

[REDACTED]

07 May 2024

Dear Mr Place,

Re: Regulation 28 Report - Jason Brown (Deceased) (Ref: 11445076)

In response to the Regulation 28 Report concerning the unfortunate passing of Mr Jason Brown which was received from Ms Julia Laidler on 12 March 2024, we acknowledge the necessity for transparency and compliance.

First, we at Lundbeck Ltd extend our deepest sympathy for the passing of Mr Jason Brown. We are committed to cooperating fully in providing the necessary information in relation to your concerns.

As stated in your report, your concerns relate to the special container status of Lundbeck branded Clopixol 2mg (zuclopenthixol dihydrochloride) film coated tablets. You have requested that our response contain details of action taken or proposed to be taken, along with a timetable for action and if no action is proposed, we must provide an explanation.

In response to your request, please find below key information relating to the storage and packaging of Lundbeck branded Clopixol 2mg (zuclopenthixol dihydrochloride) film coated tablets in the UK for which Lundbeck Ltd holds the Marketing Authorisation:

- As per the SmPC for zuclopenthixol 2mg tablets, the tablets should be stored in the original container in order to protect from light¹. In the UK, zuclopenthixol 2mg tablets are supplied in a white high-density polyethylene (HDPE) container with low density polyethylene (LDPE) twist-off cap including desiccant in quantities of one hundred (100) tablets.
- The criteria for assigning products as special containers are listed within the NHS England and Wales Drug Tariff (Part II, Clause 10B)² and the NHS Business Service Authority (NHSBSA) implement the criteria.
- Lundbeck Ltd does not specify, classify, or make any reference to zuclopenthixol 2mg tablets, nor any strength of Lundbeck branded zuclopenthixol tablets as requiring “special container status” within the Summary of Product Characteristics (SmPC) or any regulatory documents associated with this product. This classification is assessed and assigned independently².
- Following your current request, Lundbeck Ltd has queried the NHS Business Authority on 13 March 2024, regarding the criteria for assigning products as special containers and included that stability data are available supporting the storage of zuclopenthixol 2mg tablets being kept out of the container for up to 4 weeks if required.
- On 22 March 2024, Lundbeck Ltd received a response from the NHS Business Authority which provided the information outlined within the second bullet point on assignment of special container status. Within this response, the NHS Business Authority requested information on the stability of Clopixol 10mg and Clopixol 25mg packs which Lundbeck Ltd supplied on 03 May 2024.

As outlined above, the decision to classify this medicinal product as requiring special container status is a decision that is made independently from Lundbeck Ltd. We hope that by providing the supportive summarised stability data for Lundbeck branded zuclopenthixol 2mg, 10mg and 25mg tablets, it will prove helpful in any future assessment of the special container status classification of all strengths of Lundbeck branded zuclopenthixol film coated tablets.

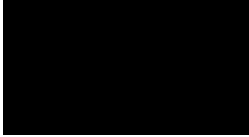
Should you require any further information or clarification, please do not hesitate to contact us.

Lundbeck Ltd

Iveco House
Station Road
Watford
Hertfordshire
WD17 1ET



Yours sincerely



Country Manager
Lundbeck United Kingdom

References

1. Lundbeck UK Limited. Clopixol 2mg tablets Summary of Product Characteristics: June 2022; Available from: [Clopixol 2 mg film-coated tablets - Summary of Product Characteristics \(SmPC\) - \(emc\) \(medicines.org.uk\)](#) [Accessed April 2024]
2. NHS England and Wales Drug Tariff. NHS Electronic Drug Tariff; Available from: [NHS .Electronic Drug Tariff \(nhsbsa.nhs.uk\)](#) [Accessed April 2024]