

**Product Information as approved by the CHMP on 15 December 2016, pending endorsement
by the European Commission**

**Amendments to relevant sections of the summary of product characteristics
and package leaflet**

Note: These amendments to the relevant sections of the Summary of Product Characteristics and package leaflet are the outcome of the referral procedure.

*[For Daklinza, Exviera, Harvoni, Olysio, Sovaldi and Viekirax, the existing product information shall be amended (insertion, replacement or deletion of the text, as appropriate) to reflect the agreed wording as provided below (new text in **bold and underlined**)]*

Summary of product characteristics

4.4 Special warnings and precautions for use

~~The safety and efficacy of [product name] in the treatment of HCV infection in patients who are co-infected with HBV have not been investigated.~~

[...]

Cases of hepatitis B virus (HBV) reactivation, some of them fatal, have been reported during or after treatment with direct-acting antiviral agents. HBV screening should be performed in all patients before initiation of treatment. HBV/HCV co-infected patients are at risk of HBV reactivation, and should therefore be monitored and managed according to current clinical guidelines.

[...]

Package Leaflet

Section 2: What you need to know before you take <invented name>

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine if you:

[...]

- Have a current or previous infection with the hepatitis B virus, since your doctor may want to monitor you more closely;

[...]