Safety Notice 016/21

Identification and Monitoring of Post-Injection Syndrome Olanzapine Pamoate Long Acting Injection (updated)

9 August 2021

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Director, Regulation and Compliance Unit

Action required by:

- Chief Executives
- Directors of Clinical Governance
- Directors of Emergency Departments

We recommend you also inform:

- Directors of Mental Health Services
- Directors of Nursing & Midwifery
- Directors of Pharmacy
- Managers of Community Mental Health Services
- Drug and Therapeutics Committees

Expert Reference Group

Content reviewed by:

- Mental Health Branch
- Nursing and Midwifery Office
- Medication Safety Expert Advisory Committee
- Clinical Excellence Commission

Clinical Excellence Commission

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Review date

August 2024

Olanzapine long acting injection (LAI) is an atypical antipsychotic used in the maintenance treatment of schizophrenia.[1] A rare serious adverse event related to the use of olanzapine LAI is post-injection syndrome (PIS). Non-recognition of PIS symptoms has resulted in the death of a patient in NSW.

PIS results from inadvertent intravascular injection of olanzapine, causing a range of olanzapine overdose-type symptoms. PIS is not dose, frequency or time point specific, and the risk of occurrence exists following every administration.[2] PIS has not been reported with other long acting antipsychotic injections.

Cases of PIS associated with olanzapine LAI have been described in the literature. The two largest studies include a pre-marketing analysis on the safety data across eight clinical trials[2] and a post marketing observational study following consumers for five years.[3] Both studies reported PIS associated with olanzapine LAI to be a rare adverse event that occurred in 0.07%and 0.04% administrations, respectively. The signs and symptoms of PIS included sedation (ranging from mild sedation to deep sleep and unconsciousness), and/or delirium (including confusion, disorientation, anxiety and agitation). Other symptoms included dizziness, weakness, altered speech/dysarthria, altered gait, muscle spasms, seizures and hypertension.[2]

The post marketing study reported that the time to onset of the initial signs and symptoms of PIS occurred within the first hour after injection in 91% of cases, within 2 hours in 96% of cases and within 3 hours in 98% of cases. The remaining 2% of cases were identified beyond 3 hours.[3] The pre-marketing study reported the time to incapacitation ranged from 10 to 300 minutes, with the median time to incapacitation being 35 minutes later than the median time of symptom onset.[2] This highlights the importance of the post monitoring period as it may be some time before a consumer develops overt symptoms, which may interfere with their ability to seek assistance. Full recovery from PIS usually occurred within 24 - 72 hours.[2,3]

References

1. Eli Lily and Company. Australian Product Information Zyprexa Relprevv (olanzapine pamoate monohydrate). Therapeutic Goods Administration website [updated 28 October 2019]; available from: www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2010-PI-04325-3&d=202105051016933
2. Detke HC, et al. Post-injection delirium/sedation syndrome in patients with schizophrenia treated with olanzapine long-acting injection: analysis of cases. BMC Psychiatry. 2010; 10(43):1-10. Available from: www.ncbi.nlm.nih.gov/pmc/articles/PMC2895589/
3. Meyers KJ, et al. Postinjection delirium/sedation syndrome in patients with schizophrenia receiving olanzapine long-acting injection: results from a large observational study. BJPsych Open. 2017; 3:186-92. Available from: https://pubmed.ncbi.nlm.nih.gov/28811926/

Suggested actions by Local Health Districts/Networks

1. Distribute this Safety Notice to all relevant clinical staff.
2. Ensure that emergency department staff are aware of olanzapine LAI post-injection syndrome (PIS) and its management.
3. Ensure PIS is considered if a consumer with a mental health condition presents to an emergency department with symptoms of sedation and/or delirium.
4. Ensure that staff administering olanzapine LAI are appropriately trained in its administration.
5. Ensure that staff administering olanzapine LAI are aware of the signs and symptoms of PIS.
6. Ensure that services administering olanzapine LAI have a local Drug and Therapeutics Committee (DTC) approved guideline in place that stipulates:
   a. The criteria that assesses the suitability of olanzapine LAI for each consumer including considerations regarding the requirements for PIS monitoring and need for travel post injection with a responsible person.
   b. Monitoring of a consumer's alertness every 30 minutes, for a minimum of 2 hours post injection and noting that extending the monitoring period to 3 hours will capture a greater number of cases and take into account the delay time to incapacitation.
   c. Assessment by a medical officer or delegate prior to discharge to ensure no signs and symptoms of PIS are evident.
   d. Provision of information and understanding by the consumer/responsible person of the possible signs and symptoms of PIS and the need for urgent medical attention if they occur. This information should be outlined in an agreed management plan.
   e. Services administering olanzapine LAI have access to emergency services for treatment of PIS.
7. Report PIS incidents in the incident monitoring system (ims+) and to the Therapeutic Goods Administration.