

## **Package leaflet: Information for the patient**

### **Posaconazole Clonmel 100 mg gastro-resistant tablets** 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, pharmacist, or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet**

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

#### **1. What Posaconazole Clonmel is and what it is used for**

Posaconazole Clonmel contains the active substance 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.

Posaconazole Clonmel can be used in adults to treat fungal infections caused by fungi of the *Aspergillus* family.

Posaconazole Clonmel can be used in adults and children from 2 years of age weighing more than 40 kg to treat the following types of fungal infections:

- infections caused by fungi of the *Aspergillus* family that have not improved during treatment with the anti-fungal 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.

This medicine can also be used to prevent fungal infections in adults and children from 2 years of age weighing more than 40 kg 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 leukaemia” (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 Posaconazole Clonmel**

**DO NOT take Posaconazole Clonmel if:**

- you are allergic to posaconazole or any of the other ingredients of this medicine (listed in section 6).

- 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.
- you have just started taking venetoclax or your venetoclax dose is being slowly increased for treatment of chronic lymphocytic leukaemia (CLL)

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

See “Other medicines and Posaconazole Clonmel” below for more information including information on other medicines which may interact with Posaconazole Clonmel.

### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse before taking Posaconazole Clonmel 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, pharmacist or nurse before taking Posaconazole Clonmel.

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

### **Children and adolescents**

Posaconazole Clonmel should not be given to children younger than 2 years of age).

### **Other medicines and Posaconazole Clonmel**

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

#### **Do not take Posaconazole Clonmel 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).

Posaconazole Clonmel 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. Posaconazole Clonmel 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 Posaconazole Clonmel 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 Posaconazole Clonmel. 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 Posaconazole Clonmel. 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 Posaconazole Clonmel by increasing the amount of Posaconazole Clonmel in the blood.

The following medicines may decrease the effectiveness of Posaconazole Clonmel by decreasing the amount of Posaconazole Clonmel 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.

Posaconazole Clonmel 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 Posaconazole Clonmel.

#### **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.

Do not take Posaconazole Clonmel 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 Posaconazole Clonmel, contact your doctor straight away.

Do not breast-feed while taking Posaconazole Clonmel. 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 Posaconazole Clonmel, 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.

#### **Posaconazole Clonmel 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 Posaconazole Clonmel**

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

Do not switch between taking Posaconazole Clonmel tablets and posaconazole 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.

#### **How much to take**

The usual dose is 300 mg posaconazole (three 100 mg gastro-resistant tablets) twice a day on the first day, then 300 mg posaconazole (three 100 mg gastro-resistant tablets) once a day, thereafter.

The length of treatment may 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 regimen.

#### **Taking this medicine**

- Swallow the tablet whole with some water.
- Do not crush, chew, break or dissolve the tablet.
- Tablets may be taken with or without food.

#### **If you take more Posaconazole Clonmel than you should**

If you think that you may have taken too much Posaconazole Clonmel, talk to a doctor or go to the hospital straight away.

#### **If you forget to take Posaconazole Clonmel**

- If you forget a dose, take it as soon as you remember it.
- However, if it is almost time for your next dose, skip the missed dose and go back to your regular schedule.
- 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, 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, pharmacist or nurse if you notice any of the following side effects:

Common: 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: 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: 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 posaconazole

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

**Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:  
Ireland:  
HPRA Pharmacovigilance  
Website: [www.hpra.ie](http://www.hpra.ie)

Malta:  
ADR Reporting  
Website: [www.medicinesauthority.gov.mt/adrportal](http://www.medicinesauthority.gov.mt/adrportal)  
By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Posaconazole Clonmel**

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 blister / bottle and the outer carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Posaconazole Clonmel contains**

The active substance is posaconazole. Each gastro-resistant tablet contains 100 mg of posaconazole.

The other ingredients are: Methacrylic acid-ethyl acrylate copolymer (1:1) (Type B), triethyl citrate, xylitol, hydroxypropylcellulose, propyl gallate, microcrystalline cellulose, anhydrous colloidal silica, croscarmellose sodium, sodium stearyl fumarate (see section 2 “Posaconazole Clonmel contains sodium”), polyvinyl alcohol, titanium dioxide (E171), macrogol 3350, talc, iron oxide yellow (E172).

### **What Posaconazole Clonmel looks like and contents of the pack**

Posaconazole Clonmel gastro-resistant tablets are yellow coated and capsule shaped, debossed with “100P” on one side and plain on the other side. The tablets are packaged in cartons of 24 or 96 tablets in non-perforated blisters, 24x1 or 96x1 tablets in perforated unit dose blisters or 60 tablets in HDPE bottles.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### Marketing Authorisation Holder

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

#### Manufacturer

STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany  
Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

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

Germany	Posaconazol AL 100 mg magensaftresistente Tabletten
Austria:	Posaconazol STADA 100 mg magensaftresistente Tabletten
Croatia	Posakonazol STADA 100 mg želučanootporne tablete
Denmark:	Posaconazol STADA
Spain:	Posaconazol STADA 100 mg comprimidos gastrorresistentes EFG
Estonia	Posaconazole STADA
Finland:	Posaconazole STADA 100 mg enterotabletit
France:	POSACONAZOLE EG 100 mg, comprimé gastrorésistant
Greece	Posaconazole STADA

Iceland:	Posaconazole STADA
Ireland:	Posaconazole Clonmel 100 mg gastro-resistant tablets
Italy:	Posaconazolo EG STADA
Lithuania	Posaconazole STADA 100 mg skrandyje neirios tabletės
Latvia	Posaconazole STADA 100 mg zarnās šķīstošās tabletes
Malta	Posaconazole Clonmel 100 mg Gastroresistant Tablets
The Netherlands:	Posaconazol CF 100 mg, maagsapresistente tabletten
Poland	Posaconazole STADA
Romania:	Posaconazol STADA 100 mg comprimate gastrorezistente
Sweden:	Posaconazole STADA 100 mg enterotablett
Slovenia	Posakonazol STADA 100 mg gastrorezistentne tablete
Slovak Republic:	Posakonazol STADA 100 mg gastrorezistentne tablete
United Kingdom:	Posaconazole STADA 100 mg Gastro-resistant tablets

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