Rykindo® (risperidone) – New drug approval

- On January 15, 2023, Luye Pharma announced the FDA approval of Rykindo (risperidone) extended-release injectable suspension, for the treatment of schizophrenia in adults and as monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of bipolar I disorder in adults.

- In addition to generically available oral formulations, risperidone is also available in two other branded injectable formulations: Risperdal Consta® and Perseris®.

    — Like Rykindo, Risperdal Consta is administered intramuscularly (IM) and shares the same indications.
    — Perseris is administered subcutaneously and is only approved for the treatment of schizophrenia in adults.

- The effectiveness of Rykindo is based on adequate and well-controlled studies with other risperidone products.

- Rykindo carries a boxed warning for increased mortality in elderly patients with dementia-related psychosis.

- Refer to the Rykindo drug label for a complete list of warnings and precautions.

- The most common adverse reactions with Rykindo use in patients with schizophrenia (≥ 5%) were headache, parkinsonism, dizziness, akathisia, fatigue, constipation, dyspepsia, sedation, weight increase, pain in extremity, and dry mouth.

- The most common adverse reactions with Rykindo use in patients with bipolar disorder were (5% in monotherapy trial) increased weight and (≥ 10% in adjunctive therapy trial) tremor and parkinsonism.

- The recommended dosage of Rykindo for the treatment of schizophrenia is 25 mg IM every 2 weeks. The first dose of Rykindo should be administered along with 7 days of oral risperidone.

    — Patients not responding to 25 mg may benefit from a higher dose of 37.5 mg or 50 mg. The maximum dose should not exceed 50 mg every 2 weeks. No additional benefit was observed with dosages greater than 50 mg of risperidone long-acting injection (IM); however, a higher incidence of adverse reactions was observed. Dose titration should not be made more frequently than every 4 weeks.

- The recommended dosage of Rykindo for monotherapy or adjunctive therapy to lithium or valproate for the maintenance treatment of bipolar I disorder is 25 mg every 2 weeks. The first dose of Rykindo should be administered along with 7 days of oral risperidone.

    — Some patients may benefit from a higher dose of 37.5 mg or 50 mg. Dosages above 50 mg have not been studied in this population. Dose titration should not be made more frequently than every 4 weeks.

- For patients who have never taken oral risperidone, tolerability with oral risperidone should be established prior to initiating Rykindo.

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- Rykindo should be administered every 2 weeks by IM gluteal injection by a health care professional.
- Luye Pharma's launch plans for Rykindo are pending. Rykindo will be available as a 12.5 mg, 25 mg, 37.5 mg, and 50 mg extended-release injectable suspension.