26 May 2016
EMA/CHMP/342247/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Zepatier

elbasvir /grazoprevir

On 26 May 2016 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Zepatier, intended for the treatment of chronic hepatitis C. The applicant for this medicinal product is Merck Sharp & Dohme Limited.

Zepatier is a fixed dose combination of two direct acting antivirals, elbasvir and grazoprevir (ATC code: J05AX68). It will be available as film-coated tablets (containing 50 mg elbasvir and 100 mg grazoprevir). Elbasvir is an inhibitor of the hepatitis C virus (HCV) NS5A protein, while grazoprevir is an inhibitor of the HCV NS3/4A protease. Both proteins are essential for viral replication.

The benefit with Zepatier when used with or without ribavirin is its very high efficacy against HCV genotypes 1 and 4 including in patients with compensated cirrhosis and severe kidney disease. The most common side effects are fatigue and headache.

The full indication is: "Zepatier is indicated for the treatment of chronic hepatitis C (CHC) in adults (see sections 4.2, 4.4 and 5.1). For hepatitis C virus (HCV) genotype-specific activity see sections 4.4 and 5.1."

It is proposed that Zepatier be prescribed by physicians experienced in the management of patients with chronic hepatitis C.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after 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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact