

11 December 2020

Dear Healthcare Professional,

Clopine Central Database: Updated blood monitoring threshold levels and its impact on colour coding has been delayed.

Douglas would like to notify you of an important update delay to the Clopine Central Database that may impact some of your patients who are taking Clopine (clozapine).

Summary:

- As of the 31st of October 2020, the Clopine monitoring threshold levels for white cell counts (WBC) and absolute neutrophil count (ANC) were updated so there is no change after the first 18 weeks of treatment.
- The Clopine Data Sheet has been updated to reflect the new threshold levels. However, updates to the Clopine Central Database System have been delayed due to the implementation of added security measures, system validation and testing to ensure a successful launch. The projected implementation date (go-live) is 15th January 2020.
- The threshold for monitoring twice a week is indicated for all patients with a WBC between 3000/mm³ and 3500/mm³ and/or ANC between 1500/mm³ and 2000/mm³
- The threshold for immediate discontinuation is indicated for all patients with a WBC less than 3000/mm³ and/or ANC is less than 1500/mm³.

Further information and recommendations to healthcare professionals

Since the Clopine Central database is yet to be updated, the colour status may not be accurate for some patients.

Please note the following:

- Interpret WBCs and ANC in accordance with the ranges stated in the Clopine Data Sheet at Medsafe.govt.nz and not in accordance with the displayed colour status on Clopine Central. Special attention to be given to the "amber" colour range displayed as it may be "red" in accordance with the Data Sheet and may require immediate discontinuation.
- All WBC and ANC readings entered on Clopine Central after the implementation (go-live) date will be treated as per new blood monitoring threshold levels.
- See alert communication posted by Medsafe at <https://www.medsafe.govt.nz/safety/Alerts/ClozapineDatasheetUpdates.asp>

Reporting adverse events

Reporting suspected adverse reactions has an important role in monitoring the benefit/risk balance of medicines. Please report any suspected adverse events via email to Douglas Pharmaceuticals Ltd at drugsafety@douglas.co.nz. Alternatively, suspected adverse events may be reported to the Centre for Adverse Reactions Monitoring (CARM) at <https://nzphvc.otago.ac.nz/reporting> or by email to nzphvc@otago.ac.nz. When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset and treatment dates. The Clopine Data Sheet is available at:

<https://www.medsafe.govt.nz/profs/datasheet/c/Clopinetaborsuspen.pdf>. If you have any questions related to this database, please contact Clopine Central on 0800 435 811 or clopinecentral@pfizer.com.

Kind regards,



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