Indication

Posaconazole Sandoz (Posaconazole) is indicated for:

- Prophylaxis of invasive Aspergillus and Candida infections, including both yeasts and moulds, in patients, 13 years of age and older who are at high risk of developing these infections, such as patients with prolonged neutropenia or hematopoietic stem cell transplant (HSCT) recipients.

Posaconazole Sandoz is indicated for use in the treatment of the following fungal infections in patients 13 years of age or older:

- Refractory Invasive Fungal infections/Intoler ant Patients with invasive fungal infections.

Recommended dose for Posaconazole Sandoz according to indication

Prophylaxis of Invasive Fungal Infections:

- Loading dose of 300 mg (three 100 mg tablets) twice a day on the first day, then 300 mg (three 100 mg tablets) once a day thereafter. Each dose may be taken without regard to food intake.
- Duration of therapy is based on recovery from neutropenia or immuno suppression. For patients with acute myelogenous leukemia or myelodys plastic syndromes, prophylaxis with Posaconazole Sandoz should start several days before the anticipated on set of neutropenia and continue for 7 days after the neutrophil count rises above 500 cells per mm^3.

Refractory Invasive Fungal Infections (IFI)/Patients with IFI intolerant to 1st line therapy:

- Loading dose of 300 mg (three 100 mg tablets) twice a day on the first day, then 300 mg (three 100 mg tablets) once a day thereafter.
- Duration of therapy should be based on the severity of the underlying disease, recovery from immunosuppression, and clinical response.

Posaconazole Sandoz Gastro Resistant Tablets 100mg Basic Succinct Statement

Composition: Posaconazole Sandoz gastro-resistant tablet contains 100 mg of posaconazole. **Indications:** Posaconazole Sandoz (posaconazole) is indicated for prophylaxis of invasive Aspergillus and Candida infections, including both yeasts and moulds, in patients, 13 years of age and older, who are at high risk of developing these infections, such as patients with prolonged neutropenia or hematopoietic stem cell transplant (HSCT) recipients. Posaconazole Sandoz is indicated for use in the treatment of the following fungal infections in patients 13 years of age or older:Refractory Invasive Fungal infections/Intolerant Patients with IFI: Fusariosis, zygomycosis, cryptococcosis, coccidioidomycosis, chromoblastomycosis, and mycetoma in patients with disease refractory to other therapy, or patients who are intolerant of other therapy. Refractoriness is defined as progression of infection or failure to improve after a minimum of 7 days of prior therapeutic doses of effective antifungal therapy. **Dose and Method of Administration:** Posaconazole Sandoz should be swallowed whole, and not be divided, crushed, or chewed. Posaconazole Sandoz may be taken without regard to food intake. **Contraindications**: Posaconazole Sandoz is contraindicated in patients with known hypersensitivity to posaconazole or any component of the product.Although not studied in vitro or in vivo, coadministration of the CYP3A4 substrates terfenadine, astemizole, cisapride, pimozide, or quinidine with Posaconazole Sandoz are contraindicated since increased plasma concentrations of these drugs can lead to QT prolongation and rare occurrences of torsade de pointes.Coadministration with the HMG-CoA reductase inhibitors that are primarily metabolized through CYP3A4 is contraindicated since increased plasma concentration of these drugs can lead to rhabdomyolysis.Although not studied in vitro or in vivo, Posaconazole Sandoz may increase the plasma concentrations of ergot alkaloids which may lead to ergotism. Coadministration of Posaconazole Sandoz and ergot alkaloids is contraindicated. **Special Warnings and Precautions:** Hepatic Toxicity, QT Prolongation, Electrolyte disturbances, Vincristine toxicity, Gastrointestinal dysfunction, Plasma exposure. **FERTILITY, PREGNANCY AND LACTATION:** There is insufficient information on the use of posaconazole in pregnant women. Studies in animals have shown reproductive toxicity. Posaconazole has been shown to cause skeletal malformations in rats at exposures lower than those obtained at therapeutic doses in humans. In rabbits, posaconazole was embryotoxic at exposures greater than those obtained at therapeutic doses. The potential risk for humans is unknown. Posaconazole should be used in pregnancy only if the potential benefit justifies the potential risk to the fetus. Women of childbearing potential must be advised to always use effective contraceptive measure during treatment and for at least 2 weeks after completing therapy. Posaconazole is excreted into the milk of lactating rats. The excretion of posaconazole in human breast milk has not been investigated. Posaconazole should not be used by nursing mothers unless the benefit clearly outweighs the risk to the infant. **Effects on ability to drive and use machines:** The effects of this medicine on a person's ability to drive and use machines were not assessed. **Interactions with other medicinal products:** No clinically relevant effects were observed when posaconazole gastro-resistant tablets are concomitantly used with antacids, H2-receptor antagonists and proton pump inhibitors. No dosage adjustment of posaconazole gastro-resistant tablets is required when posaconazole gastro-resistant tablets are concomitantly used with antacids, H2-receptor antagonists and proton pump inhibitors.No clinically meaningful effect on the pharmacokinetics of posaconazole was observed when posaconazole gastro-resistant tablets were concomitantly administered with metoclopramide. No dosage adjustment of posaconazole gastro-resistant tablets is required when given concomitantly with metoclopramide.Posaconazole is not metabolized to a clinically significant extent through the cytochrome P450 system. However, posaconazole is an inhibitor of CYP3A4 and thus the plasma levels of drugs that are metabolized through this enzyme pathway may increase when administered with posaconazole. **Common side effects:** Nausea and diarrhea. **Important note: Before prescribing, consult full prescribing information. Based on Posaconazole Sandoz Gastro Resistant Tablets 100mg PI Nov 2019.**

Reference: 1. Posaconazole Sandoz Bioequivalent (BE) Fasting Study Report. **2.** Posaconazole Sandoz Bioequivalent (BE) Fed study report

For Healthcare Professionals Only

NOVARTIS

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