

VIRSO SOFOSBUVIR TABLETS 400MG

Sofosbuvir (400 mg)

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What Virso is used for

Virso is used in combination with other medicinal products for the treatment of chronic hepatitis C in adults.

How Virso works

Hepatitis C is a virus that infects the liver. This medicine works by lowering the amount of hepatitis C virus in your body and removing the virus from your blood over a period of time.

Before you use Virso

- When you must not use it

Do not take Virso if you:

- You are allergic (hypersensitive) to sofosbuvir or to any one of the ingredients of this medicine.

- Before you start use it

Tell your doctor if you have any of the following:

- Have liver problems other than hepatitis C, e.g. if you are awaiting a liver transplantation.
- Have a current or previous infection with the hepatitis B virus, since your doctor may want to monitor you more closely.
- Have kidney problems

- Taking other medicines

Virso may influence the effectiveness of other medicines, so tell your doctor if you are taking:

- Rifampicin and rifabutin (antibiotics used to treat infections, including tuberculosis)
- St. John's wort (Hypericum perforatum – herbal medicine used to treat depression)

- Carbamazepine, phenobarbital and phenytoin (medicines used to treat epilepsy and prevent seizures).
- Oxcarbazepine (a medicine used to treat epilepsy and prevent seizures).
- Modafinil (a medicine to treat people with narcolepsy to help them stay awake).
- Amiodarone, used to treat irregular heartbeats.

How to use Virso

Always take Virso tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Virso tablets should be administered orally. Swallow the tablet as a whole. Do not chew or crush the tablet due to the bitter taste of the active substance. The tablet should be taken with food.

- How much to use

The recommended dose is one 400 mg tablet, taken orally, once daily with food.

- Virso should be used in combination with other medicinal products.
- If the other medicinal products used in combination with Virso are permanently discontinued, Virso should also be discontinued

Virso treatment should be initiated and monitored by a physician experienced in the management of patients with Hepatitis.

- When to use it

Take the medicine as instructed by your doctor. Preferably take at the same time each day.

- How long to use it

Your doctor will tell you for how long you should take Virso.

- If you forget to use it

It is important not to miss a dose of this medicine.

If you do miss a dose:

- and you notice within 18 hours of the time you usually take Virso, you must take the tablet as soon as possible. Then take the next dose at your usual time.
- and you notice 18 hours or more after the time you usually take Virso, wait and take the next dose at your usual time. Do not take a double dose (two doses close together).

- If you use too much (overdose)

If you accidentally take more than the recommended dose you should contact your doctor or nearest emergency department immediately for advice. Keep the tablet bottle with you so that you can easily describe what you have taken.

While you are using it

- Things you must do

Always take Virso exactly as your doctor has told you.

Virso should always be taken in combination with other medicinal products for use against hepatitis C.

If you are sick (vomit) less than 2 hours after taking Virso, take another tablet. If you vomit more than 2 hours after taking it you do not need to take another tablet until your next regularly scheduled tablet.

- Things you must not do

Do not stop taking the tablets without first talking to your doctor or pharmacist.

Do not take more than the recommended dose.

- Things to be careful of

Driving and using machines

When taking Virso together with other medicines for the treatment of hepatitis C infection, patients have reported tiredness, dizziness, blurred vision and reduced attention. If you have any of these side effects, do not drive or use any tools or machines.

VIRSO 400 MG

Sofosbuvir 400 mg

Pregnancy and breast feeding

Pregnancy must be avoided due to the use of Virso together with ribavirin. Ribavirin can be very damaging to an unborn baby. Hence, women of childbearing potential or their male partners must use an effective form of contraception during the treatment and for a period of time after the treatment.

If you or your partner become pregnant during Virso treatment or in the months that follow, you must contact your doctor immediately.

Breast-feeding

You should not breast-feed during treatment with Virso. It is not known whether sofosbuvir, the active substance of Virso, passes into human breast milk.

Side effects

Like all medicines, Virso tablets can cause side effects although not everybody gets them. Tell your doctor immediately if you experience any of the following symptoms after taking this medicine as the symptoms can be severe.

Sofosbuvir + Ribavirin

Very Common:

- Headache
- Haemoglobin (a component of the red blood cell) decreased
- blood bilirubin increased (a substance made during the normal breakdown of red blood cells)
- fatigue
- irritability
- insomnia
- nausea

Common:

- Common cold
- Anaemia (deficiency in the number or quality of red blood cells)
- Depression
- disturbance in attention
- breathing difficulty
- Breathing difficulty on exertion
- cough

- abdominal discomfort
- constipation
- indigestion
- alopecia (spot baldness)
- dry skin
- severe itching of the skin
- joint pain
- back pain
- muscle cramps
- muscle pain
- fever
- weakness

Sofosbuvir + ribavirin + peginterferon alfa

Very Common:

- anaemia (deficiency in the number or quality of red blood cells)
- neutropenia (low white blood neutrophil cells)
- lymphocyte count decreased (lymphocyte is a type of white blood cell)
- platelet count decreased
- decreased appetite
- insomnia (sleep disorder)
- difficulty breathing
- cough
- dizziness
- headache
- diarrhea
- nausea
- vomiting
- blood bilirubin increased ((a substance made during the normal breakdown of red blood cells)
- rash
- severe itching of the skin
- arthralgia (joint pain)
- myalgia (muscle pain)
- chills
- fatigue
- influenza-like illness (flu-like syndrome/symptoms)
- irritability
- pain
- fever

Common:

- weight decreased
- depression
- anxiety

- agitation
- migraine
- memory impairment
- disturbance in attention
- vision blurred
- difficulty breathing on exertion
- constipation
- dry mouth
- gastroesophageal reflux (digestive disorder)
- alopecia (spot baldness)
- dry skin
- back pain
- muscle cramps
- chest pain
- asthenia (weakness)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.gov.my (Consumer Reporting → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI).

Storage and Disposal of Pantaz tablets

- Storage

Store below 30°C and protect from moisture.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

VIRSO Sofosbuvir Tablets 400mg are Blue colored, capsule shaped, biconvex bevel edged film coated tablets debossed with "400" on one side and plain on other side.

- Ingredients

- Active ingredient
Sofosbuvir 400 mg

- Inactive ingredients
Mannitol 60 [Pearlitol 160C] #2,
Microcrystalline Cellulose,

VIRSO 400 MG

Sofosbuvir 400 mg

Croscarmellose Sodium, Colloidal
Silicon Dioxide, Magnesium stearate,
Opadry II Blue.

- MAL number(s):

Manufacturer

Strides Pharma Science Limited
36/7, Suragajakkanahalli,
Indlavadi cross, Anekal Taluk
Bangalore – 562 106, INDIA
Tel: 91-80-67840630
Fax: 91-80-67840606

Product Registration Holder

Unimed Sdn Bhd
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Date of revision

11/03/2019

Serial Number:

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