New Dosage Form – Paliperidone Palmitate (Erzofri®) ER injectable suspension
Shandong Luye Pharmaceutical Co. Ltd.; FDA approved July 2024

Indication

Erzofri® is indicated for use in adults for the treatment of

- Schizophrenia
- Schizoaffective disorder, either as a standalone therapy or in combination with mood stabilizers or antidepressants

Dosage

Indication	Initial Dose (deltoid) Day 1	Monthly Dosage (deltoid or gluteal)	Maximum Monthly Dosage
Schizophrenia,	351 mg	39 mg to 234 mg	234 mg
Schizoaffective Disorder	351 mg	78 mg to 234 mg	234 mg

	Erzofri®	Invega Sustenna®
Manufacturer	Shandong Luye Pharmaceutical Co. Ltd	Janssen Pharmaceuticals, Inc
Approval	July 2024	July 2009
Injection interval	4 weeks	
Dose strengths	39 mg/0.25 mL, 78 mg/0.5 mL, 117 mg/0.75 mL, 156 mg/mL, 234 mg/1.5 mL, 351 mg/2.25 mL	39 mg/0.25 mL, 78 mg/0.5 mL, 117 mg/0.75 mL, 156 mg/mL, or 234 mg/1.5 mL
Dose range	39 mg to 351 mg Q 4 weeks	39 mg to 234 mg Q 4 weeks
Maximum dose	234 mg Q 4 weeks	
Administration	Must be administered by a health care provider. Shake the syringe for 10 seconds before use. Use a 1½ inch, 22-gauge needle for patients ≥90 kg, and 1 inch, 23-gauge needle for patients <90 kg	
Conversion from oral tablets	Switching from oral paliperidone to either Erzofri or Invega Sustenna follows the same protocol for steady state exposure	
Missed maintenance dose	May be administered up to 7 days before or after the scheduled dose. Management of missed maintenance dose is the same except when the missed dose is more than 6 months since the last injection	
Missed dose > 6 months	Single initiation dose of 351 mg deltoid injection on Day 1, followed by monthly maintenance	2-step initiation with 234 mg deltoid injection, followed by 156 mg deltoid injection 1 week later, before resuming monthly dosing
Renal impairment	Mild impairment (CrCl ≥ 50 mL/min): max dose 156 mg/month Not recommended for moderate/severe impairment	
Injection site	Initial: Deltoid; Maintenance: Deltoid or gluteal	
Adverse Effects (≥5%)	Injection site reactions, somnolence/sedation, dizziness, akathisia, & extrapyramidal disorder	

Role in therapy

- Erzofri® provides a new once-monthly treatment for schizophrenia as an alternative to long acting injectables, particularly Invega Sustenna®, which was

approved 15 years ago. Its simplified initial dosing may enhance patient adherence with fewer injections

- Unlike Invega Sustenna, Erzofri omits the day-8 injection, aiming to improve compliance by providing comparable drug exposure without an additional early dose
- FDA approval of Erzofri did not require new efficacy trials; it relied on previous data from Invega Sustenna and an open label study demonstrating bioequivalence at steady state
- Erzofri does not show significant differences in efficacy or safety compared to Invega Sustenna but offers an additional option for patients needing monthly LAI therapy, focusing on simplified initial dosing
- Erzofri is the first patented paliperidone palmitate LAI developed in China to be approved in the US (patented in 2023, protected until 2039)
- It is the second FDA approved once-monthly paliperidone palmitate formulation following Invega Sustenna. Other extended release formulations (e.g., Invega Trinza, Invega Hafyera) offer dosing every 3 or 6 months, which may be preferred for longer intervals

Pricing Comparison

Erzofri	Monthly Cost	Invega Sustenna	Monthly Cost
39mg/0.25ml	$ 650	39mg/0.25ml	$ 580
78mg/0.5ml	$1300	78mg/0.5ml	$1160
117mg/0.75ml	$1950	117mg/0.75ml	$1218
156mg/1ml	$2598	156mg/1ml	$2319
234mg/1.5ml	$3896	234mg/1.5ml	$3478
351mg/2.25ml	$5844		
FDB WAC pricing as of 11/8/2024			

Formulary Recommendation

- Invega Sustenna has the advantage of a longer history of clinical use, an established safety profile, and less costly
- Erzofri has the advantage of simplified initial dosing that may enhance adherence by using 351mg dose
- Recommend adding 351mg dose to BHRS and CA Formularies with Quantity Limit of 1.5ml per 28 days