

SUNVEPRA[®] Capsules

Asunaprevir (a soo na pre veer)

Consumer Medicine Information

Warnings and Precautions

While you are taking SUNVEPRA, your doctor will frequently monitor you for signs of how well your liver is working. This will be done with regular blood tests.

If the results of these tests show a decline in how well your liver is working, a decision will be made to stop your treatment with SUNVEPRA.

What is in this leaflet

Read this leaflet carefully before taking SUNVEPRA. This leaflet answers some common questions about SUNVEPRA.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking SUNVEPRA against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What SUNVEPRA is used for

SUNVEPRA is a trade name (manufacturer's name) for the medicine, asunaprevir. SUNVEPRA is a direct acting antiviral agent (DAA) against the hepatitis C virus (HCV). SUNVEPRA is an inhibitor of the HCV protein 3/4A (NS3/4A), a protease that is required to form new HCV particles.

You should not take Sunvepra alone to treat chronic (lasting a long time) hepatitis C infection in adults. SUNVEPRA should only be used together with another antiviral medicine, daclatasvir (DAKLINZA), or together with DAKLINZA, peginterferon alfa, and ribavirin.

How SUNVEPRA Works

SUNVEPRA (in combination with other medicines) works by stopping the HCV from multiplying and infecting liver cells. After you stop taking SUNVEPRA, your doctor will monitor your blood for HCV. If HCV is still not detected in your blood at least 12 weeks after stopping treatment, you have what is called a sustained virologic response (SVR), also referred to as virologic cure.

It is not known if SUNVEPRA is safe and effective in children under 18 years of age.

Ask your doctor if you have any questions about why SUNVEPRA has been prescribed for you.

SUNVEPRA is not addictive. This medicine is available only with a doctor's prescription.

Before you take SUNVEPRA

It is important that you check the information below before you take SUNVEPRA.

When you must not take SUNVEPRA

SUNVEPRA is sometimes used with peginterferon alfa and ribavirin. Peginterferon alfa and ribavirin may cause birth defects or death of your unborn baby. If you are pregnant or planning to become pregnant, or your sexual partner is pregnant or plans to become pregnant, do not take these medicines. You or your sexual partner should not become pregnant while taking peginterferon alfa and ribavirin, and for 6 months after treatment ends.

- **Two effective forms of birth control must be used, one by each partner, male and female, during treatment and for the 6 months after treatment with peginterferon alfa and ribavirin. Talk with your doctor about forms of birth control that may be used during this time.**
- Females must have a negative pregnancy test before starting treatment with peginterferon alfa and ribavirin, every month while being treated, and every month for 6 months after your treatment ends.

If you or your female sexual partner becomes pregnant while taking, or within 6 months after you stop taking, peginterferon alfa and ribavirin, tell your doctor right away.

Tell your doctor if you have or have had:

- have a current or previous infection with the hepatitis B virus.
- liver problems other than hepatitis C. Your doctor may tell you not to take SUNVEPRA if you have certain liver problems.

Do not take SUNVEPRA if you have an allergy to it or to any other ingredients in the formulation listed at the end of this leaflet.

Do not take SUNVEPRA if you are currently taking any of these medicines:

- atazanavir
- bosentan
- carbamazepine
- clarithromycin
- cobicistat
- cyclosporin
- darunavir/ritonavir
- dexamethasone (when administered by injection or taken by mouth)
- diltiazem
- efavirenz
- erythromycin
- etravirine
- fluconazole
- fosamprenavir
- gemfibrozil
- indinavir
- itraconazole
- ketoconazole
- lopinavir/ritonavir
- modafinil
- nevirapine
- oxcarbazepine
- phenobarbital
- phenytoin
- posaconazole
- rifabutin
- rifampicin
- ritonavir
- saquinavir

- St. John's wort (*Hypericum perforatum*) or a product that contains St John's wort
- thioridazine
- verapamil
- voriconazole

If you are not sure if any of these medicines are in the products you are taking, talk to your doctor or pharmacist.

Do not use SUNVEPRA after the expiry date printed on the back of the pack. If this medicine is taken after the expiry date has passed, it may not work as well.

Do not take SUNVEPRA if the packaging is torn or shows signs of tampering.

Before you start to take SUNVEPRA

Tell your doctor if you:

- had a liver transplant
- have kidney problems
- have diabetes
- have any other medical condition

SUNVEPRA, when used with DAKLINZA, should not be used during pregnancy.

Tell your doctor if you are pregnant or intend to become pregnant.

It is not known if SUNVEPRA will harm your unborn baby.

If you can become pregnant and use oral contraception, use a "high-dose" contraceptive that includes at least 30 mcg of ethinyl estradiol combined with norethindrone acetate/norethindrone.

A lower dose contraceptive may not work with SUNVEPRA.

If you are also taking ribavirin, you must follow the contraception instructions under "When you must not take SUNVEPRA" above.

Tell your doctor or pharmacist if you are breast-feeding or plan to breast-feed.

It is recommended that you do not breast-feed while taking SUNVEPRA. It is not known if SUNVEPRA passes into breast milk.

If you have not told your doctor about any of the above, tell them before you use SUNVEPRA.

As SUNVEPRA should only be used together with another antiviral medicine such as DAKLINZA, or together with DAKLINZA, peginterferon alfa, and ribavirin, please read the Consumer Medicine Information for the other products prescribed by your doctor before starting SUNVEPRA.

Taking other medicines

Be sure to inform your doctor of all medications you are taking including prescribed drugs, over the counter products, natural therapies, vitamin supplements and recreational drugs.

SUNVEPRA and other medicines may affect each other. This can cause you to have too much or not enough SUNVEPRA or other medicines in your body, which may affect the way SUNVEPRA or your other medicines work, or may cause side effects.

