule: 2 hard capsules 2 x daily (equivalent to 400 mg of itraconazole per day) for one week. Interval treatments are always interrupted by a 3-week intake-free interval (see enclosed table). Two interval treatments are recommended for finger nail infections, while three are recommended for toenail infections. If the nail regrows after treatment has ended, then treatment was successful.					
Ultimate therapeutic success can only occur after an additional 3 months (without treatment), particularly in case of infestation of the toenails. Treatment should be no longer than 3 months for safety reasons when treating fungal diseases of the nail. <u>Note:</u> In order to achieve a good result, the diseased nail area should be removed as atraumatically as possible (e.g. using urea ointment) before treatment starts.									
Location of fungal diseases of the nails	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8	Week 9
Toenails with or without fingernail involvement	Interval 1	Itraconazole-free weeks			Interval 2	Itraconazole-free weeks			Interval 3

Fingernails only	Interval 1	Itraconazole-free weeks	Interval 2	
Continuous therapy (intake without interruption)		Dose	Duration of treatment	
		2 hard capsules 1 x daily (equivalent to 200 mg of itraconazole per day)	3 months as a rule (if only the fingernails are infested, a shorter duration of treatment may suffice).	

Itraconazole remains in the skin and nails significantly longer than in the blood.

Optimal healing is achieved for fungal skin diseases at 2 to 4 weeks and for fungal nail diseases at 6 to 9 months after cessation of itraconazole capsules.

If you take more /.../ than you should

If you have taken more /.../ than you should, contact your doctor, hospital or pharmacist to get an opinion of the risk and advice on action to be taken. Symptoms of an overdose include nausea, abdominal pain, dizziness, headache and other of the described adverse reactions listed in section 4.

If you forget to take /.../

If you miss a dose, take it as soon as you remember. If it is near the time of your next dose, skip the missed dose and take your next dose as usual. Do not take a double dose to make up for a forgotten capsule.

If you stop taking /.../

Your doctor will tell you how long your treatment will last. Do not stop taking the capsules before the prescribed course is finished because the infection may not be completely cured. It may take several weeks after you have finished your treatment before all symptoms disappear.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Medicines can cause serious allergic reactions.

Stop taking /.../ and contact your doctor immediately if you have:

- any sudden wheeziness, difficulty in breathing, swelling of the face, rash, itching (especially affecting the whole body) or a severe skin disorder (widespread rashes with peeling skin and blisters in the mouth, eyes and genitals, or rashes with small pustules or blisters)
- severe lack of appetite, feeling sick, being sick, unusual tiredness, abdominal (stomach) pain, unusually dark urine, or pale stools. These may be symptoms of severe liver problems.
- symptoms that resemble heart failure such as shortness of breath, unexpected weight gain, swelling of the legs, unusual fatigue (tiredness), repeated waking at night.

You should also let your doctor know immediately if you have any of the side effects below:

- a tingling sensation, sensitivity to light, numbness or weakness in the limbs.
- blurred vision/double vision, ringing in your ears, lose the ability to control your urine or increased need to urinate (pass water).
- if you experience any hearing loss symptoms
- severe upper stomach pain, often with nausea and vomiting due to inflammation of the

pancreas (pancreatitis).

Other side effects include:

Common side effects (occur in less than 1 in 10 patients) are:

- headache
- stomach ache
- feeling sick (nausea)

Uncommon side effects (occur in less than 1 in 100 patients) are:

- inflammation of the nose, infection of the upper respiratory tract, inflammation of the sinuses
- hypersensitivity
- diarrhoea, being sick (vomiting), constipation, indigestion, wind
- abnormal liver function
- hives, rash, itching
- abnormal menstrual bleeding

Rare side effects (occur in less than 1 in 1000 patients) are:

