

Viracept caution issued by Pfizer

September 10 2007

Pfizer Inc. issued a "Dear Healthcare Professional" letter Monday warning of the presence of an impurity in its Viracept medication.

Pfizer said it had discovered ethyl methanesulfonate, or EMS, had been introduced during the production process into Viracept (nelfinavir), which is indicated to help control human immunodeficiency virus infection.

The U.S. Food and Drug Administration said EMS is a potential human carcinogen. Data from animal studies indicate EMS is teratogenic, mutagenic and carcinogenic -- however, no data from humans exist.

The FDA said it asked Pfizer to implement new specifications to limit the presence of EMS in Pfizer-manufactured Viracept products marked in the United States.

However, the FDA and Pfizer agreed the benefit-risk ratio remains favorable for the continued use of Viracept. But pediatric patients and pregnant women who need to begin HIV or antiretroviral treatment should not start regimens containing Viracept until further notice, the FDA said.

Copyright 2007 by United Press International

Citation: Viracept caution issued by Pfizer (2007, September 10) retrieved 26 April 2024 from

<https://medicalxpress.com/news/2007-09-viracept-caution-issued-pfizer.html>

This document is subject to copyright. Apart from any fair dealing for the purpose of private study or research, no part may be reproduced without the written permission. The content is provided for information purposes only.