Supplemental Approvals

Generic Name (Trade Nameâ€"Company)

July 31, 2018

Risperidone injectable

(Perseris—Indivior PLC)

New once-monthly S.C. risperidone offers easier treatment option for adults with schizophrenia

Uses/Notes

Indivior PLC announced FDA approval of the first once-monthly, long-acting injectable (LAI) containing risperidone to treat schizophrenia in adults. Clinically relevant levels were reached after the first injection without use of a loading dose or any supplemental oral risperidone.

The extended-release delivery system forms an S.C. depot that provides sustained levels of risperidone over 1 month. Initial peak risperidone plasma levels occur within 4 to 6 hours of dosing and are due to an initial release of the drug during the depot formation process.

Efficacy of the new formulation was evaluated in a pivotal Phase III randomized, double-blind, placebo-controlled, 8-week study of 354 patients. The study demonstrated an improvement in the primary clinical endpoint, Positive and Negative Syndrome Scale (PANSS) total score at day 57. The improvement in Clinical Global Impression Severity of Illness (CGI-S) was also statistically significant at day 57. Clinical trials were designed for the product to be initiated with neither a loading dose nor any supplemental risperidone.

Safety was evaluated in 814 adults with schizophrenia who received at least one dose during clinical trials. A total of 322 patients were treated with the injectable agent for at least 6 months, with 234 of those treated for at least 12 months. The systemic safety profile was consistent with the known safety profile of oral risperidone.

The most common systemic adverse reactions were increased weight, sedation/somnolence, and musculoskeletal pain. The most common injection-site reactions were injection-site pain and reddening of the skin.

The labeling comes with a boxed warning cautioning that older adult patients with dementia-related psychosis who are treated with antipsychotic drugs are at an increased risk of death. The agent is not approved for use in patients with dementia-related psychosis.

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