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Denzapine 50 mg/mL Oral Suspension (clozapine): risk of loss of efficacy due to crystallisation of the suspension; always follow instructions for use, including 24 hours before first dosing

Dear Healthcare Professional,

In agreement with the Medicines Healthcare Regulatory Agency (MHRA), Britannia Pharmaceuticals Ltd would like to inform you of important safety information:

Summary

- Recently reported adverse events have indicated a loss of efficacy of the product in relation to increased crystallisation in affected batches, which are being recalled from the market

- For all remaining batches of Denzapine 50mg/mL Oral Suspension, it is essential to follow the shaking instructions as per the Summary of Product Characteristics and Patient Information Leaflet as follows:

    - Following extended storage, the active substance is known to settle and can become visible at the base of the liquid.
    - 24 hours before first use only (i.e., when first dispensed or after prolonged storage where there is visible settling of the suspension) vigorously shake the bottle for 90 seconds. This vigorous shaking can aerate the suspension and lead to variability in dosing. Therefore, it is vital that the bottle is allowed to stand for the 24 hours before first dosing.
    - Immediately before the first and each subsequent dose, shake the bottle for 10 seconds, this is to ensure that a homogenous suspension remains suspended.

Further Information:

Denzapine oral suspension is authorised for the treatment of treatment-resistant schizophrenia or psychosis in Parkinson's disease. Denzapine Oral Suspension is known to crystallise across its shelf life and this is expected.

Britannia Pharmaceuticals is currently evaluating further evidence and will work with the MHRA to consider any appropriate changes which may be required. Any new advice for healthcare professionals and patients will be communicated properly.

Adverse Event Reporting

Healthcare professionals should report any suspect adverse reactions associated with the use of Denzapine in accordance with the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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Alternatively, prepaid Yellow Cards for reporting are available by writing to FREEPOST YELLOW CARD (no other address details necessary), by emailing yellowcard@mhra.gov.uk, at the back of the British National Formulary (BNF), by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789, or by downloading and printing a form from the Yellow Card section of the MHRA website.

Adverse events should also be reported to Britannia Pharmaceuticals Ltd at dso@britannia-pharm.com or 01483 920 763.

Full prescribing information and further information is available from Britannia Pharmaceuticals by emailing Enquiries@medicalinformation.co.uk or calling 01483 920 763.

Yours faithfully,

Dr Balpreet Matharu BSc MBBS
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