VELPACRUZ S

To be sold by retail on the prescription of " Gastroenterologist " only.

Abbreviated Prescribing information for Velpacruz S tablet [Sofosbuvir + velpatasvir] [Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES: Direct acting antiviral. Sofosbuvir is a pan-genotypic inhibitor of the HCV NS5B RNA-dependent RNA polymerase, which is essential for viral replication. Sofosbuvir is a nucleotide prodrug that undergoes intracellular metabolism to form the pharmacologically active uridine analogue triphosphate (GS-461203), which can be incorporated into HCV RNA by the NS5B polymerase and acts as a chain terminator. GS-461203 (the active metabolite of sofosbuvir) is neither an inhibitor of human DNA and RNA polymerases nor an inhibitor of mitochondrial RNA polymerase. Velpatasvir is a HCV inhibitor targeting the HCV NS5A protein, which is essential for both RNA replication and the assembly of HCV virions. In vitro resistance selection and cross-resistance studies indicate velpatasvir targets NS5A as its mode of action. **INDICATION:** indicated for the treatment of chronic hepatitis C virus (HCV) infection in adults. **DOSAGE AND ADMINISTRATION:** The recommended dose of Sofosbuvir+velpatasvir is one tablet, taken orally, once daily with or without food. **CONTRAINDICATION:** Hypersensitivity to the active substances or to any of the excipients. Use with potent P-gp and potent CYP inducers. **WARNINGS & PRECAUTIONS**: Severe bradycardia and heart block: Cases of severe bradycardia and heart block have been observed when sofosbuvir used in combination with another direct acting antiviral (DAA), is used with concomitant amiodarone with or without other medicinal products that lower heart rate. Renal Impairment: No dose adjustment of Sofosbuvir+velpatasvir is required for patients with mild or moderate renal impairment. Use with moderate P-gp inducers or moderate CYP inducers: Co-administration of such medicinal products with Sofosbuvir+velpatasvir is not recommended. Use with certain HIV antiretroviral regimens: Sofosbuvir+velpatasvir has been shown to increase tenofovir exposure, especially when used together with an HIV regimen containing tenofovir disoproxil fumarate and a pharmacokinetic enhancer (ritonavir or cobicistat). HCV/HBV (hepatitis B virus) co-infection: Cases of hepatitis B virus (HBV) reactivation, some of them fatal, have been reported during or after treatment with direct-acting antiviral agents. CPT Class C cirrhosis: Safety and efficacy of Sofosbuvir+velpatasvir has not been assessed in patients with CPT Class C cirrhosis. Liver transplant patients: Treatment with Sofosbuvir+velpatasvir in accordance with the recommended posology should be guided by an assessment of the potential benefits and risks for the individual patient. **DRUG INTERACTIONS:** Potential for Sofosbuvir+velpatasvir to affect other medicinal products: Co-administration of Sofosbuvir+velpatasvir with medicinal products that are substrates of these transporters may increase the exposure of such medicinal products. Potential for other medicinal products to affect Sofosbuvir+velpatasvir: Medicinal products that are potent inducers of P-gp or potent inducers of CYP2B6, CYP2C8, or CYP3A4 (e.g. rifampicin, rifabutin, St. John's wort, carbamazepine, phenobarbital and phenytoin) may decrease plasma concentrations of sofosbuvir or velpatasvir leading to reduced therapeutic effect of sofosbuvir/velpatasvir. Medicinal products that are moderate P-gp inducers or moderate CYP inducers (e.g. oxcarbazepine, modafinil or efavirenz) may decrease sofosbuvir or velpatasvir plasma concentration leading to reduced therapeutic effect of Sofosbuvir+velpatasvir. Patients treated with vitamin K antagonists: As liver function may change during treatment with Sofosbuvir+velpatasvir, a close monitoring of International Normalised Ratio (INR) values is recommended. Interactions between Sofosbuvir+velpatasvir and other medicinal products: acid reducing agents, Antacids, H2-receptor antagonists (Famotidine, Cimetidine, Ranitidine etc.), Proton pump inhibitors (Omeprazole, Lansoprazole, Esomeprazole etc.), Antiarrhythmics (Amiodarone, Digoxin etc.), Anticoagulants (Dabigatran etexilate etc.), Anticonvulsants (Carbamazepine, Phenytoin etc.), Antifungals (Ketoconazole

etc.), Antimycobacterials (Rifampicin etc.), HIV Antiviral Agents: Reverse Transcriptase Inhibitors (Tenofovir disoproxil fumarate etc.), HIV Antiviral Agents: Hiv Protease Inhibitors (Atazanavir etc.), HMG-CoA Reductase Inhibitors (Rosuvastatin etc.), Narcotic Analgesics (Methadone etc.), Immunosuppressants (Ciclosporin etc.) and Oral Contraceptives. **ADVERSE REACTIONS:** headache, fatigue, nausea, Cardiac arrhythmias, bradycardia and heart block.

MARKETED BY

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(Additional information is available on request)