Information for Health Professionals

Itraconazole brand change on SA Medicines Formulary

Prescribing Information for Paediatric Patients

Background:

Itraconazole is used for the prevention and treatment of fungal infections. Lozanoc \mathbb{R} is a new formulation of itraconazole capsule with some advantages over Sporanox \mathbb{R} .

- It has a more consistent and improved absorption profile with less variability between patients
- It can be taken with or without food.
- Absorption is not affected by stomach pH

Availability/Formulary Listing:

The brand of itraconazole *capsules* on the SA Medicines Formulary will be changed from Sporanox® to Lozanoc®. Sporanox® oral solution will remain available.

Bioequivalence:

Lozanoc® 50mg capsules, Sporanox® 100mg capsules and Sporanox® 10mg/mL oral solution are NOT interchangeable.

- Lozanoc® 50mg capsule is therapeutically equivalent to Sporanox® 100mg capsule.
- Sporanox ® 100mg capsule is approximately equivalent to Sporanox® oral solution 50 mg (5 mL).
- The bioavailability from the Sporanox® oral solution taken in the fasting state is 60% higher than from a Sporanox® capsule taken with a meal.

<u>Dosing:</u>

There are no current dosing recommendations for paediatric patients for the Lozanoc® formulation.

- If a patient is on a therapeutic dose of Sporonox® capsules, the dose should be halved when changed to Lozanoc® capsules.
- WCHN Infectious Diseases and Pharmacy Departments recommend a starting dose of 2-3mg/kg/day Lozanoc® (to the nearest 50mg) for itraconazole naïve patients. Max dose 200mg daily or 100mg twice daily.

Therapeutic drug monitoring (TDM):

TDM should be performed for ALL patients that are:

- Changed from Sporonax® capsules to the Lozanoc® capsules
- Changed from Sporanax® solution to Lozanoc® capsules
- Commenced on itraconazole (any formulation); should occur after patient has taken for at least 7 days

NOTE: Itraconazole MUST be prescribed by <u>brand name and formulation</u>.

	Lozanoc [®] Capsules	Sporanox [®] Capsules	Sporanox [®] Oral Liquid
SA Medicines Formulary	Yes	No	Yes
Food	Can be given with or without food	Take with food (not rice)	Take at least 1hr before or 2hrs after food
Antacids, Proton Pump Inhibitors & H2 Antagonists	Can be given without affecting absorption	Avoid taking within 2 hours of the dose.	Can be given without affecting absorption

For more information contact: Your hospital pharmacist or SA Pharmacy Medicines Information Service Obstetric and Paediatric (08) 8161 7222



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