Risvan® (risperidone) – New drug approval

- On April 2, 2024, Rovi announced the FDA approval of Risvan (risperidone), for the treatment of schizophrenia in adults.

- Risvan is an intramuscular (IM) administered atypical antipsychotic. Risperidone is available in several other oral and injectable formulations for treatment of schizophrenia.

- The efficacy of Risvan was established based on adequate and well-controlled studies of oral risperidone as well as one randomized, double-blind, placebo-controlled study in 390 adult patients with schizophrenia. In this study, patients were randomized to receive 3 doses of IM Risvan (75 mg or 100 mg) or placebo every 4 weeks. The primary endpoint was the change in Positive and Negative Syndrome Scale (PANSS) total score from baseline to end of study at day 85.

    — Both Risvan 75 mg and 100 mg doses demonstrated a statistically significant improvement compared with placebo based on the primary endpoint (PANSS total score).

	Mean baseline score (standard deviation)	Least-squares mean change from baseline (standard error)	Placebo-subtracted difference (95% CI)
Risvan 75 mg	96.3 (8.47)	-24.6 (1.51)	-13.0 (-17.3 to -8.8)
Risvan 100 mg	96.1 (8.42)	-24.7 (1.54)	-13.3 (-17.6 to -8.9)
Placebo	96.1 (7.21)	-11.0 (1.56)	--

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

- Additional warnings and precautions for Risvan include cerebrovascular adverse reactions, including stroke, in elderly patients with dementia-related psychosis; neuroleptic malignant syndrome; tardive dyskinesia; metabolic changes; hyperprolactinemia; orthostatic hypotension and syncope; falls; leukopenia, neutropenia, and agranulocytosis; potential for cognitive and motor impairment; seizures; dysphagia; priapism; and body temperature regulation.

- The most common adverse reactions (≥ 5% and twice placebo) with Risvan use were hyperprolactinaemia, increased blood prolactin, akathisia, headache, sedation (including somnolence), increased weight, injection site pain, and increased alanine aminotransferase.

- The recommended initial dose of Risvan is 75 mg or 100 mg once monthly by deltoid or gluteal IM injection. Risvan should not be administered more than one dose (75 mg or 100 mg total) per month.

    — For patients who have never taken risperidone, establish tolerability with oral risperidone prior to initiating Risvan.
    — Refer to the Risvan drug label for recommendations in patients with prior treatment with oral risperidone.
    — Risvan must be administered by a healthcare professional.

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- Rovi's launch plans for Risvan are pending. Risvan will be available as a 75 mg and 100 mg extended-release injectable suspension.