Medicines & Healthcare products Regulatory Agency

MEDICINES RECALL

CLASS 2 MEDICINES RECALL

Action Within 48 hours
Patient/Pharmacy/Wholesaler Level Recall

Date: 30 September 2024 EL (24)A/44 Our Ref: DMRC-32749585

Dear Healthcare Professional,

Pfizer Limited

Oxbryta 500 mg Tablets **PLGB 00057/1720**

SNOMED Code 41075911000001100

Batch No	Expiry Date	Pack Size	First Distributed
1941738	31-Mar-2025	90	22-Jan-2023
1997214	30-Nov-2025	90	15-Jul-2024

Active Pharmaceutical Ingredient: voxelotor

Brief description of the problem
Pfizer Limited is recalling all distributed batches of Oxbryta 500 mg Tablets. Pfizer Limited has informed the MHRA that the product is being withdrawn due to emerging data from clinical trials and registry-based studies suggesting an unfavourable imbalance in the number of vaso-occlusive crises and fatal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.

Oxbryta is indicated 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 and treatment is only initiated by physicians/specialist prescribers experienced in the management of SCD. The information in this recall reinforces action already being undertaken by Pfizer Limited and ensures that healthcare professionals in NHS Trusts and other care settings take appropriate action to recall all batches from patients as soon as possible. The recall notification is being shared with all healthcare professionals in the event that any patients experience any adverse events and require appropriate medical attention.

Advice for healthcare professionals
Stop supplying the above product immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.

Physicians, specialist prescribers, homecare company providers or any other healthcare professional responsible for prescribing Oxbryta should contact all patients undergoing treatment and advise them to discontinue treatment and, where appropriate, discuss alternative treatment options. Patients should be instructed to return the product to the hospital pharmacy or homecare company that dispensed it.

Patients should continue to be monitored for adverse events after their treatment with Oxbryta is discontinued and ensure appropriate follow-up as needed. New patients should not start treatment with Oxbryta. More information can be found in the Direct Healthcare Professional Letter shared with this notification.

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Advice for patients

Pfizer Limited has informed the MHRA that all batches of Oxbryta 500 mg Tablets are being withdrawn due to emerging data from clinical trials and registry-based studies that now indicate the overall benefit of Oxbryta no longer outweighs the risk in the approved sickle cell patient population. The data suggest an unfavourable imbalance in vaso-occlusive crises (acute painful crises) and fatal events (deaths).

Your healthcare professional responsible for your care and treatment will contact you to advise you or the child under your care being treated to stop taking Oxbryta 500 mg Tablets, and where appropriate, discuss alternative treatment options. They will also advise how to return any remaining packs of Oxbryta 500mg Tablets that you have in your possession. If you have not already been contacted by your healthcare professional, please contact them.

If you experience adverse reactions, have a sudden worsening of clinical condition, or have any questions about your medication, you should seek medical attention. If you have any concerns about your health or the health of somebody else, consult with your healthcare professional. Any suspected adverse reactions should also be reported via the MHRA Yellow Card scheme.

Further Information

For medical information enquiries please contact Pfizer Medical Information at www.pfizermedicalinformation.co.uk or telephone 01304 616161

Recipients of this Medicines Recall should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to hospitals, community pharmacists and dispensing general practitioners for information.

Yours faithfully

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