

New Formulation – Aripiprazole Oral Film
(Opipza® Xiamen Pharmaceutical)
FDA Approved July 2024

Indications

1. Treatment of schizophrenia in patients aged 13 years and older.
2. Adjunctive treatment of Major Depressive Disorder (MDD) in adults.
3. Treatment of irritability associated with autistic disorder in pediatric patients aged 6 years and older.
4. Treatment of Tourette’s disorder in pediatric patients aged 6 years and older.

Mechanism

Aripiprazole’s mechanism of action is not fully understood. However, its efficacy may be mediated through a combination of partial agonist activity at dopamine D2 and serotonin 5-HT1A receptors and antagonist activity at serotonin 5-HT2A receptors.

Dosage & Administration

	Initial Dosage	Recommended Dosage	Maximum Dosage
Schizophrenia (adults)	10 to 15 mg/day	10 to 15 mg/day	30 mg/day
Schizophrenia (pediatrics ≥13 yo)	2 mg/day	10 mg/day	30 mg/day
MDD Adjunctive Treatment (adults)	2 to 5 mg/day	5 to 10 mg/day	15 mg/day

Administration	<ul style="list-style-type: none"> ▪ Instruct patients/caregivers to read the “Instructions for Use” carefully to ensure proper administration ▪ Place the film on top of the tongue and allow it to dissolve completely in saliva; do not chew, split, or swallow the undissolved film ▪ Administer with or without food, but avoid eating or drinking immediately after administration to ensure absorption ▪ Administer one film at a time. If additional films are needed to complete the dose, administer them sequentially after each film has dissolved
How Supplied	Oral Film: 2 mg, 5 mg, 10 mg

DDI

Factors	Dosage Recommendations
CYP2D6 poor metabolizers taking strong CYP3A4 inhibitors	Administer quarter of recommended dosage
Strong CYP2D6 or CYP3A4 inhibitors	Administer half of recommended dosage
Strong CYP2D6 & CYP3A4 inhibitors	Administer quarter of recommended dosage
Strong CYP3A4 inducers	Double the recommended dosage over 1 to 2 weeks

Adverse Effects - Incidence \geq5% & at least twice that of placebo as monotherapy	
Schizophrenia (adults)	▪ Akathisia
Schizophrenia (pediatrics 13 to 17 yo)	▪ Extrapyramidal disorder, somnolence, and tremor
MDD Adjunctive treatment (adults)	▪ Akathisia, restlessness, insomnia, constipation, fatigue, and blurred vision

Pharmacokinetics

Comparative Bioavailability	Aripiprazole oral film (10 mg) C _{max} & AUC ratios to tablets (10 mg): 114%/106% (fasting) & 91%/95% (fed)
Steady state	Attained within 14 days
Metabolism	Mainly hepatic involving CYP2D6 & CYP3A4
T_{max}	1.5 hrs
Effect of food	High fat meal (800 – 1,000 Kcal) delays T _{max} (1.5 to 6 hrs) but doesn't affect C _{max}
Excretion	Feces: 55% (~18% unchanged, 37% changed); urine: 25% (<1% unchanged, 25% changed)

Role in therapy

- Opipza provides a new, convenient oral film formulation of aripiprazole, catering to patients with swallowing difficulties or aversion to tablets.
- It offers flexibility in administration possibly enhancing adherence
- Unclear comparative advantage over other aripiprazole formulations; further studies are needed to establish distinct benefits.
- Provides a new formulation of aripiprazole, a well-established atypical antipsychotic.
- The safety and efficacy of Opipza are supported by well controlled studies of another oral aripiprazole product.

Cost Comparison

Aripiprazole	Dose	Monthly Cost*
Oral tablets generic	Up to 30mg/day	\$ 9
Oral tablets brand	Up to 30mg/day	\$ 825
ODT tablets generic	Up to 30mg/day	\$ 570
Oral solution	Up to 30mg/day	\$ 900
Oral Film Opipza	Up to 30mg/day	\$6930

*Wholesale acquisition price accessed 12/20/2024

Formulary Recommendation

CMS does not require Opipza to be added to the medicare formulary due to availability of aripiprazole oral formulations on the formulary. In addition, the price premium for the oral film

formulation exceeds that of ODT and oral solution, both are formulary with PA criteria.
Recommend that Opiqua stays nonformulary for BHRS, CareAdvantage and HealthWorx.