- certain blood disorders (leukopenia)
- serum sickness, painful swelling of skin and mucous membranes (angioneurotic oedema), hypersensitivity reactions (anaphylactic reaction)
- excess of triglycerides (fats) in the blood
- tremors, sensations like tingling or weakness in your hands and feet (paraesthesia), reduced sensation to pain (hypoesthesia), unpleasant taste (dysgeusia)
- visual disturbances including blurred vision and double vision
- transient or permanent hearing loss, ringing or buzzing in the ears (tinnitus)
- heart failure with symptoms such as shortness of breath, unexpected weight gain, swelling of your legs or abdomen, feeling unusually tired, repeated waking at night (congestive heart failure)
- difficulty breathing (dyspnoea)
- severe upper stomach pain, often with nausea and vomiting (pancreatitis)
- severe liver problems (hepatotoxicity including fatal acute liver failure), high blood levels of bilirubin
- severe allergic skin reactions (such as toxic epidermal necrolysis, Stevens-Johnson syndrome, acute generalized exanthematous pustulosis, erythema multiforme, exfoliative dermatitis or leukocytoclastic vasculitis) accompanied by several skin changes, hair loss, sensitivity to light
- abnormally frequent urination (pollakiuria)
- erection difficulties (erectile dysfunction)
- fluid retention (oedema)
- increase in blood creatine phosphokinase levels

Side effects with frequency **not known** (frequency cannot be estimated from the available data):

- symptoms of increased levels of the hormone 'aldosterone' (such as high blood pressure or low blood potassium levels), even though the 'aldosterone' blood level is normal or low

The following side effects have been reported in patients taking other formulations of itraconazole:

- certain blood disorder (granulocytopenia, thrombocytopenia)
- hypersensitivity reactions (anaphylactoid reactions)
- high blood sugar levels
- muscle cramps or irregular heart beat (possible symptoms of high or low blood levels of potassium)
- muscle cramps or irregular heart beat (possible symptoms of low blood levels of magnesium)
- confusion

- nerve damage in arms and legs causing pain or numbness, burning and tingling, dizziness, sleepiness
- heart failure (when the heart does not pump blood as well as it should with shortness of breath, tiredness and ankle swelling), increase in heart rate
- high blood pressure, low blood pressure
- fluid in the lungs, difficulty speaking, cough
- stomach and gut disturbances
- liver failure, inflammation of the liver (hepatitis), yellowing of the skin (jaundice)
- rash with reddening of the skin, excess sweating
- muscle pain, painful joints
- kidney problems
- lack of control over passing urine
- general swelling, facial swelling, chest pain, fever, pain, fatigue, chills
- abnormal urine and blood findings, increases in specific liver function tests (hepatic enzyme increased)

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 /.../

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after EXP.
The expiry date refers to the last day of that month.

Do not store above 25°C.

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. Contents of the pack and other information

What /.../ contains

- The active substance is itraconazole. 1 hard capsule contains 100 mg itraconazole.
- The other ingredients are sugar spheres (sucrose and maize starch), poloxamer and hypromellose.
- Capsule shell: Gelatine and colouring agents (indigo carmine (E 132), quinoline yellow (E 104) and titanium dioxide (E 171)).

What /.../ looks like and contents of the pack

Opaque green gelatine capsules with yellowish-beige spherical micro-granules.

/.../ is available in the following pack sizes: 4, 6, 15, 18, 28, 30 and 100 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

[To be completed nationally]

Manufacturer:

LABORATORIOS LICONSA S.A.
Avda. Miralcampo, No 7,
Polígono Industrial Miralcampo
19200 Azuqueca de Henares (Guadalajara)
Spain

This medicine is authorised in the Member States of the European Economic Area under the following names:

[To be completed nationally]

This leaflet was last revised in 2025-07-01

QR code and URL

<Other sources of information>

<Latest approved information on this medicine is available by scanning the <QR code> <other 2D bar code> <NFC> included in the <PL> <outer carton> <immediate packaging> with a smartphone/device. The same information is also available on the following URL: {URL} <and the <{NCA}> website>>
<{QR code}> <{other 2D bar code}> <{NFC}>

URL only

<Other sources of information>

<Latest approved information on this medicine is available on the following URL: {URL} <and the <{NCA}> website>>