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IN BRIEF

Twice-Yearly Paliperidone (*Invega Hafyera*) for Schizophrenia

Invega Hafyera (Janssen), a long-acting, extended-release (ER) formulation of the second-generation antipsychotic paliperidone palmitate, has been approved by the FDA for twice-yearly IM treatment of schizophrenia in adults who have been adequately treated with another injectable ER formulation of the drug (*Invega Sustenna* or *Invega Trinza*). It is the first drug to become available in the US for twice-yearly treatment of schizophrenia.

Pronunciation Key

Invega Hafyera: in vay' guh haf' ye ra"

LONG-ACTING INJECTABLE ANTIPSYCHOTICS – Long-acting injectable antipsychotics are generally used in patients with a history of relapse due to poor adherence to oral maintenance therapy. They are

believed to improve adherence, hospitalization and relapse rates, and long-term outcomes in patients with schizophrenia, even though a benefit has not been consistently demonstrated in controlled trials comparing long-acting injectable formulations with oral second-generation antipsychotics.^{1,2}

CLINICAL STUDIES – FDA approval of *Invega Hafyera* was based on the results of an unpublished (summarized in the package insert) double-blind, active-controlled, noninferiority trial in 702 adults with schizophrenia. At 12 months, a relapse event occurred in 7.5% of patients who received *Invega Hafyera* every 6 months and in 4.9% of those who received the drug every 3 months (*Invega Trinza*); twice-yearly paliperidone was noninferior to the drug given every 3 months.

ADVERSE EFFECTS – Adverse effects of the new twice-yearly paliperidone palmitate formulation appear to be similar to those with the other injectable ER formulations of the drug.

Table 1. Long-Acting Injectable Second-Generation Antipsychotics

| Drug | Formulations | Usual Adult Dosage ^{1,2} | Cost ³ |
|--|---|---|-------------------|
| Aripiprazole – <i>Abilify Maintena</i> (Otsuka/Lundbeck) | 300, 400 mg prefilled syringes, vials | 400 mg IM once/month | \$2388.50 |
| Aripiprazole lauroxil – <i>Aristada</i> (Alkermes) | 441, 662, 882, 1064 mg prefilled syringes | 441, 662, or 882 mg IM once/month or 882 mg IM q6 weeks or 1064 mg q2 months ⁴ | 1413.60 |
| Olanzapine pamoate – <i>Zyprexa Relprevv</i> (Lilly) | 210, 300, 405 mg vials | 150 or 300 mg IM q2 weeks or 300 or 405 mg IM once/month | 842.40 |
| Paliperidone palmitate – <i>Invega Sustenna</i> (Janssen) | 39, 78, 117, 156, 234 mg prefilled syringes | 117, 156, or 234 mg IM once/month | 1470.00 |
| <i>Invega Trinza</i> | 273, 410, 546, 819 mg prefilled syringes | 410, 546, or 819 mg IM q3 months | 4410.00 |
| <i>Invega Hafyera</i> | 1092, 1560 mg prefilled syringes | 1092 or 1560 mg IM q6 months ⁵ | 11,760.30 |
| Risperidone – <i>Risperdal Consta</i> (Janssen) | 12.5, 25, 37.5, 50 mg vials | 25, 37.5, or 50 mg IM q2 weeks | 1065.80 |
| <i>Perseris</i> (Indivior) | 90, 120 mg kits | 90 or 120 mg SC once/month | 1185.30 |

1. Dosage adjustments may be needed for renal or hepatic impairment.

2. 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*.

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. December 5, 2021. Reprinted with permission by First Databank, Inc. All rights reserved. ©2021. www.fdbhealth.com/policies/drug-pricing-policy.

4. A single 675-mg IM dose of *Aristada Initio* and one 30-mg dose of oral aripiprazole or 21 days of oral aripiprazole should be given in conjunction with the first dose of *Aristada*.

5. The starting dose is 1092 mg if switching from *Invega Sustenna* 156 mg once/month or *Invega Trinza* 546 mg q3 months. The starting dose is 1560 mg if switching from *Invega Sustenna* 234 mg once/month or *Invega Trinza* 819 mg q3 months.

DRUG INTERACTIONS – Concurrent use of strong CYP3A4 and P-glycoprotein (P-gp) inducers can decrease serum concentrations of paliperidone and should be avoided; if coadministration is necessary, oral paliperidone extended-release tablets can be added.³ Paliperidone may antagonize the effects of levodopa and other dopamine agonists.

DOSAGE AND ADMINISTRATION – *Invega Hafyera* is injected into the gluteal muscle once every 6 months. The starting dosage (1092 or 1560 mg) is based on the previous dose of the monthly or 3-month injectable ER formulations of paliperidone palmitate and should be administered at the time

the next dose of paliperidone palmitate is scheduled. Dosage adjustments can be made every 6 months between 1092 mg and 1560 mg. *Invega Hafyera* is not recommended for use in patients with any degree of renal impairment (CrCl <90 mL/min). ■

1. Drugs for psychotic disorders. *Med Lett Drugs Ther* 2016; 58:160.
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. Inhibitors and inducers of CYP enzymes, P-glycoprotein, and other transporters. *Med Lett Drugs Ther* 2021 October 20 (epub). Available at: http://secure.medicalletter.org/downloads/CYP_PGP_Tables.pdf.

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