Three Deaths on Olysio Lead Japan to Issue Package Warning

October 29, 2014

The deaths of three people with hepatitis C virus (HCV) taking Olysio (simeprevir) has led Japanese health authorities to revise the drug's packaging to issue a warning about its safety, GlobalPost reports. Since Olysio hit the Japanese market under the name Sovriad in December 2013, an estimated 18,900 people have received treatment with the drug. The three who died all experienced what the revised packaging describes as a "remarkable increase in blood bilirubin levels" followed by dysfunction of the liver, kidney impairment, or both. The individuals ranged in age from 40s to 60s.

The drug packaging already warns about the potential for diminished liver function while taking Olysio. However, the Japanese Ministry of Health, Labor and Welfare has ordered Janssen, which manufactures the drug, to revise the packaging to state that Olysio use should cease if routine tests indicate abnormal bilirubin levels. Physicians should then monitor patients carefully, as bilirubin levels may be elevated even after discontinuation of Olysio.

If you are taking Olysio, your physician should regularly test your bilirubin levels. You should alert your clinician immediately if you develop yellowing of the eyes or skin, brown urine, or general malaise—which is a feeling of discomfort, weakness, or being out of sorts.

The Pharmaceuticals and Medical Devices Agency of Japan has published what is known as a Blue Letter of the revised packaging details on its website. Janssen plans to distribute the letter to Japanese clinicians to alert them of the revisions.

"The safety and well-being of patients are our top priorities and we take all reports of adverse events seriously," Janssen representative Lisa Vaga wrote in an email. She said that in each of the three deaths the cause of death was confounded by other treatments the individuals were receiving, including interferon and ribavirin, as well as their personal health conditions.

"If patients are uncertain about their [Olysio, interferon] and ribavirin combination treatment or have any questions about the therapy, they should speak to their health care professional," Vaga said. "Patients should not discontinue [treatment] without the guidance of a trained physician."

To read the GlobalPost story, click here.

© 2026 Smart + Strong All Rights Reserved.
http://beta.docker.hepmag.com/article/Olysio-deaths-26345-495678813