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16th November 2023

Dear Healthcare Professional

Shortage ZYPREXA RELPREVV olanzapine (as pamoate monohydrate) 210mg powder for injection vial with diluent vial AUST R: 143658 ZYPREXA RELPREVV olanzapine (as pamoate monohydrate) 300mg powder for injection vial with diluent vial AUST R: 143657 ZYPREXA RELPREVV olanzapine (as pamoate monohydrate) 405mg powder for injection vial with diluent vial AUST R: 143636 and alternative supply arrangement under section 19A of the *Therapeutic Goods Act 1989*

The Australian registered medicine, **ZYPREXA RELPREVV olanzapine (as pamoate monohydrate) 210mg powder for injection vial with diluent vial AUST R: 143658, ZYPREXA RELPREVV olanzapine (as pamoate monohydrate) 300mg powder for injection vial with diluent vial AUST R: 143657, ZYPREXA RELPREVV olanzapine (as pamoate monohydrate) 405mg powder for injection vial with diluent vial AUST R: 143636** sponsored by Eli Lilly Australia Pty Ltd is currently unavailable or in short supply.

LINK has been able to arrange supply of an alternative product **ZYPADHERA olanzapine (as pamoate monohydrate) 210 mg powder and solvent for prolonged release suspension for injection (Germany), ZYPADHERA olanzapine (as pamoate monohydrate) 300 mg powder and solvent for prolonged release suspension for injection (Germany), ZYPADHERA olanzapine (as pamoate monohydrate) 405 mg powder and solvent for prolonged release suspension for injection (Germany)** on a temporary basis. This product is NOT registered in Australia and supply is authorised under an approval granted by the Therapeutic Goods Administration (TGA) under section 19A of the *Therapeutic Goods Act 1989* until **29th February 2024** for the following indication(s):

It is a long-acting injectable formulation of olanzapine indicated for maintenance treatment of schizophrenia in adult patients sufficiently stabilised during acute treatment with oral olanzapine.

Please see the following similarities and differences between the ARTG and section 19A approved products:

	ARTG Products **ZYPREXA RELPREVV olanzapine (as pamoate monohydrate) 210mg, 300mg and 405mg powder for injection vial with diluent vial (ARTG 143658, ARTG 143657, ARTG 143636)**	**S19A Products** **ZYPADHERA olanzapine (as pamoate monohydrate) 210 mg, 300mg and 405mg powder and solvent for prolonged release suspension for injection (Germany)**
Excipients	Carmellose sodium Mannitol Polysorbate 80 Water for injections	Carmellose sodium Mannitol Polysorbate 80 Water for injections Hydrochloric acid (for pH adjustment)

	Hydrochloric acid and/or sodium hydroxide may have been added during manufacture to adjust pH	Sodium hydroxide (for pH adjustment)
Storage	The injection is kept in a cool dry place, protected from light, where the temperature stays below 30°C.	Do not refrigerate or freeze.
Shelf Life after reconstitution	After reconstitution, chemical and physical in-use stability has been demonstrated for 24 hours at 25°C. However, the product should be used as soon after reconstitution as possible. If necessary, the reconstituted product should be stored for not more than 6 hours at room temperature.	**After reconstitution in the vial:** 24 hours. If the product is not used right away, it should be shaken vigorously to re-suspend. Once withdrawn from vial into syringe, the suspension should be used immediately. Chemical and physical stability of the suspension in the vials has been demonstrated for 24 hours at 20-25 °C. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 20-25°C.

ZYPADHERA olanzapine (as pamoate monohydrate) 210 mg powder and solvent for prolonged release suspension for injection (Germany), ZYPADHERA olanzapine (as pamoate monohydrate) 300 mg powder and solvent for prolonged release suspension for injection (Germany), ZYPADHERA olanzapine (as pamoate monohydrate) 405 mg powder and solvent for prolonged release suspension for injection (Germany) are registered and marketed in **Germany** and therefore all labelling is in German language. The English translation of the Package leaflet will be provided with this letter for the reconstitution and preparation instructions.

Please refer to the Australian Product Information for **ZYPREXA RELPREVV olanzapine (as pamoate monohydrate) 210mg powder for injection vial with diluent vial AUST R: 143658 , ZYPREXA RELPREVV olanzapine (as pamoate monohydrate) 300mg powder for injection vial with diluent vial AUST R: 143657, ZYPREXA RELPREVV olanzapine (as pamoate monohydrate) 405mg powder for injection vial with diluent vial AUST R: 143636**
available at https://www.ebs.tga.gov.au when prescribing and administering **(Approved S19a product)**

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 **ZYPADHERA olanzapine (as pamoate monohydrate) 210 mg powder and solvent for prolonged release suspension for injection (Germany), ZYPADHERA olanzapine (as pamoate monohydrate) 300 mg powder and solvent for prolonged release suspension for injection (Germany), ZYPADHERA olanzapine (as pamoate monohydrate) 405 mg powder and solvent for prolonged release suspension for injection (Germany)** should be reported by healthcare professionals and patients to the LINK healthcare Pharmacovigilance at pv@linkhealthcare.co or 1800 181 060. Alternatively, this information can be reported to the TGA at https://www.tga.gov.au/reporting-problems

Any product complaints regarding **ZYPADHERA olanzapine (as pamoate monohydrate) 210 mg powder and solvent for prolonged release suspension for injection (Germany), ZYPADHERA olanzapine (as pamoate monohydrate) 300 mg powder and solvent for prolonged release**

suspension for injection (Germany), ZYPADHERA olanzapine (as pamoate monohydrate) 405 mg powder and solvent for prolonged release suspension for injection (Germany) should be reported to LINK on 1800 161 181.

Please forward this information to relevant staff members in your organisation.
For further information, please contact LINK on 1800 161 060 or email customerservice@linkhealthcare.com.au.

Yours faithfully

Kay Roweth

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Unlicenced Medicine Associate
Link Healthcare