

Version 01
Effective Date December 2021

Patient Alert Card

Voriconazole Sala 200mg Powder for Solution for Infusion EFG

Approved by the Malta Medicines Authority
on the 07th of April 2025

REPORTING OF ADVERSE REACTIONS

Suspected adverse reactions and medication errors should be reported either to:

ADR Reporting, The Medicines Authority, Post-Licensing Directorate,
Sir Temi Zammit Buildings, Malta Life Sciences Park,
San Gwann SGN 3000, Malta

Website: <https://medicinesauthority.gov.mt/adversedrugreactions?l=1>

e-mail: postlicensing.medicinesauthority@gov.mt

OR

Prohealth Limited,
Mdina Road,
Zebbug, ZBG 9019,
Malta

Email: pharmacovigilance@prohealth.com.mt, regulatory@prohealth.com.mt

Tel: +356 23385327

Marketing Authorisation Holder

Laboratorio Reig Jofré, S.A.

Article 126a Authorisation Holder

Prohealth Limited

**Date of start of processing and
contact details**

Date of first dose:

Patient's Name:

Doctor's Name:

Name of the health centre:

Doctor's contact details:

Trade name:

Make sure you have a list of all your medications when you see a healthcare professional.

Ask your doctor or nurse if you have any questions about the information on this card.

If you experience any side effects, consult your doctor or pharmacist, including possible side effects that are not listed in the package leaflet. You can also report side effects directly via www.medicinesauthority.gov.mt/adrportal. By reporting side effects you can help provide more information on the safety of this medicine.

**PATIENT
INFORMATION
CARD**

VORICONAZOLE

Information on risk prevention agreed with the
Malta Medicines Authority (MMA), March 2025

Available on the MMA website: www.medicinesauthority.gov.mt

Why did I get this card?

This card contains important safety information that you should be aware of before starting voriconazole treatment and for the entire duration of voriconazole:

It also includes your name and the doctor's name and phone number.

What should I do with this card?

Always carry this card with you, for

- example, in your wallet or purse.

Show this card to any doctor or healthcare professional who treats

- you.

If you do not understand this information, ask your doctor for

- clarification.

What precautions should I take while taking voriconazole?

During voriconazole treatment, you should avoid intense and prolonged exposure to direct sunlight. It is important that you cover areas of skin exposed to the sun and use a sufficient amount of sunscreen with a high sun protection factor (SPF), as it can lead to increased sensitivity of the skin to the sun's ultraviolet rays.

In patients treated with this drug, there is a small chance that skin cancer will develop over time.

What should I do if I have a skin reaction?

You should contact your doctor if you develop: sunburn or severe skin reaction after exposure to light or sun.

Don't forget to go to all follow-up visits. In these cases, your doctor may deem it necessary to do a blood test and skin evaluations. At each visit you make to a health care professional, keep a list of all the medications you are taking and the medical conditions you have handy.

Where can I get more information?

See package insert for more information.