

MyVital ALL™

Sofosbuvir and Velpatasvir Film Coated Tablets 400 mg/100 mg

1. NAME OF THE MEDICAL PRODUCT
Sofosbuvir and Velpatasvir Film Coated Tablets 400 mg/100 mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Sofosbuvir 400 mg
Velpatasvir 100 mg

3. PHARMACOLOGICAL ACTION
Sofosbuvir and Velpatasvir are direct-acting antiviral agents (DAA) that inhibit the RNA polymerase of the hepatitis C virus (HCV).

4.1 Therapeutic indication
Sofosbuvir and Velpatasvir film coated tablets are indicated for the treatment of chronic hepatitis C virus (HCV) infection in adults aged 18 years and older.

4.2 Dosage and method of administration
Sofosbuvir and Velpatasvir film coated tablets should be taken once daily with or without food.

4.3 Contraindications
Sofosbuvir and Velpatasvir film coated tablets are contraindicated in patients with severe renal impairment (creatinine clearance < 30 mL/min).

4.4 Special warnings and precautions for use
Patients should be monitored for adverse effects, including changes in liver function tests.

4.5 Interactions
Sofosbuvir and Velpatasvir film coated tablets may interact with other medications, including antacids and proton pump inhibitors.

4.6 Fertility, pregnancy and lactation
Sofosbuvir and Velpatasvir film coated tablets should be used with caution in pregnant women.

4.7 Side effects
Common side effects include headache, fatigue, and nausea.

4.8 Laboratory tests
Liver function tests should be performed regularly during treatment.

4.9 Use in specific populations
Sofosbuvir and Velpatasvir film coated tablets are used in patients with mild to moderate renal impairment.

4.10 Use in children
Sofosbuvir and Velpatasvir film coated tablets are not recommended for use in children.

4.11 Use in the elderly
Sofosbuvir and Velpatasvir film coated tablets are used in elderly patients.

4.12 Use in patients with hepatic impairment
Sofosbuvir and Velpatasvir film coated tablets are contraindicated in patients with severe hepatic impairment.

4.13 Use in patients with renal impairment
Sofosbuvir and Velpatasvir film coated tablets are used in patients with mild to moderate renal impairment.

4.14 Use in patients with cardiovascular disease
Sofosbuvir and Velpatasvir film coated tablets are used in patients with cardiovascular disease.

4.15 Use in patients with respiratory disease
Sofosbuvir and Velpatasvir film coated tablets are used in patients with respiratory disease.

4.16 Use in patients with hematological disorders
Sofosbuvir and Velpatasvir film coated tablets are used in patients with hematological disorders.

4.17 Use in patients with immunodeficiency
Sofosbuvir and Velpatasvir film coated tablets are used in patients with immunodeficiency.

4.18 Use in patients with other chronic diseases
Sofosbuvir and Velpatasvir film coated tablets are used in patients with other chronic diseases.

4.19 Use in patients with drug interactions
Sofosbuvir and Velpatasvir film coated tablets may interact with other medications.

4.20 Use in patients with laboratory test results
Sofosbuvir and Velpatasvir film coated tablets may affect laboratory test results.

4.21 Use in patients with clinical trial results
Sofosbuvir and Velpatasvir film coated tablets have shown efficacy in clinical trials.

4.22 Use in patients with safety data
Sofosbuvir and Velpatasvir film coated tablets have a favorable safety profile.

4.23 Use in patients with efficacy data
Sofosbuvir and Velpatasvir film coated tablets have shown high efficacy.

4.24 Use in patients with tolerability data
Sofosbuvir and Velpatasvir film coated tablets are well-tolerated.

4.25 Use in patients with quality of life data
Sofosbuvir and Velpatasvir film coated tablets improve quality of life.

4.26 Use in patients with health economics data
Sofosbuvir and Velpatasvir film coated tablets are cost-effective.

4.27 Use in patients with patient satisfaction data
Sofosbuvir and Velpatasvir film coated tablets are patient-friendly.

Concomitant use with other DAA	Sofosbuvir	4.0/9.0	++		
Concomitant use with other DAA	Velpatasvir	0.8/2.0	++		
Concomitant use with other DAA	Sofosbuvir	1.6/7.4	++		
Concomitant use with other DAA	Velpatasvir	0.7/1.8	++		

Concomitant use with other DAA	Sofosbuvir	1.1/1.2	++		
Concomitant use with other DAA	Velpatasvir	1.0/1.1	++		

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