

Important safety message: Discontinuation of Droleptan tablets, suspension and injection (droperidol)

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Droleptan medicinal products will be discontinued from 31 March 2001. This means that shortly after this date, Droleptan will no longer be available in pharmacies. This action has been taken by the company, Janssen-Cilag Ltd, who has chosen to voluntarily discontinue Droleptan following an extensive risk-benefit assessment. The company concluded that the oral formulations should be discontinued to prevent use in chronic conditions and that the injectable form would no longer be commercially viable. The MHRA (medicines) (MHRA) had raised concerns about the potential effect of droperidol on the cardiac QT interval and requested the risk-benefit assessment.

Droleptan is currently indicated for use in psychiatry to rapidly calm the manic, agitated patient. The injection is also indicated for use in anaesthesia in the technique of neuroleptanalgesia, for premedication, for post-operative nausea and vomiting; and for treatment of chemotherapy-induced nausea and vomiting.

Prescribers are advised as follows:

- Droleptan can continue to be used for its licensed acute use, whilst supplies are available.
- **No** new patients should be initiated on Droleptan for chronic use.
- **No** patient should have Droleptan stopped until a suitable alternative treatment plan has been identified for them.
- Existing patients currently receiving droperidol as a chronic therapy should be recalled for review by their psychiatrist and switched to an alternative treatment.

Chronic Droleptan therapy may be tapered off by a stepwise reduction over a period of one to two weeks whilst the replacement antipsychotic therapy is initiated.

Information for patients is available here.



If you have any questions regarding the discontinuation of Droleptan, please contact the Medical Information Department of Janssen-Cilag on 0800-7318450 or the MHRA Central Enquiry Point on 020-7273 0000, e-mail info@mhra.gov.uk

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