



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 September 2021
EMA/CHMP/505022/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Zepatier

elbasvir / grazoprevir

On 16 September 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Zepatier. The marketing authorisation holder for this medicinal product is Merck Sharp & Dohme B.V.

The CHMP adopted an extension to the existing indication as follows:²

Zepatier is indicated for the treatment of chronic hepatitis C (CHC) in adults **and paediatric patients 12 years of age and older who weigh at least 30 kg** (see sections 4.2, 4.4 and 5.1).

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

² New text in bold

