Walton Oaks
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30 September 2024

Oxbryta ▼ (voxelotor): Withdrawal from UK market

Dear Healthcare Professional,

Pfizer Limited in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA) need to inform you that Oxbryta (voxelotor) is being withdrawn from the UK market while a review of the benefits and risks is carried out:

Summary

- **Oxbryta is being withdrawn from the UK market as a precautionary measure while a review of the benefits and risks is carried out.**
- **All batches of Oxbryta are being recalled in the United Kingdom.**
- **The use of Oxbryta in clinical trials and early access programmes is also being discontinued.**
- **The withdrawal follows emerging clinical data from clinical trials and registry-based studies suggesting an unfavourable imbalance in the number of vaso-occlusive crises and fatal events in patients treated with Oxbryta.**
- **New patients should not start treatment with Oxbryta.**
- **Physicians should contact patients currently on treatment with Oxbryta to discontinue treatment, and where appropriate to discuss alternative treatment options with them. Physicians should instruct their patients to return the product to the hospital pharmacy or homecare company that dispensed it.**
- **Physicians should continue to monitor patients for adverse events after their treatment with Oxbryta is discontinued and ensure appropriate follow-up as needed.**

Background Information

Oxbryta is authorised in the UK for the treatment of haemolytic anaemia due to sickle cell disease (SCD) in adults and paediatric patients 12 years of age and older as monotherapy or in combination with hydroxycarbamide.

In July 2024, EMA started an EU-wide review of Oxbryta. This was triggered by data from ongoing clinical trials which showed that a higher number of deaths occurred with Oxbryta than with placebo in one trial and the total number of deaths was higher than anticipated in another trial.

Emerging data from two registry-based studies in the United States show an increase in vaso-occlusive crises (VOC) in patients who started treatment with the medicine. Data collection and analysis of the studies is continuing.

In view of these newly emerging data Oxbryta is being withdrawn from the UK market, while these data are assessed in detail in the ongoing review. MHRA is further investigating the implication of these findings for the currently authorised use of Oxbryta.

All ongoing clinical trials and early access programmes are also being discontinued.

Patients should no longer be prescribed Oxbryta. Physicians should contact patients currently on treatment with Oxbryta to stop treatment, and where appropriate to discuss alternative treatment options.

Physicians should continue to monitor patients for adverse events after their treatment with Oxbryta is discontinued and ensure appropriate follow-up as needed. Possible complications when treatment is interrupted abruptly cannot be excluded, although a dosing regimen for gradual discontinuation has not been established. For further information please contact Pfizer Medical Information at www.pfizermedicalinformation.co.uk or 01304 616161

Other healthcare professionals who receive any questions from patients currently prescribed Oxbryta should direct these patients to their prescriber.

Further advice will be communicated as appropriate at the end of the review.

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) 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 ▼
    - Oxbryta ▼ 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.

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.

Company contact point

If you have any questions about this letter or for more information about Oxbryta, please contact Pfizer Medical Information at www.pfizermedicalinformation.co.uk, Telephone: 01304 616161 or Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS.

Yours sincerely,

Dr Berkeley Phillips

Country Medical Director

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