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November 2024

Welireg®▼ (belzutifan) Patient alert cards

IMPORTANT: RISK MINIMISATION MATERIALS TO MINIMISE THE RISK OF HYPOXIA-RELATED ADVERSE REACTIONS

Provision of patient card

Direct Healthcare Professional Communication

Dear Healthcare Professional,

Merck Sharp & Dohme (UK) Limited (MSD) would like to inform you that as part of the agreed risk management plan with the MHRA, a patient alert card should be provided to all UK patients prescribed Welireg to specifically provide guidance related to the risks of treatment associated hypoxia.

- Belzutifan can cause severe hypoxia that may require discontinuation, supplemental oxygen, or hospitalisation (see Summary of Product Characteristics).
- Patients should be monitored for oxygen saturation with pulse oximetry before initiation of and periodically throughout treatment with belzutifan with more frequent monitoring within the first 6 months of treatment.
- In the event of Grade 2 hypoxia, providing supplemental oxygen and continuing or withholding treatment should be considered. If withheld, belzutifan should be resumed at a reduced dose.
- For patients who have Grade 3 hypoxia, belzutifan should be withheld, hypoxia treated, and dose reduction should be considered. If Grade 3 hypoxia continues to recur, treatment should be discontinued.
- For Grade 4 hypoxia, treatment should be permanently discontinued.

We request that prescribing clinicians ensure that all patients are supplied with the wallet sized card after treatment initiation and that they are advised to carry it with them at all times. Please request a card by telephoning MSD Medical Information services on 0208 1548000 (see example copy of card in appendix below).

Welireg is indicated for the treatment of adult patients with VHL disease who require therapy for VHL-associated renal cell carcinoma (RCC), central nervous system (CNS) haemangioblastomas, or pancreatic neuroendocrine tumours (pNET), and for whom localised procedures are unsuitable or undesirable.

Call for reporting

- Welireg▼ is subject to additional monitoring. This will allow quick identification of new safety information.
- Please report ANY suspected adverse drug reactions (ADRs) to drugs and vaccines identified by the black triangle▼ to the MHRA through the Yellow Card Scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason.
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

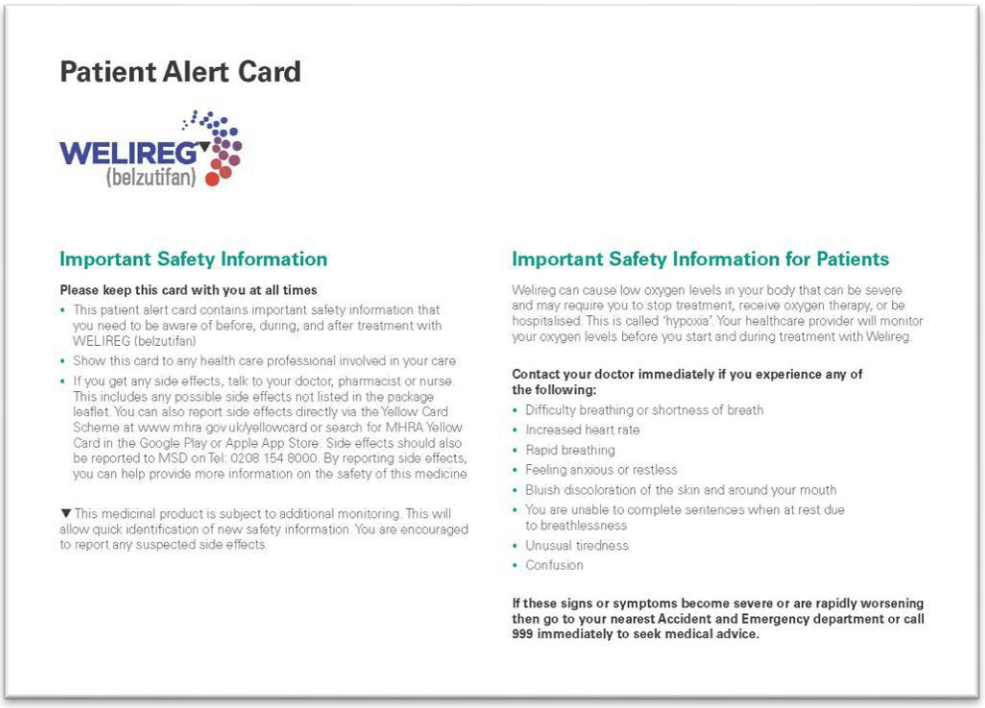
Company contact point: If you require further information about Welireg please contact medicalinformationuk@msd.com or call MSD Medical Information services on 0208 1548000. The SmPC, Patient Information Leaflet and the risk minimisation materials are also available at www.medicines.org.uk/emc.

