

Olanzapine long acting injection (OLAI) – guidance on managing the 3 hours of post-injection monitoring during the coronavirus outbreak

General information

Olanzapine Long Acting Injection (OLAI) [Zypadhera] is a non-formulary antipsychotic and only used in a small number of OHFT patients following approval on a case-by-case basis by the Trust's Drugs & Therapeutics Group. It is given by deep gluteal injection every two or four weeks. There is a risk of Post Injection Syndrome after **every** injection. There is a requirement for three hours of post-injection observation monitoring after **every** injection administered.

What is post-injection syndrome (PIS)?

During pre-marketing clinical studies, reactions that presented with signs and symptoms consistent with olanzapine overdose were reported in patients following an injection of Zypadhera. These reactions occurred in <0.1% of injections and approximately 2% of patients. Most of these patients have developed symptoms of sedation (ranging from mild in severity up to coma) and/or delirium (including confusion, disorientation, agitation, anxiety and other cognitive impairment). Other symptoms noted include extrapyramidal symptoms, dysarthria, ataxia, aggression, dizziness, weakness, changes in blood pressure, and convulsions. In most cases, initial signs and symptoms related to this reaction have appeared within 1 hour following injection, and in all cases full recovery was reported to have occurred within 24 - 72 hours after injection. Reactions occurred rarely (<1 in 1,000 injections) between 1 and 3 hours, and very rarely (<1 in 10,000 injections) after 3 hours.

What is the usual "monitoring" that is required?

Patients should be observed in a healthcare facility (hospital, clinic etc.) by appropriately qualified personnel for at least 3 hours for signs and symptoms consistent with olanzapine overdose.

- Specific physical monitoring (e.g. pulse, BP etc.) is **not** routinely required.
- Locate the patient where they can be seen and heard at all times.
- Patients should be *observed* at least hourly (more frequently during the first hour) to confirm that they are:
 - o Alert
 - o Orientated

If an overdose is suspected call an ambulance.

What advice should the patient be given?

For the remainder of the day after the injection patients should be advised:

- to be vigilant for signs and symptoms of PIS and be able to obtain assistance if needed.
- not to drive or operate machinery.

A patient leaflet for [olanzapine LAI \(Zypadhera\)](#) is available.

What does the Trust recommend during the coronavirus (COVID-19) outbreak?

Every effort should be made to continue with the three hours of PIS observations wherever possible. This is a requirement of the product licence.

If it is not possible to observe the patient for the full three hours in a healthcare facility, individual arrangements should be made that aim to maximise safety but without compromising treatment efficacy. As a minimum this should include:

- ✓ a consultant assessment of risks and benefits that are documented in the Electronic Health Record.
- ✓ where a patient cannot come to a healthcare facility (e.g. if self-isolating) a clinical decision should be made about whether it is appropriate and possible to delay administration (see OH COVID-19 memo: "[Guidance on amending the dosing interval of antipsychotic long-acting-injections](#)"). If this is not appropriate, the injection should be administered at the patient's home, using personal protective equipment and techniques as recommended by OHFT (See Covid-19 OH '[Carrying Out Essential Care](#)': [Standard Operating Procedure](#).) For patient's who are isolating because they are COVID-19 positive, the documented risk benefit decision, must also have considered the implications of developing PIS in this group of patient (e.g. severity of COVID symptoms and the

potential difficulty in determining which symptoms might indicate PIS, and the possible requirement for hospital attendance to manage PIS symptoms, should they occur).

- ✓ observing the patient (as specified above) for **at least the full first hour** [*risk of PIS falls off significantly after the first hour*].
- ✓ ensuring that the patient is not alone for the remaining time of the required 3 hour observation period and that the patient and the person they are with fully understand what the signs and symptoms of PIS are and the action to be taken if they suspect PIS.
- ✓ ensure that the patient continues to be vigilant for signs and symptoms for the remainder of the day and knows how to obtain assistance if required.
- ✓ advising the patient not to drive or operate machinery.

If it is not possible to facilitate the above, the decision to proceed with olanzapine LAI **must be reviewed**.



Need more information/advice?

Please contact the Medicines Advice Service: 01865 904365 or medicines.advice@oxfordhealth.nhs.uk