VELPIS TABLETS

(Sofosbuvir 400 mg + Velpatasvir 100 mg)

COMPOSITION

Each film-coated tablet contains Sofosbuvir 400 mg and Velpatasvir 100 mg. Excipients: as per approved formulation.

DESCRIPTION & PHARMACOLOGY

Velpis combines two direct-acting antivirals against hepatitis C virus (HCV). Sofosbuvir is a nucleotide analogue inhibitor of HCV NS5B RNA-dependent RNA polymerase; velpatasvir inhibits the HCV NS5A protein. Together they block viral replication across HCV genotypes 1-6.

INDICATIONS

Treatment of chronic hepatitis C infection, genotypes 1-6, in adults and eligible paediatric patients according to locally approved indications: without cirrhosis or with compensated cirrhosis; with decompensated cirrhosis when combined with ribavirin.

DOSAGE & ADMINISTRATION

Adults: one 400 mg/100 mg tablet orally once daily, with or without food. Usual treatment duration is 12 weeks. Patients with decompensated cirrhosis generally require concomitant ribavirin for 12 weeks under specialist care.

Treatment regimen must be individualised according to prior treatment, cirrhosis status, co-infection and local guidance.

ADDITIONAL DOSAGE GUIDANCE

A 28-tablet pack supplies 28 days at one tablet daily; a standard 12-week course requires 84 tablets (three packs of 28). Do not stop treatment after a single pack unless instructed by the prescriber.

PAEDIATRIC USE

Use in children aged 3 years and older is weight-based under the referenced label. The 400 mg/100 mg tablet strength is appropriate only for patients weighing at least 30 kg; lower weights require an approved lower-strength formulation.

RENAL & HEPATIC IMPAIRMENT

No dosage adjustment is recommended for renal impairment, including dialysis, under the referenced label. Decompensated cirrhosis requires ribavirin combination treatment; follow ribavirin-specific precautions and dose adjustments.

PRE-TREATMENT ASSESSMENT

Before treatment, test for current or prior hepatitis B infection (HBsAg and anti-HBc). Evaluate HCV status, liver disease severity, medication interactions and other relevant baseline laboratory tests.

CONTRAINDICATIONS

For a regimen with ribavirin, all ribavirin contraindications apply, including pregnancy-related restrictions. Known hypersensitivity to formulation components warrants avoidance. Follow locally approved contraindications.

WARNINGS & PRECAUTIONS

HEPATITIS B REACTIVATION: HBV reactivation during or after direct-acting antiviral treatment can cause severe hepatitis, liver failure or death. Screen before treatment and monitor HBV-coinfected patients during and after therapy.

Serious symptomatic bradycardia may occur with amiodarone; coadministration is not recommended. If unavoidable, specialist cardiac monitoring is required.

Monitor patients taking diabetes medicines for hypoglycaemia and patients taking warfarin for INR changes as liver function improves during antiviral treatment.

DRUG INTERACTIONS

Rifampin, carbamazepine, phenytoin, phenobarbital and St John's wort can reduce antiviral exposure and should generally be avoided. Acid-reducing agents can reduce velpatasvir absorption.

Separate antacids by at least 4 hours. H2 blockers require dose limits; proton-pump inhibitors are not recommended unless a specific approved administration schedule is followed. Review interactions with amiodarone, digoxin, statins and certain HIV medicines.

PREGNANCY & LACTATION

Human pregnancy and breastfeeding data for this combination are limited. Assess benefit and risk. If ribavirin is used, strict pregnancy avoidance and contraception requirements apply to both female and male patients and their partners.

ADVERSE REACTIONS

Common reactions with sofosbuvir/velpatasvir include headache and fatigue. With added ribavirin, anaemia, nausea, insomnia and diarrhoea may occur. Seek urgent medical advice for severe dizziness, fainting, jaundice or signs of hepatitis flare.

OVERDOSAGE

No specific antidote is available. Provide supportive management and monitoring. Seek urgent medical care if overdose is suspected.

STORAGE CONDITIONS

Store according to approved product specifications, protected from moisture and excessive heat. Keep out of reach of children. Do not use after expiry.

PRESENTATION

Velpis Tablets: Sofosbuvir 400 mg + Velpatasvir 100 mg; pack of 28 tablets.

PATIENT ADVICE

Take one tablet at the same time daily as prescribed. Complete the full treatment course. Inform the physician about all medicines, including antacids and herbal products. Do not discontinue or change doses without medical advice. Attend scheduled laboratory monitoring.

MANUFACTURED BY

Vega Pharmaceuticals (Pvt.) Ltd.