Package leaflet: Information for the user

Posaconazol Devatis 40 mg/ml suspensie voor oraal gebruik
posaconazole

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

1. What Posaconazol Devatis is and what it is used for

Posaconazol Devatis contains a medicine called posaconazole. This belongs to a group of medicines called "antifungals". It is used to prevent and treat many different fungal infections.

This medicine works by killing or stopping the growth of some types of fungi that can cause infections.

Posaconazol Devatis can be used in adults to treat the following types of fungal infections when other antifungal medicines have not worked or you have had to stop taking them:
- infections caused by fungi of the *Aspergillus* family that have not improved during treatment with the antifungal medicines amphotericin B or itraconazole or when these medicines have had to be stopped;
- infections caused by fungi of the *Fusarium* family that have not improved during treatment with amphotericin B or when amphotericin B has had to be stopped;
- infections caused by fungi that cause the conditions known as "chromoblastomycosis" and "mycetoma" that have not improved during treatment with itraconazole or when itraconazole has had to be stopped;
- infections caused by a fungus called *Coccidioides* that have not improved during treatment with one or more of amphotericin B, itraconazole or fluconazole or when these medicines have had to be stopped.
- Infections in the mouth or throat area (known as "thrush") caused by fungi called *Candida*, which were not previously treated.

This medicine can also be used to prevent fungal infections in adults who are at high risk of getting a fungal infection, such as:
- patients who have a weak immune system due to having chemotherapy for "acute myelogenous leukemia" (AML) or "myelodysplastic syndromes" (MDS)
- patients having "high-dose immunosuppressive therapy" after "hematopoietic stem cell transplant" (HSCT).

2. What you need to know before you take Posaconazol Devatis

Do not take Posaconazol Devatis
- if you are allergic to posaconazole or any of the other ingredients of this medicine (listed in section 6).
- if you are taking: terfenadine, astemizole, cisapride, pimozide, halofantrine, quinidine, any medicines that contain "ergot alkaloids" such as ergotamine or dihydroergotamine, or a "statin" such as simvastatin, atorvastatin or lovastatin.
- if you have just started taking venetoclax or your venetoclax dose is being slowly increased for treatment of chronic lymphocytic leukaemia (CLL).

Do not take Posaconazol Devatis if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Posaconazol Devatis.

See "Other medicines and Posaconazol Devatis" below for more information including information on other medicines which may interact with Posaconazol Devatis.

Warnings and precautions
Talk to your doctor or pharmacist before taking Posaconazol Devatis if you:
- have had an allergic reaction to another antifungal medicine such as ketoconazole, fluconazole, itraconazole or voriconazole.
- have or have ever had liver problems. You may need to have blood tests while you are taking this medicine.
- develop severe diarrhoea or vomiting, as these conditions may limit the effectiveness of this medicine.
- have an abnormal heart rhythm tracing (ECG) that shows a problem called long QTc interval
- have a weakness of the heart muscle or heart failure
- have a very slow heartbeat
- have heart rhythm disturbance
- have any problem with potassium, magnesium or calcium levels in your blood
- are taking vincristine, vinblastine and other "vinca alkaloids" (medicines used to treat cancer).
- are taking venetoclax (a medicine used to treat cancer).

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Posaconazol Devatis.

If you develop severe diarrhoea or vomiting (being sick) while taking Posaconazol Devatis, talk to your doctor or pharmacist straight away, as this may stop it from working properly. See Section 4 for more information.

Children and adolescents
Posaconazol Devatis should not be used in children and adolescents (17 years of age and younger).

Other medicines and Posaconazol Devatis
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take Posaconazol Devatis if you are taking any of the following:
- terfenadine (used to treat allergies)
- astemizole (used to treat allergies)
- cisapride (used to treat stomach problems)
- pimozide (used to treat symptoms of Tourette's and mental illness)
- halofantrine (used to treat malaria)
- quinidine (used to treat abnormal heart rhythms).

Posaconazol Devatis can increase the amount of these medicines in the blood which may lead to very serious changes to your heart rhythm:

- any medicines that contain “ergot alkaloids” such as ergotamine or dihydroergotamine used to treat migraines. Posaconazol Devatis can increase the amount of these medicines in the blood which may lead to a severe decrease in blood flow to your fingers or toes and could cause damage to them.
- a “statin” such as simvastatin, atorvastatin or lovastatin used to treat high cholesterol.
- venetoclax when used at the start of the treatment of a type of cancer, chronic lymphocytic leukaemia (CLL).

