

31 Jan 2023



RE: Shortage of ZYPREXA IM olanzapine 10mg powder for injection vial and alternative supply arrangement under Section 19A of the *Therapeutic Goods Act*.

PO Box 718
Mona Vale
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Australia

Dear Healthcare Professional,

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This notification is sent by LINK to inform your organisation that due to the shortage of Australian registered **ZYPREXA IM olanzapine 10mg powder for injection vial (AUST R 76867)**, LINK has arranged the supply of an alternative product, ***Olanzapine for intramuscular injection 10mg single dose vial (AuroMedics)*** registered and marketed in *the United States of America*.

Olanzapine for intramuscular injection 10mg single dose vial (AuroMedics) is NOT registered in Australia and supply is authorised under an exemption granted by the Therapeutic Goods Administration (TGA) under Section 19A of the *Therapeutic Goods Act, 1989* until **30 April 2023**

Olanzapine for intramuscular injection 10mg single dose vial (AuroMedics) is indicated for:

Treatment of acute agitation associated with schizophrenia and bipolar I mania.

The s19A approved USA product is identical in active ingredient, strength and excipient ingredients to the Australian registered product.

Please refer to the Australian Product Information for **ZYPREXA IM olanzapine 10mg powder for injection vial (AUST R 76867)** (available at <https://www.ebs.tga.gov.au>) when prescribing and administering ***Olanzapine for intramuscular injection 10mg single dose vial (AuroMedics)***.

Olanzapine for intramuscular injection 10mg single dose vial (AuroMedics) is registered in ***the United States of America*** with the outer package and package insert in both English. The active ingredient, strength and dosage form included on the vial label are in English.

Adverse Event Reporting

Reporting any suspected adverse event is important for the continued monitoring of the safety of all medicines. Any adverse events which are experienced with ***Olanzapine for intramuscular injection 10mg single dose vial (AuroMedics)*** should be reported by healthcare professionals and patients to Link Healthcare Medical Information. This information can also be reported to the TGA at <https://www.tga.gov.au/reporting-problems>.

Link Healthcare Medical Information can be contacted by phone on 1800 181 060 or via email at medinfo@linkhealthcare.com.au.

Link Healthcare Customer Service contact details

Link Healthcare Customer Service can be contacted via phone on 1800 181 060 or via email at customerservice@linkhealthcare.com.au.

Please contact Link Healthcare Customer Service for further information.

We would appreciate if you could distribute this information to those in your organisation who would be affected by the shortage of the Australian registered **ZYPREXA IM olanzapine 10mg powder for injection vial (AUST R 76867)**.

Yours sincerely,

Anita Sharma

Anita Sharma
Medicine Access Associate