DAKLINZA® Tablets

Daclatasvir (dak lat as vir)

Consumer Medicine Information

What is in this leaflet

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

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 DAKLINZA 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 DAKLINZA is used for

DAKLINZA is a trade name (manufacturer's name) for the medicine, daclatasvir. DAKLINZA is a direct acting antiviral agent (DAA) against the hepatitis C virus (HCV). DAKLINZA is an inhibitor of NS5A, which is a protein that is required to form new HCV particles.

You should not take DAKLINZA alone to treat chronic (lasting a long time) hepatitis C infection in adults. DAKLINZA should only be used together with other antiviral medicines such as sofosbuvir, or asunaprevir (SUNVEPRA), or together with SUNVEPRA, peginterferon alfa, and ribavirin.

How DAKLINZA Works

DAKLINZA (in combination with other medicines) works by stopping the HCV from multiplying and infecting liver cells. After you stop taking DAKLINZA, 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 DAKLINZA is safe and effective in children under 18 years of age.

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

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

Before you take DAKLINZA

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

When you must not take DAKLINZA

DAKLINZA 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.

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

- carbamazepine
- dexamethasone (when administered by injection or taken by mouth)
- oxcarbazepine
- phenobarbital
- phenytoin
- rifabutin
- rifampicin
- St. John's wort (Hypericum perforatum) or a product that contains St. John's wort

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 DAKLINZA 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 DAKLINZA if the packaging is torn or shows signs of tampering.

Before you start to take DAKLINZA

Tell your doctor if you:

- have a current or previous infection with the hepatitis B virus
- have liver problems other than hepatitis C infection
- have had, or are intending to have, a liver transplant
- have any other medical condition

DAKLINZA should not be used during pregnancy.

Tell your doctor if you are pregnant or intend to become pregnant.
It is not known if DAKLINZA will harm your unborn baby.

If you can become pregnant, continue the use of effective contraception for 5 weeks after the end of your treatment with DAKLINZA.

If you are also taking ribavirin, you must follow the contraception instructions under "When you must not take DAKLINZA" 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 DAKLINZA. It is not known if DAKLINZA passes into breast milk.

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

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

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.

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

Medicines for other conditions:

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

- amiodarone
- atazanavir. You may need a lower dose of DAKLINZA (30 mg).
- boceprevir or telaprevir. You may need a lower dose of DAKLINZA (30 mg).
- clarithromycin, erythromycin. You may need a lower dose of DAKLINZA (30 mg).
- dabigatran
- digoxin
- diltiazem, verapamil
- efavirenz, etravirine, or nevirapine. You may need a higher dose of DAKLINZA (90 mg).
- elvitegravir, cobicistat, emtricitabine, or tenofovir disoproxil fumarate. You may need a lower dose of DAKLINZA (30 mg).
- fluconazole, ketoconazole, itraconazole, posaconazole, or voriconazole. You may need a lower dose of DAKLINZA (30 mg).
- rosuvastatin, atorvastatin, fluvastatin, simvastatin, pitavastatin, or pravastatin

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 DAKLINZA.

How to take DAKLINZA

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

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

How to take it

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

When to take DAKLINZA

Take DAKLINZA once each day with or without food.

How long to take it

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

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

If you forget to take it

If you miss a dose of DAKLINZA and less than 20 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 DAKLINZA and more than 20 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 2 doses of DAKLINZA 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 DAKLINZA.
Do this even if there are no signs of discomfort or poisoning.

While you are using DAKLINZA

Things you must do

- If you become pregnant while taking DAKLINZA, tell your doctor immediately.
- If you are about to start taking any new medicines, tell your doctor and pharmacist that you are taking DAKLINZA. DAKLINZA and the other medicine may interfere with each other.
- If you are taking DAKLINZA together with SUNVEPRA, your doctor may perform additional tests that will determine how well your liver is working. Please read the Consumer Medicine Information for SUNVEPRA.

Things you must not do

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

Things to be careful of

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

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking DAKLINZA. 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 DAKLINZA is taken in combination with SUNVEPRA include:

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

The most common side effects when DAKLINZA is taken in combination with sofosbuvir (some patients in studies of this regimen also received ribavirin) include:

- tiredness
- headache
- nausea
- joint pain
- diarrhoea

The most common side effects when DAKLINZA is taken in combination with SUNVEPRA, 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 DAKLINZA. 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 DAKLINZA

Storage

Store DAKLINZA tablets in a cool dry place where the temperature stays below 30°C.

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

Do not store DAKLINZA 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 DAKLINZA tablets 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 DAKLINZA tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

DAKLINZA tablets come in three strengths:

- DAKLINZA 60 mg tablets are light green biconvex pentagonal debossed with "BMS" on one side and "215" on the other side. Available in packs of 7 and 28 tablets.
- DAKLINZA 30 mg tablets are green biconvex pentagonal debossed with "BMS" on one side and "213" on the other side. Available in packs of 7 and 28 tablets.

Ingredients

Each capsule contains:

Active ingredients:

- DAKLINZA 60 mg tablets - 60 mg of daclatasvir as daclatasvir dihydrochloride per tablet
- DAKLINZA 30 mg tablets - 30 mg of daclatasvir as daclatasvir dihydrochloride per tablet

Other ingredients:
anhydrous lactose, microcrystalline cellulose, croscarmellose sodium, silicon dioxide, magnesium stearate, and OPADRY Green.

Opadry Green contains hypromellose, titanium dioxide, Macrogol 400, indigo carmine aluminum lake, and iron oxide yellow.

DAKLINZA tablets do not contain gluten or sucrose.

Registration Numbers

DAKLINZA 60 mg - AUST R 222742

DAKLINZA 30 mg - AUST R 222743

Sponsored by

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

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