Do not take Posaconazol Devatis if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Other medicines
Look at the list of medicines given above that must not be taken while you are taking Posaconazol Devatis. In addition to the medicines named above there are other medicines that carry a risk of rhythm problems that may be greater when they are taken with Posaconazol Devatis. Please make sure you tell your doctor about all the medicines you are taking (prescribed or non-prescribed).

Certain medicines may increase the risk of side effects of Posaconazol Devatis by increasing the amount of Posaconazol Devatis in the blood.

The following medicines may decrease the effectiveness of Posaconazol Devatis by decreasing the amount of Posaconazol Devatis in the blood:
- rifabutin and rifampicin (used to treat certain infections). If you are already taking rifabutin, you will need a blood test and you will need to look out for some possible side effects of rifabutin.
- phenytoin, carbamazepine, phenobarbital or primidone (used to treat or prevent fits).
- efavirenz and fosamprenavir used to treat HIV infection.
- medicines used to decrease stomach acid such as cimetidine and ranitidine or omeprazole and similar medicines that are called proton pump inhibitors.

Posaconazol Devatis may possibly increase the risk of side effects of some other medicines by increasing the amount of these medicines in the blood. These medicines include:
- vincristine, vinblastine and other “vinca alkaloids” (used to treat cancer)
- venetoclax (used to treat cancer)
- ciclosporin (used during or after transplant surgery)
- tacrolimus and sirolimus (used during or after transplant surgery)
- rifabutin (used to treat certain infections)
- medicines used to treat HIV called protease inhibitors (including lopinavir and atazanavir, which are given with ritonavir)
- midazolam, triazolam, alprazolam or other “benzodiazepines” (used as sedatives or muscle relaxants)
- diltiazem, verapamil, nifedipine, nisoldipine or other “calcium channel blockers” (used to treat high blood pressure)
- digoxin (used to treat heart failure)
- glipizide or other “sulfonylureas” (used to treat high blood sugar)
- all-trans retinoic acid (ATRA), also called tretinoin (used to treat certain blood cancers).

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Posaconazol Devatis.

Posaconazol Devatis with food, drink and alcohol
To improve absorption of posaconazole, whenever possible it should be taken during or immediately after food or a nutritional drink (see section 3 “How to take Posaconazol Devatis”). There is no information on the effect of alcohol on posaconazole.

Pregnancy and breast-feeding
Tell your doctor if you are or think you are pregnant before you start to take Posaconazol Devatis.
Do not take Posaconazol Devatis if you are pregnant unless you are told to by your doctor.

If you are a woman who could become pregnant you should use effective contraception while you are taking this medicine. If you become pregnant while you are taking Posaconazol Devatis, contact your doctor straight away.

Do not breast-feed while taking Posaconazol Devatis. This is because small amounts may pass into breast milk.

Driving and using machines
You may feel dizzy, sleepy, or have blurred vision while taking Posaconazol Devatis, which may affect your ability to drive or use tools or machines. If this happens, do not drive or use any tools or machines and contact your doctor.

Posaconazol Devatis contains glucose
Posaconazol Devatis contains approximately 1.75 g of glucose per 5 mL of suspension. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Posaconazol Devatis contains sodium benzoate (E 211)
Posaconazol Devatis contains approximately 10.00 mg of sodium benzoate per 5 mL of suspension. Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

Posaconazol Devatis contains propylene glycol (E 1520)
Posaconazol Devatis contains approximately 14.35 mg propylene glycol per 5 mL of suspension.

Posaconazol Devatis contains sodium
Posaconazol Devatis contains less than 1 mmol sodium (23 mg) per 5 mL of suspension, that is to say essentially 'sodium-free'.

3. How to take Posaconazol Devatis

Posaconazole is available in other forms and strengths, however not under this tradename.
Do not switch between posaconazole oral suspension and tablets or gastro-resistant oral suspension without talking to your doctor or pharmacist because it may result in a lack of efficacy or an increased risk of adverse reactions.

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will monitor your response and condition to determine how long Posaconazol Devatis needs to be given and whether any change is needed to your daily dose.

The table below shows the recommended dose and length of treatment which depend on the type of infection that you have and may be individually adapted for you by your doctor. Do not adapt your dose yourself before consulting your doctor or change your treatment regime.

Whenever possible you should take posaconazole during or immediately after food or a nutritional drink.

