

REBLOZYL® (luspatercept) Patient Card

Patient Card – Front (when folded)

REBLOZYL® (luspatercept)

Patient Card

(For women of childbearing potential)

19 January 2022

2007-MT-2200002
EU-RMP Version 1.0, Procedure Number EMEA/H/C/004444

REBLOZYL® (Iuspaterecept) Patient Card

Patient Card – Inside (when unfolded)

Patient Information

REBLOZYL (Iuspaterecept) should not be used during pregnancy and for 3 months before getting pregnant. REBLOZYL may cause harm to your unborn baby.

Do not use REBLOZYL if you are pregnant or breast-feeding, or could become pregnant and are not using at least one highly effective method of birth control.

- Before starting treatment with REBLOZYL:
 1. You must have a negative pregnancy test verified by your prescriber.
 2. You must discuss effective methods of birth control with your doctor and use of at least one highly effective method of birth control while taking REBLOZYL and for at least 3 months after stopping treatment with REBLOZYL.
- A pregnancy test must be repeated at suitable intervals.
- Tell your doctor right away if you are pregnant or think you might be pregnant during treatment with REBLOZYL or for 3 months after stopping REBLOZYL.

Please see the back of this reminder card for your prescriber's contact information.

For more information about the effects and side effects of REBLOZYL, please refer to the Patient Information Leaflet for REBLOZYL.

For more information or to obtain a copy of the Pregnancy Reminder Card, call AM Mangion Ltd on 00 356 23976333 or contact Medicines Authority on <http://www.medicinesauthority.gov.mt/contact-details?l=1>

Patient Card – Back (when folded)

I have been prescribed REBLOZYL

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Important Contact Information

My healthcare professional who prescribed REBLOZYL:

Name: _____

Office phone number: _____

Institution address: _____

REPORTING OF ADVERSE REACTIONS

Suspected adverse reactions and medication errors should be reported at ADR Reporting, The Medicines Authority, Post-Licensing Directorate, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000, Malta

Website: www.medicinesauthority.gov.mt

e-mail: postlicensing.medicinesauthority@gov.mt

OR

ADR Reporting: www.medicinesauthority.gov.mt/adrportal

AND

AM Mangion Ltd

Mangion House

New Street off Valletta Road

Luqa LQA6000, Malta

Email: pv@ammangion.com

Tel – 00 356 23976333

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CONTACT DETAILS

For information and questions on the risk management of Bristol Myers Squibb's products, and the Pregnancy Prevention Programme,

AM Mangion Ltd.

Regulatory Office, "Mangion Building", New Street Off Valletta Road, Luqa.

Tel : +356 23976333

Fax: +356 239 76123

Email : pv@ammangion.com

18 January, 2022