REBLOZYL® (luspatercept) Prescriber's Checklist

Important information for healthcare providers prescribing REBLOZYL for women of childbearing potential

The Prescriber's Checklist is to be used before initiating treatment, at each administration, and then at regular intervals when performing follow-up.

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions. More information regarding how to report adverse reactions or a pregnancy can be found) in Section 4.8 of the Summary of Product Characteristics (SmPC - http://www.medicinesauthority.gov.mt/contact-details?l=1)

For more information about REBLOZYL or to obtain further copies of this document*, please contact AM Mangion Ltd – 00356 23976333*

Please see the REBLOZYL SmPC for complete prescribing information.

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REBLOZYL
Prescriber's Checklist for Women of Childbearing Potential

Patient Identification	Prescriber Details
Name:	Name:
	Signature:
	Date:

Prior to Initiation of Treatment
Treatment with REBLOZYL should not be started if the woman is pregnant or in women of childbearing potential not using at least one highly effective method of contraception. - The use of REBLOZYL is contraindicated in pregnancy and in women of childbearing potential not using effective contraception. - There are no data from the use of REBLOZYL in pregnant women. Studies in animals have shown reproductive toxicity and embryo-foetal toxicity. Clinical implications are potential foetal loss and teratogenicity.
☐ Provide counselling before treatment initiation regarding the potential teratogenic risk of REBLOZYL and required actions to minimise this risk.
☐ Inform women of childbearing potential of the necessity for at least one highly effective method of contraception while on treatment and for 3 months after discontinuation.
☐ A pregnancy test must be carried out and a negative result must be verified in women of childbearing potential before starting treatment.
☐ Provide the Patient Card to a women of childbearing potential.
Duration of Treatment
☐ Provide regularly counselling regarding the potential teratogenic risk of REBLOZYL and required actions to minimise this risk
☐ Remind women of childbearing potential that they must use at least one highly effective method of contraception during treatment with REBLOZYL.
During treatment with REBLOZYL, women must not become pregnant. If a woman becomes pregnant or wants to become pregnant, REBLOZYL should be discontinued.
During treatment with REBLOZYL, pregnancy tests must be repeated at suitable intervals and medically verified as negative.
Discontinuation of Treatment
☐ Counsel women of childbearing potential that at least one highly effective method of contraception should be maintained for at least 3 months following discontinuation of treatment with REBLOZYL.
☐ Provide counselling in the event of pregnancy and evaluation of the outcome of any pregnancy. ☐ Not applicable (this patient did not become pregnant while on treatment or within 3 months of discontinuation of REBLOZYL.)

Should a pregnancy occur during treatment or within 3 months following discontinuation of treatment with REBLOZYL, remind the patient that it should be reported to the prescriber, Medicines Authority and to BMS by *AM Mangion Ltd on Tel 00 356 23976333 and email - pv@ammangion.com*, irrespective of adverse outcomes observed.

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

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