This checklist was approved according to the guidelines of the ministry of health in March 2022

# 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.

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse event should be reported to the Ministry of Health according to the National Regulation by using an online form at https://sideeffects.health.gov.il. You may also report adverse events to BMS at medinfo.Israel@bms.com or 1809-054-388 (a toll free number).

For more information about REBLOZYL please contact BMS at medinfo.Israel@bms.com or 1809-388-054. To obtain further copies of this document, please contact BMS by phone: 03-5231021 or fax: 03-9226896.

Please see the REBLOZYL Full prescribing information for complete prescribing information.

### 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 all 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, the Israeli MOH using an online form at https://sideeffects.health.gov.il**
**You may also report adverse events to BMS Israel at 1809-388054 (Toll free number) or Medinfo.Israel@BMS.com**

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