Consumer Update April 2022

Ribavirin risk of Embryo-Fetal Toxicity

EDA performs label update to include the following:

WARNING: EMBRYO-FETAL TOXICITY, HEMOLYTIC ANEMIA, and MONOTHERAPY NOT RECOMMENDED

Significant teratogenic and embryocidal effects have been demonstrated in all animal species exposed to ribavirin. Therefore, REBETOL therapy is contraindicated in women who are pregnant and in the male partners of women who are pregnant. Avoid pregnancy during therapy and for 9 months after completion of treatment in female patients and for 6 months in female partners of male patients who are taking ribavirin therapy.

5Warnings and Precautions

5.1 Embryo-Fetal Toxicity

Female patients should use effective contraception and have periodic monitoring with pregnancy tests during treatment and during the 9-monthperiod after treatment has been stopped. Male patients and their female partners should use effective contraception during treatment and during the 6-month period after treatment has been stopped.

Background on the safety concerns

Ribavirin is a nucleoside analogue indicated in combination with interferon alfa-2b (pegylated and non-pegylated) for the treatment of Chronic Hepatitis C (CHC) in patients 3 years of age or older with compensated liver disease. Patients with the following characteristics are less likely to benefitfrom re-treatment after failing a course of therapy: previous nonresponse, previous pegylated interferon treatment, significant bridging fibrosis or cirrhosis, and genotype 1 infection.

References:

1. *FDA Article (Click here)*
2. *FDA Label (Click here)*