WELIREG®
▼ (belzutifan)

Guide for Healthcare Professionals

▼ 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 via HPRA Pharmacovigilance Website: www.hpra.ie

Before prescribing belzutifan, please refer to the Summary of Product Characteristics.

Contents

Information in this guide

This guide contains safety information on the important potential risk of embryo-foetal harm, and includes guidance on pregnancy and appropriate methods of contraception that you need to consider when prescribing belzutifan to female patients of childbearing potential.

In addition, it contains information on the Patient Card that is included in the product package.

Please review the Summary of Product Characteristics as well as this guide prior to prescribing belzutifan.

This educational/safety advice tool is mandatory as a condition of the marketing authorisation. The information in this brochure is provided by Merck Sharp & Dohme (MSD) for oncologists and other healthcare professionals (HCPs) who are involved in the treatment of patients who are receiving belzutifan. Healthcare professionals are asked to report any suspect adverse reactions. See page 7 of this brochure for how to report adverse reactions.

Potential risk of embryo-foetal harm, pregnancy and contraception

Embryo-foetal toxicity

- Belzutifan may cause embryo-foetal harm, including foetal loss, when administered to a pregnant woman.
    - There are no or limited amount of data from the use of belzutifan in pregnant women. Studies in animals have shown reproductive toxicity. In a rat embryo-foetal development study, administration of belzutifan during organogenesis caused embryo-foetal lethality up to 100%, reduced foetal body weight, and foetal skeletal abnormalities at exposures similar to or below the human exposure at the recommended dose of 120 mg daily.
- Belzutifan is contraindicated in pregnant women treated for Von Hippel-Lindau (VHL) disease-associated tumours. Treatment with belzutifan needs to be discontinued if a pregnancy is planned or a pregnancy is detected.
- Belzutifan should not be used during pregnancy in women treated for renal cell carcinoma (RCC) unless the clinical condition of the woman requires treatment with belzutifan.
- Women of childbearing potential should be informed of the potential risk to a foetus.

Reducing the potential risk in women of childbearing potential

- The potential risk of exposure to belzutifan during pregnancy for women of childbearing potential should be reduced by the following:
    - The pregnancy status of women of childbearing potential should be verified through a pregnancy test prior to initiating treatment with belzutifan.

    Contraception methods

    - Women of childbearing potential should be informed about the potential risk of embryo-foetal harm, including foetal loss, when belzutifan is administered to a pregnant woman, and about appropriate contraceptive measures before starting treatment with belzutifan.
    - Women of childbearing potential have to use a highly effective contraception method during treatment with belzutifan and for at least 1 week after the last dose.
    - Use of belzutifan may reduce the efficacy of hormonal contraceptives. Coadministration of belzutifan with hormonal contraceptives may lead to contraceptive failure or an increase in breakthrough bleeding. Patients using hormonal contraceptives should be advised to use an alternative non-hormonal contraceptive method or have their male partner use a condom during treatment with belzutifan.

Patient Card

A Patient Card is provided as part of the product package (multipack; contains 90 tablets (3 packs of 30 tablets)) to inform patients about the potential risk of embryo-foetal harm during pregnancy and the need of appropriate methods of contraception.

Please explain the importance of the Patient Card when discussing the potential risk of embryo-foetal harm with belzutifan with your female patients of childbearing potential or patient caregivers.
It contains important information that patients and caregivers need to know before, during, and after treatment with belzutifan.

- Tell patients and caregivers to read the Patient Card along with the Package Leaflet.
- Tell patients and caregivers that the contact details on the Patient Card should be completed and that the Patient Card should be shown to other HCPs involved in their care.

Where can I obtain additional information?

More information about belzutifan is available in the Summary of Product Characteristics, on the website of the European Medicines Agency (http://www.ema.europa.eu), or by calling MSD Medical Information at 01 299 8700 for more information.

Reporting of suspected adverse reactions

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. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance; Website: www.hpra.ie.

Adverse events should also be reported to MSD, Red Oak North, South County Business Park, Leopardstown, Dublin D18 X5K7, Ireland by calling 01-2998700 or at medinfo_ireland@msd.com.

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If you require any additional information regarding the use of belzutifan, or would like to obtain additional copies of this guide, the Patient Card, contact the Merck Sharp & Dohme Medical Information department at 01-2998700 or at medinfo_ireland@msd.com.

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MSD