Regards.

Yours sincerely

Country Executive Medical Director
MSD UK & Ireland

Appendix: Copy of patient alert card for your awareness (please order original for patient use):



Patient Alert Card

WELIREG (belzutifan)

Important Safety Information

Please keep this card with you at all times

- This patient alert card contains important safety information that you need to be aware of before, during, and after treatment with WELIREG (belzutifan)
- Show this card to any health care professional involved in your care
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Side effects should also be reported to MSD on Tel: 0208 154 8000. By reporting side effects, you can help provide more information on the safety of this medicine

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. You are encouraged to report any suspected side effects.

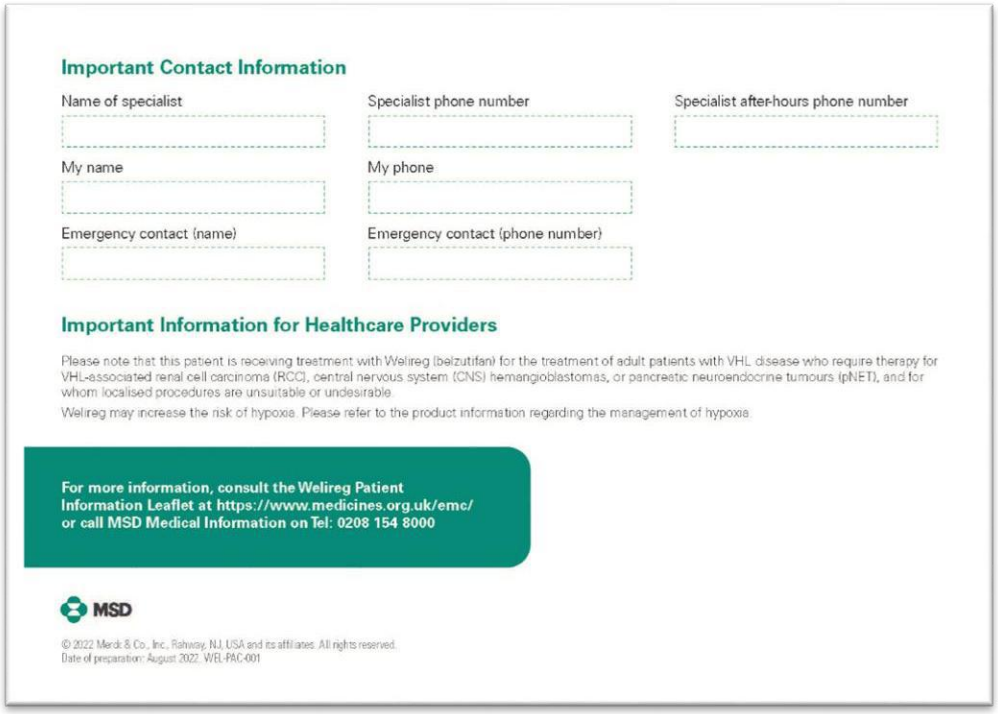
Important Safety Information for Patients

Welireg can cause low oxygen levels in your body that can be severe and may require you to stop treatment, receive oxygen therapy, or be hospitalised. This is called 'hypoxia'. Your healthcare provider will monitor your oxygen levels before you start and during treatment with Welireg.

Contact your doctor immediately if you experience any of the following:

- Difficulty breathing or shortness of breath
- Increased heart rate
- Rapid breathing
- Feeling anxious or restless
- Bluish discoloration of the skin and around your mouth
- You are unable to complete sentences when at rest due to breathlessness
- Unusual tiredness
- Confusion

If these signs or symptoms become severe or are rapidly worsening then go to your nearest Accident and Emergency department or call 999 immediately to seek medical advice.



Important Contact Information

Name of specialist	Specialist phone number	Specialist after-hours phone number
My name	**My phone**	
Emergency contact (name)	**Emergency contact (phone number)**	

Important Information for Healthcare Providers

Please note that this patient is receiving treatment with Welireg (belzutifan) for the treatment of adult patients with VHL disease who require therapy for VHL-associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumours (pNET), and for whom localised procedures are unsuitable or undesirable.

Welireg may increase the risk of hypoxia. Please refer to the product information regarding the management of hypoxia.

For more information, consult the Welireg Patient Information Leaflet at https://www.medicines.org.uk/emc/ or call MSD Medical Information on Tel: 0208 154 8000

MSD

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