Indication	**Recommended dose and length of treatment**
Treatment of refractory Fungal Infections (*Invasive aspergillosis, Fusariosis, Chromoblastomycosis/Mycetoma, Coccidioidomycosis)*	The recommended dose is 200 mg (5 mL) taken four times daily. Alternatively, if recommended by your doctor, you may take 400 mg (5 mL) twice a day provided that you are able to take both doses during or after food or a nutritional drink.
First time treatment of Thrush	On the first day of treatment take 200 mg (5 mL) once. After the first day, take 100 mg (2.5 mL) once a day.

Prevention of serious Fungal Infections	Take 200 mg (5 mL) three times a day.

When you use the medicine follow the instructions below:

1. Shake the bottle well.
2. Remove the bottle cap and push the adaptor firmly into the top of the bottle and leave in place for future doses.
3. Push the tip of the dosing syringe into the hole in the adaptor.
4. Turn the bottle upside down.
5. Pull the plunger of the syringe back so that the medicine is drawn from the bottle into the syringe. Pull the plunger back to the point on the scale that corresponds to the dose prescribed.
6. Turn the bottle back the right way up and carefully remove the syringe from the adaptor, holding it by the barrel rather than the plunger.
7. Gently put the tip of the syringe into your mouth and to the inside of your cheek.
8. Slowly and gently push the plunger down to gently squirt the medicine into the inside of your cheek and swallow it. Do not forcefully push down the plunger, or squirt the medicine to the back of your mouth or throat, as you may choke.
9. Remove the syringe from your mouth.
10. Put the cap back on the bottle with the adaptor left in place.
11. Wash the syringe with warm water and rinse well. Hold the syringe under water and move the plunger up and down several times to make sure the inside of the syringe is clean. Let the syringe air dry completely before you use it again for dosing. Store the syringe in a hygienic place with the medicine.

If you take more Posaconazol Devatis than you should
If you are concerned that you may have taken too much, contact your doctor or healthcare professional immediately.

If you forget to take Posaconazol Devatis
If you have missed a dose, take it as soon as you remember and then carry on as before. However, if it is almost time for your next dose, take your dose when it is due. Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

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

Serious side effects
Tell your doctor or pharmacist or nurse straight away if you notice any of the following serious side effects – you may need urgent medical treatment:
- nausea or vomit (feeling or being sick), diarrhoea
- signs of liver problems - these include yellowing of your skin or whites of the eyes, unusually dark urine or pale faeces, feeling sick for no reason, stomach problems, loss of appetite or unusual tiredness or weakness, an increase in liver enzymes shown up in blood tests
- allergic reaction

Other side effects
Tell your doctor or pharmacist if you notice any of the following side effects:

Common: the following may affect up to 1 in 10 people
- a change in the salt level in your blood shown in blood tests - signs include feeling confused or weak
- abnormal skin sensations, such as numbness, tingling, itching, creeping, pricking or burning

- headache
- low potassium levels – shown up in blood tests
- low magnesium levels – shown up in blood tests
- high blood pressure
- loss of appetite, stomach pain or upset stomach, passing wind, dry mouth, changes in your taste
- heartburn (a burning sensation in the chest rising up to the throat)
- low levels of "neutrophils" a type of white blood cell (neutropenia) –this can make you more likely to get infections and be shown up in blood tests
- fever
- feeling weak, dizzy, tired or sleepy
- rash
- itching
- constipation
- rectal discomfort

Uncommon: the following may affect up to 1 in 100 people

- anaemia - signs include headaches, feeling tired or dizzy, being short of breath or looking pale and a low level of haemoglobin shown up in blood tests
- low level of platelets (thrombocytopenia) shown in blood tests – this may lead to bleeding
- low level of "leukocytes" a type of white blood cell (leukopenia) shown in blood tests – this can make you more likely to get infections
- high level of "eosinophils" a type of white blood cell (eosinophilia) – this can happen if you have inflammation
- inflammation of the blood vessels
- heart rhythm problems
- fits (convulsions)
- nerve damage (neuropathy)
- abnormal heart rhythm – shown up on a heart trace (ECG), palpitations, slow or fast heartbeat, high or low blood pressure
- low blood pressure
- inflammation of the pancreas (pancreatitis) – this may cause severe stomach pain
- oxygen supply to the spleen is interrupted (splenic infarction) - this may cause severe stomach pain
- severe kidney problems – signs include passing more or less urine, that is a different colour than usual
- high blood levels of creatinine – shown in blood tests
- cough, hiccups
- nose bleeds
- severe sharp chest pain when breathing in (pleuritic pain)
- swelling of lymph glands (lymphadenopathy)
- reduced feeling of sensitivity especially on the skin
- tremor
- high or low blood sugar levels
- blurred vision, sensitivity to light
- hair loss (alopecia)
- mouth ulcers
- shivering, feeling generally unwell
- pain, back or neck pain, pain in arms or legs
- water retention (oedema)
- menstrual problems (abnormal vaginal bleeding)
- inability to sleep (insomnia)
- being completely or partially unable to talk
- swelling of the mouth
- abnormal dreams, or difficulty sleeping
- problems with co-ordination or balance
- mucosal inflammation
- stuffy nose
- difficulty breathing

