

The Medical Letter[®]

on Drugs and Therapeutics

Volume 66

Published online October 14, 2024

Online
Article

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IN BRIEF

Erzofri – Another Once-Monthly Paliperidone Formulation

The FDA has approved *Erzofri* (Luye), an extended-release injectable formulation of the second-generation antipsychotic drug paliperidone palmitate, for treatment of schizophrenia and schizoaffective disorder in adults. It is the second once-monthly formulation of paliperidone palmitate to be approved in the US for these indications; *Invega Sustenna* was the first. Longer-acting injectable formulations of paliperidone palmitate are also available (see Table 1).¹

Pronunciation Key

Erzofri: er zoh' free

LONG-ACTING INJECTABLE ANTIPSYCHOTICS –

Extended-release injectable second-generation antipsychotic drugs are generally used in patients with a history of relapse due to poor adherence to oral maintenance therapy.²

CLINICAL STUDIES – No new clinical efficacy trials were required for FDA approval of *Erzofri*; approval was based on earlier trials with *Invega Sustenna* and an open-label study showing that the bioavailability of paliperidone palmitate with *Erzofri* was similar to that with *Invega Sustenna*.³

DOSAGE AND ADMINISTRATION – The initial dose of *Erzofri* is 351 mg injected IM into the deltoid muscle; subsequent doses can be given in the gluteal or deltoid muscle. For schizophrenia, the recommended dosage is 117 mg IM (range 39-234 mg) once monthly. In patients with mild renal impairment, the recommended initial dose is 234 mg, followed by 78 mg once monthly (max 156 mg). *Erzofri* is not recommended for use in patients with moderate or severe renal impairment.

CONCLUSION – A once-monthly, extended-release injectable formulation of the second-generation antipsychotic drug paliperidone palmitate (*Invega Sustenna*) has been available for years. *Erzofri* has not been shown to offer any advantage in efficacy or safety over *Invega Sustenna*. Extended-release formulations of paliperidone palmitate that are administered once every 3 months or 6 months are also available and may be preferred. ■

1. In brief: Twice-yearly paliperidone (*Invega Hafyera*) for schizophrenia. *Med Lett Drugs Ther* 2022; 64:7.
2. GA Keepers et al. The American Psychiatric Association practice guideline for the treatment of patients with schizophrenia. *Am J Psychiatry* 2020; 177:868.
3. ClinicalKey Clinical Trial. A study to evaluate the PK profiles of LY03010 and relative bioavailability at steady-state of LY03010 versus *Invega Sustenna* in schizophrenia patients. Available at: <https://bit.ly/4gc2jLQ>. Accessed September 12, 2024.

Table 1. Paliperidone Palmitate Extended-Release Injectable Products

Drug	Formulations	Usual Adult Maintenance Dosage ^{1,2}	Cost ³
<i>Erzofri</i> (Luye)	39, 78, 117, 156, 234, 351 mg prefilled syringes	117, 156, or 234 mg IM once/month ^{4,5}	\$1948.10
<i>Invega Sustenna</i> (Janssen)	39, 78, 117, 156, 234 mg prefilled syringes	117, 156, or 234 mg IM once/month ⁶	1674.00
<i>Invega Trinza</i>	273, 410, 546, 819 mg prefilled syringes	410, 546, or 819 mg IM q3 months	5022.10
<i>Invega Hafyera</i>	1092, 1560 mg prefilled syringes	1092 or 1560 mg IM q6 months	13,277.90

1. Dosage adjustments may be needed for renal impairment or for drug interactions.
2. In patients who have never received oral or injectable paliperidone or risperidone, tolerability should be established with oral paliperidone or risperidone before starting treatment with long-acting injectable paliperidone. Initial dosage of long-acting formulations for schizophrenia is based on patient's stable oral maintenance dosage. Dosage of *Invega Trinza* is based on the previous dose of *Invega Sustenna*; dosage of *Invega Hafyera* is based on the previous dose of *Invega Sustenna* or *Invega Trinza*. *Invega Trinza* and *Invega Hafyera* are only approved for treatment of schizophrenia.
3. Approximate WAC for 4 weeks' or 1 month's treatment with the lowest usual adult dosage (3 months' treatment with *Invega Trinza*, 6 months' treatment with *Invega Hafyera*). WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly. September 5, 2024. Reprinted with permission by First Databank, Inc. All rights reserved. ©2024. www.fdbhealth.com/policies/drug-pricing-policy.
4. Dosage for treatment of schizophrenia. Dosage for treatment of schizoaffective disorder is 78-234 mg (based on efficacy and tolerability) once/month.
5. Initial dosage is 351 mg on day 1, then 39-234 mg four weeks later and once monthly thereafter.
6. Initial dosage is 234 mg on day 1, then 156 mg on day 8, followed by 39-234 mg (based on efficacy and tolerability) on day 36.

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