Safety Notice SN:034/23

Issue date
24 November 2023

Distributed to:
Chief Executives
Directors of Clinical Governance
Director, Regulation and Compliance Unit

Action required by:
Chief Executives
Directors of Clinical Governance

We recommend you also inform:
Directors, Managers and Staff of:
- Emergency
- Medical Services
- Mental Health
- Nursing
- Outpatient and Community Mental Health
- Pharmacy
- Psychiatry

Drug and Therapeutics Committees
Other relevant clinicians, departments and committees.

Expert Reference Group
Content reviewed by:
Medicines Shortage Assessment and Management Team
Medication Safety Expert Advisory Committee
Ministry of Health Mental Health Branch

Clinical Excellence Commission
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Intranet

Review date
November 2024

Disruption to supply – Olanzapine long-acting injection (Zyprexa Relprevv)

Situation

There is a global disruption to the supply of all strengths of olanzapine pamoate monohydrate (Zyprexa Relprevv) powder for injection ("olanzapine long-acting injection") until mid-December 2023 with limited stock available due to global manufacturing and supply constraint.

At the time of publication, alternatives are available under both Section 19A (S19A) of the Therapeutics Goods Act 1989 and the Therapeutic Goods Administration's Special Access Scheme (SAS).

Background

Olanzapine is an atypical antipsychotic medicine and mood stabiliser used in the maintenance treatment of schizophrenia. Olanzapine long-acting injection is indicated for use in Australia for adult patients sufficiently stabilised during acute treatment with oral olanzapine.

Assessment

At the time of publication, there are:

- S19A alternatives available for all strengths of olanzapine long-acting injection from Link Healthcare. The alternatives are identical in active ingredient, excipients, and storage to the Australian registered product, however, are labelled in German.
- SAS alternatives available from Medsurge Healthcare from Germany, Belgium and India. Contact Medsurge Healthcare for further details.

See Table 1 (over page) for a comparison between the Australian registered product and the S19A/SAS alternatives.

Recommendations

Stock management

- Develop a local plan to manage the disruption to the supply of olanzapine long-acting injection that includes (but is not limited to):
  - assessing the current status and availability of the medicine in each facility, ensuring all locations of stock are identified
  - reviewing historical stock usage
  - determining ongoing clinical needs and ability to obtain alternative supply.
- Ensure back orders based on average usage are placed for the Australian registered product with preferred wholesalers to ensure supply can be obtained when it becomes available.
- Facilities should consider the lead time required for processing orders for the S19A/SAS alternatives and proactively place orders.
- NSW Health Pharmacy Departments are reminded that "lending" stock of medicines to community pharmacies is considered supply by wholesale and is contrary to the *Poisons and Therapeutic Goods Act 1966* and *Poisons and Therapeutic Goods Regulation 2008*.

Prioritisation of supply and alternatives

- Reserve remaining supply of olanzapine long-acting injection for patients in whom alternatives are not appropriate. For example, patients non-compliant to oral treatments.

PTO

- If S19A/SAS alternatives with non-English packaging are utilised, ensure that an English translation of the Product Insert is available with each pack. A pharmacy dispensing label is also to be attached to the box of the medicine.
- Avoid initiating new patients on olanzapine long-acting injection until supply has stabilised.
- In the case of a complete disruption to supply, alternative antipsychotic long-acting injections or oral treatments may be considered after consultation with the patient's specialist or treating team. The most appropriate alternative will need to be determined on a case-by-case basis considering individual patient factors.

Continuity of care for community patients

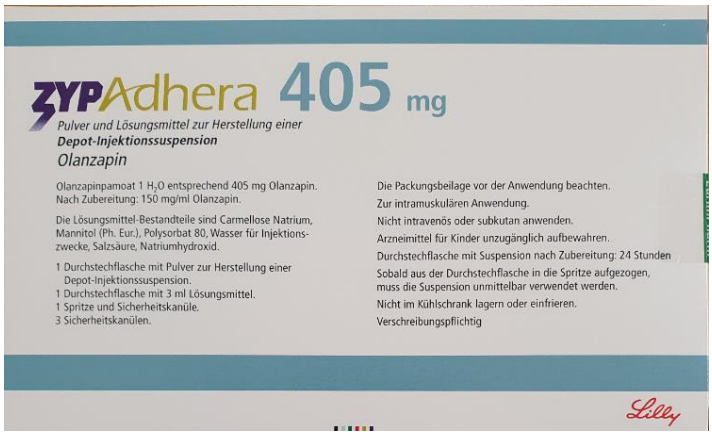
- Patients unable to obtain supply of olanzapine long-acting injection in the community, in whom alternatives are not suitable may need to attend a NSW Health facility for administration of their medicine and subsequent monitoring*.

*Clinicians are reminded of the rare but serious adverse event related to the use of olanzapine long-acting injection – post-injection syndrome, and the need for monitoring. See SN:016/21 for further information.

Table 1. Comparison between Australian registered product and S19A alternative.

Product	*ARTG listed product*	*S19A alternative – Link Healthcare*
	Olanzapine (Zyprexa Relprevv)	**Olanzapine (Zypadhera)**
Active ingredient	Olanzapine pamoate monohydrate	
Labelled strength	210 mg, 300 mg and 405 mg	
Excipients	Carmellose sodium, mannitol, polysorbate 80, water for injections, hydrochloride acid and/or sodium hydroxide	
Storage	Store below 25°C. Protect from light.	Store below 25°C.
Label language	English	German – medicine name and strength identifiable in English

Figure 1. Image of outer packaging of olanzapine long-acting injection, Zypadhera brand (S19A alternative).



Required actions for the Local Health Districts/Networks

1. Distribute this Safety Notice to all relevant clinicians and clinical departments where olanzapine long-acting injection is held, prescribed, and/or administered, and include this Safety Notice in relevant handovers and safety huddles.
2. Undertake a local risk assessment and incorporate the above recommendations to manage this issue.
3. Ensure a system is in place to document actions taken in response to this Safety Notice.
4. Confirm receipt and distribution of this Safety Notice within **72 hours** to: CEC-MedicationSafety@health.nsw.gov.au