- chest discomfort
- feeling bloated
- mild to severe nausea, vomiting, cramps and diarrhoea, usually caused by a virus, stomach pain
- belching
- feeling jittery

Rare: the following may affect up to 1 in 1,000 people
- pneumonia – signs include feeling short of breath and producing discoloured phlegm
- high blood pressure in the blood vessels in the lungs (pulmonary hypertension) this can cause serious damage to your lungs and heart
- blood problems such as unusual blood clotting or prolonged bleeding
- severe allergic reactions, including widespread blistering rash and skin peeling
- mental problems such as hearing voices or seeing things that are not there
- fainting
- having problems thinking or talking, having jerking movements, especially in your hands that you cannot control
- stroke – signs include pain, weakness, numbness, or tingling in the limbs
- having a blind or dark spot in your field of vision
- heart failure or heart attack which could lead to the heart stopping beating and death, heart rhythm problems, with sudden death
- blood clots in your legs (deep vein thrombosis) – signs include intense pain or swelling of the legs
- blood clots in your lungs (pulmonary embolism) – signs include feeling short of breath or pain while breathing
- bleeding into your stomach or gut – signs include vomiting blood or passing blood in your stool
- a blockage in your gut (intestinal obstruction) especially in the "ileum". The blockage will prevent the contents of your intestine from passing through to the lower bowel signs include feeling bloated, vomiting, severe constipation, loss of appetite, and cramps
- "haemolytic uraemic syndrome" when red blood cells breakup (haemolysis) which may happen with or without kidney failure
- "pancytopenia" low level of all blood cells (red and white blood cells and platelets) shown in blood tests
- large purple discolourations on the skin (thrombotic thrombocytopenic purpura)
- swelling of the face or tongue
- depression
- double vision
- breast pain
- adrenal glands not working properly – this may cause weakness, tiredness, loss of appetite, skin discolouration
- pituitary gland not working properly – this may cause low blood levels of some hormones that affect the function of the male or female sex organs
- hearing problems
- pseudoaldosteronism, which results in high blood pressure with a low potassium level (shown in blood test)

Not known: frequency cannot be estimated from the available data
- some patients have also reported feeling confused after taking Posaconazol Devatis.

Tell your doctor or pharmacist if you notice any of the side effects listed above.

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 Nederlands Bijwerkingen Centrum Lareb, Website: www.lareb.nl. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Posaconazol Devatis

This medicinal product does not require any special storage conditions. Do not freeze.

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 and bottle after EXP. The expiry date refers to the last day of that month. Once opened, the suspension should be used within 4 weeks.

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 Posaconazol Devatis contains
- The active substance is posaconazole.
  Each mL of oral suspension contains 40 mg of posaconazole.
- The other ingredients are polysorbate 80 (E 433), xanthan gum (E 415), sodium benzoate (E 211), citric acid monohydrate (E 330), sodium citrate (E 331), glycerol (E 422), liquid glucose, titanium dioxide (E 171), simethicone emulsion 30 %, artificial cherry flavour containing propylene glycol (E 1520), purified water.

What Posaconazol Devatis looks like and contents of the pack
Posaconazol Devatis is a white to off-white, cherry flavoured, 105 mL oral suspension packaged in amber glass bottles. Each pack contains a 5 ml dosing syringe (polypropylene/polyethylene) with 0.5 ml graduation marks and an adaptor for the syringe (polyethylene) for measuring 2.5 and 5 mL doses of the oral suspension.

Marketing Authorisation Holder and Manufacturer
Devatis GmbH
Spitalstr. 22
79539 Lörrach
Duitsland

Dit geneesmiddel is in het register ingeschreven onder:
Posaconazol Devatis 40 mg/ml suspensie voor oraal gebruik: RVG 121856

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

Niederlande:	Posaconazol Devatis 40 mg/ml suspensie voor oraal gebruik
Deutschland:	Posaconazol Devatis 40 mg/ml Suspension zum Einnehmen

Deze bijsluiter is voor het laatst goedgekeurd in december 2023.