

Direct Import

REBLOZYL<sup>®</sup>  
(luspatercept)

# Healthcare Professional Checklist

Important information for healthcare professionals prescribing and/or administering luspatercept for women of childbearing potential

Ireland  
Version 1.0

Reporting of suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions and/or pregnancies (irrespective of any adverse outcomes observed) via HPRA Pharmacovigilance at [www.hpra.ie](http://www.hpra.ie). Adverse reactions and/or pregnancies (irrespective of any adverse outcomes observed) can also be reported to Bristol-Myers Squibb Medical Information on 1 800 749 749 or [medical.information@bms.com](mailto:medical.information@bms.com).

**This Healthcare Professional (HCP) Checklist is to be used before initiating treatment, at each administration, and then at regular intervals when performing follow-up.**

To obtain copies of the luspatercept risk minimisation materials, or if you have any questions or require further information, please contact Bristol-Myers Squibb Medical Information on:

**Tel:** 1 800 749 749

**Email:** [medical.information@bms.com](mailto:medical.information@bms.com)

Please also refer to the Summary of Product Characteristics (SmPC) for complete prescribing information on luspatercept. The SmPC is available to view or download from the 'Product Information' section at <https://www.ema.europa.eu/en/medicines/human/EPAR/reblozyl>.

This material fulfils the conditions of the marketing authorisation for luspatercept and has been approved by the Health Products Regulatory Authority (HPRA).

# Luspatercept

## HCP Checklist for Women of Childbearing Potential

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

### Important Safety Information and Potential Teratogenic Risk

There are no data on the use of luspatercept in pregnant women. Studies in animals have shown reproductive toxicity and embryo-foetal toxicity. Clinical implications are potential foetal loss and teratogenicity.

- The use of luspatercept is contraindicated in pregnancy and in women of childbearing potential not using effective contraception.
- Treatment with luspatercept 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.

#### Prior to Treatment

- Provide counselling before treatment initiation regarding the potential teratogenic risk of luspatercept 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 medically verified by the prescriber in women of childbearing potential before starting treatment.
- Provide the Patient Card to women of childbearing potential.

#### During Treatment

- Confirm whether the patient has received the Patient Card prior to each administration and provide them with additional Patient Cards as needed.
- Provide regular counselling regarding the potential teratogenic risk of luspatercept 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 luspatercept.
- During treatment with luspatercept, women must not become pregnant. If a woman becomes pregnant or wants to become pregnant, luspatercept should be discontinued.
- 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 must be maintained for at least 3 months following discontinuation of treatment with luspatercept.
  - Provide counselling in the event of pregnancy and evaluation of the outcome of any pregnancy. If a pregnancy occurs during treatment or within 3 months following discontinuation of treatment with luspatercept, remind the patient that it should be reported to you, irrespective of any adverse outcomes observed.
- Or:**
- Not applicable (this patient did not become pregnant while on treatment or within 3 months of discontinuation of luspatercept).