



Safety Notice 004/21

Identification of Post-Injection Syndrome Olanzapine Pamoate Long Acting Injection

2 March 2021

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Director Regulation & 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
- Drug and Therapeutics Committees
- Directors of Nursing and Midwifery
- Directors of Pharmacy
- Managers of Community Mental Health Services

Expert Reference Group

Content reviewed by:

- Nursing and Midwifery Office
- Mental Health Branch
- Mental Health and Drug and Alcohol SAER Review Sub-Committee
- Clinical Excellence Commission
- Medication Safety Expert Advisory Committee

Clinical Excellence Commission

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Review date
 March 2024

Olanzapine Long Acting Injection (LAI) is an atypical antipsychotic used in the maintenance treatment of schizophrenia. A rare serious adverse event related to the use of olanzapine LAI is post-injection syndrome (PIS). It is reported to occur in 0.07% of injections¹. Non-recognition of PIS symptoms has resulted in the death of a patient.

PIS results from inadvertent intravascular injection of olanzapine, causing a range of olanzapine overdose-type symptoms. Post-injection syndrome is not dose, frequency or time point specific, and the risk of occurrence exists following every administration. In most cases of PIS (84%) the initial signs and symptoms occur within the first hour after injection, but onset after 3 hours has been reported¹. Full recovery usually occurs within 24-72 hours².

The signs and symptoms of PIS include sedation (ranging from mild sedation to deep sleep and unconsciousness), and/or delirium (including confusion/confused state, disorientation, anxiety and agitation). Other symptoms include dizziness, weakness, altered speech/dysarthria, altered gait, muscle spasms, possible seizures and hypertension^{1,2}.

Higher doses and therefore a larger final volume for injection and low body mass index (BMI) may present a higher risk for PIS; however, PIS has occurred in patients who do not have these risk factors¹.

PIS has not been reported with other long acting antipsychotic injections.

References

1. Olanzapine depot injection (Zyprexa Relprevv) for schizophrenia www.nps.org.au/radar/articles/olanzapine-depot-injection-zyprexa-relprevv-for-schizophrenia#r14
2. Post-injection delirium/sedation syndrome in patients with schizophrenia treated with olanzapine long-acting injection, I: analysis of cases www.ncbi.nlm.nih.gov/pmc/articles/PMC2895589/
3. Therapeutic Guidelines: Schizophrenia and related psychoses https://tgldcdp.tg.org.au.acs.hcn.com.au/viewTopic?topicfile=schizophrenia-and-related-psychoses&guidelineName=Psychotropic#toc_d1e804

Suggested actions by Local Health Districts/Networks

1. Distribute this Safety Notice to all relevant clinical staff
2. Ensure that Emergency Department clinicians are aware of olanzapine LAI post-injection syndrome and its management
3. If a patient with a mental health condition presents to an emergency department with symptoms of sedation and/or delirium, PIS is considered
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. That services administering olanzapine LAI have a local guideline in place that stipulates:
 - a. 30 minutely monitoring of the consumers alertness for 3 hours following injection^{1,3}
 - b. assessment by a medical officer or delegate prior to discharge to ensure no signs and symptoms of PIS are displayed
 - c. consumers are escorted home by a responsible person or staff member post administration
 - d. awareness by consumer/responsible person of the possible signs and symptoms of PIS and the need for urgent medical attention if they occur. An agreed management plan should be in place
 - e. That 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](#).