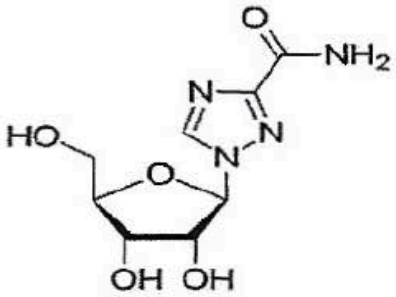
PHARMADEV

RIBAVIRIN



Ribavirin film-coated tablets manufacture patented process.

To improve the compliance with a posology of 1 to 3 g per day in up to three (3) intakes per day, we have developed a manufacturing process patented (WO 2010-058104, FR 293 84 33) which significantly reduces the tablet weight and consequently allows a range of three (3) dosages: 200, 400 and 600 mg of ribavirin film-coated tablets (FCT).

PHARMADEV expertise (10 years manufacturing) and supply in EU (GMP plant in France) are relevant of two different domains:

Human Viral hepatis C

The indication is the treatment of human chronic hepatis C in combination with interferons and from 2015 with direct antivirals agents (DAA). The treatment is in practice restricted to a small number of patients (decompensated cirrhosis and transplantation).

The Market Authorizations (MA) was granted in 2010 to IDD (International Drug Development, Paris, France) appointed by PHARMADEV for regulatory purposes for France (MA 200 mg NL38787, MA 400 mg NL38788, MA 600 mg NL38786). followed by an MRP including Germany.

Treatment and prophylaxis of hemorrhagic fevers

PHARMADEV HEALTHCARE Ltd (Dublin, Ireland) has obtained in 2018 for RIBAVIRIN the status of ORPHAN DRUG (ODD) in the treatment of acute hemorrhagic fevers: Crimean Congo Hemorrhagic Fever (CCHF: EMA 132079/2018) and Lassa Fever (LF: EMA 132080/2018).

The EMA guideline regarding Bioterrorism treatment and prophylaxis with Ribavirin (CPMP/4048/01, rev.6) is consistent with civil and/or military protection and constitution of security stock.

An injectable form, currently under development, is more appropriate for an emergency.