Medicines for other conditions:

Do not take SUNVEPRA if you are currently taking any of the medicines listed under "When you must not take SUNVEPRA" above.

Tell your doctor if you are taking or starting to take medicines that contain:

- amitriptyline, imipramine, or nortriptyline
- dabigatran
- dextromethorphan (a cough suppressant that is an ingredient in many over-the counter cold medicines)
- digoxin
- flecainide
- hormonal contraceptive
- midazolam, rosuvastatin, atorvastatin, fluvastatin, simvastatin, pitavastatin, or pravastatin

- warfarin and other similar medicines called vitamin K antagonists used to thin the blood

Your doctor will be able to advise you about the most appropriate medications to treat your condition. It is important that you tell your doctor or pharmacist about the medicines you are taking, even if they are not listed in this leaflet.

They will be able to provide you with more information than is contained within this leaflet on the medicines you need to be careful with, or should avoid while taking SUNVEPRA.

How to take SUNVEPRA

SUNVEPRA should be given only when prescribed by your doctor. Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

How much to take

Take SUNVEPRA exactly as your doctor tells you to take it. Do not change your dose unless your doctor tells you to.

Do not stop taking SUNVEPRA without first talking with your doctor. If you think there is a reason to stop taking SUNVEPRA, talk with your doctor before doing so.

How to take it

Swallow the capsule whole with a drink such as a glass of water.

When to take SUNVEPRA

Take SUNVEPRA two times each day with or without food.

How long to take it

Continue taking SUNVEPRA for as long as your doctor tells you to.

Do not stop taking SUNVEPRA unless your doctor tells you to - even if you feel better.

If you forget to take it

If you miss a dose of SUNVEPRA and less than 8 hours have passed since you were to take the missed dose, take the missed dose as soon as possible. Take the next dose at your regular time.

If you miss a dose of SUNVEPRA and more than 8 hours have passed since you were to take the missed dose, skip the missed dose. Take the next dose at your regular time.

Do not take two doses of SUNVEPRA at the same time to make up for the missed dose.

If you take too much (overdose)

Immediately call your doctor or the Poisons Information Centre on 131126 in Australia, or go to the Accident and Emergency Centre at your nearest hospital if you or anyone else takes too much Sunvepra.

Do this even if there are no signs of discomfort or poisoning.

While you are using SUNVEPRA

Things you must do

- If you become pregnant while taking SUNVEPRA, tell your doctor immediately.
- If you are about to start taking any new medicines, tell your doctor and pharmacist that you are taking SUNVEPRA. SUNVEPRA or the other medicine may interfere each other.

Liver problems:

Some people taking SUNVEPRA have had abnormal results on tests that show how well the liver is working, occasionally accompanied

by serious liver problems. Your doctor will monitor these tests while you take SUNVEPRA. If the results show a decline in how well your liver is working, your doctor may instruct you to stop taking SUNVEPRA.

Things you must not do

- Do not give SUNVEPRA to anyone else, even if they have the same condition as you.
- Do not use SUNVEPRA to treat any other complaints unless your doctor tells you to.
- Do not stop taking SUNVEPRA without checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how SUNVEPRA affects you.

Make sure that you visit your doctor regularly throughout your entire course of treatment with SUNVEPRA.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking SUNVEPRA. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects

Ask your doctor or pharmacist to answer any questions you may have.

The most common side effects when SUNVEPRA is taken in combination with DAKLINZA include:

- headache
- tiredness
- diarrhoea
- nasal congestion (blocked nose)
- nausea

The most common side effects when SUNVEPRA is taken in combination

with DAKLINZA, peginterferon alfa, and ribavirin include:

- tiredness
- headache
- itching
- unusual weakness
- flu-like symptoms
- insomnia
- rash
- anaemia
- cough
- dry skin
- diarrhoea
- nausea
- hair loss
- irritability
- fever
- muscle aches

If any of the following happen, tell your doctor immediately, or go to the Accident and Emergency Centre at your nearest hospital:

- allergic reaction - swelling of the face, lips, or throat which makes breathing difficult

If you have these side effects, you may have had a serious reaction to SUNVEPRA. You may need urgent medical attention or hospitalisation.

This is not a complete list of side effects, other side effects not listed above may also occur in some patients.

Tell your doctor if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them or only some of them.

After using SUNVEPRA

Storage

Store SUNVEPRA Capsules in a cool dry place where the temperature stays below 25°C.

Keep your capsules in the original container until it is time to take them.

Do not store SUNVEPRA or any other medicine in the bathroom or near the kitchen sink. Do not leave it in the car. Heat and dampness can destroy some medicines.

Keep SUNVEPRA capsules where children cannot reach them. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking SUNVEPRA capsules, or the capsules have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

SUNVEPRA 100 mg capsules are available as oval, opaque white to pale-yellow, soft-gelatin capsule containing 100 mg asunaprevir

Capsules are imprinted with "BMS" in black on one line and "711" in black on a second line below "BMS."

Available in packs of 14 and 56 capsules.

Ingredients

Each capsule contains:

Active ingredients:

SUNVEPRA 100 mg capsules - 100 mg of asunaprevir per capsule

Other ingredients:

medium-chain triglycerides, caprylic/capric glycerides, polysorbate 80, and butylated hydroxytoluene (BHT).

The capsule shell contains gelatin, partially dehydrated liquid sorbitol, glycerol, titanium dioxide and OPACODE Black (printing ink).

Registration Numbers

SUNVEPRA 100 mg - AUST R 222744

Sponsored by

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This information in no way replaces the advice of your doctor or pharmacist.

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