

Patient Information
DAKLINZA™ (dak lin za)
(daclatasvir)
tablets

Important: DAKLINZA is used in combination with other antiviral medicines. When taking DAKLINZA in combination with sofosbuvir, you should read the Patient Information leaflet for sofosbuvir. **When taking DAKLINZA in combination with sofosbuvir and ribavirin, you should also read the Medication Guide for ribavirin.**

What is DAKLINZA?

- DAKLINZA is a prescription medicine used to treat chronic (lasting a long time) hepatitis C genotype 1 or genotype 3 infection in adults.
- Take DAKLINZA with sofosbuvir or with sofosbuvir and ribavirin. **You should not take DAKLINZA by itself.**

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

What is the most important information I should know about DAKLINZA?

DAKLINZA can cause serious side effects, including:

- **Hepatitis B virus reactivation:** Before starting treatment with DAKLINZA, your healthcare provider will do blood tests to check for hepatitis B virus infection. If you have ever had hepatitis B virus infection, the hepatitis B virus could become active again during or after treatment of hepatitis C virus with DAKLINZA. Hepatitis B virus becoming active again (called reactivation) may cause serious liver problems, including liver failure and death. Your healthcare provider will monitor you if you are at risk for hepatitis B virus reactivation during treatment and after you stop taking DAKLINZA.

For more information about side effects, see the section “What are the possible side effects of DAKLINZA?”

Before taking DAKLINZA, tell your healthcare provider about all of your medical conditions, including if you:

- have ever had hepatitis B virus infection
- have liver problems other than hepatitis C infection
- have had a liver transplant
- have heart problems
- are pregnant or plan to become pregnant. It is not known if DAKLINZA will harm your unborn baby.
 - **When taking DAKLINZA in combination with sofosbuvir and ribavirin, tell your healthcare provider right away if you or your female sexual partner becomes pregnant.**
 - **Males and females who take DAKLINZA with sofosbuvir and ribavirin should also read the ribavirin Medication Guide for important pregnancy, contraception, and infertility information.**
- are breastfeeding or plan to breastfeed. It is not known if DAKLINZA passes into your breast milk.
 - Talk to your healthcare provider about the best way to feed your baby during treatment with DAKLINZA.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

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. This may affect the way DAKLINZA or your other medicines work or may cause side effects. **Keep a list of your medicines to show your healthcare provider and pharmacist.**

- You can ask your healthcare provider or pharmacist for a list of medicines that interact with DAKLINZA.
- **Do not start taking a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take DAKLINZA with other medicines.

How should I take DAKLINZA?

- Take DAKLINZA exactly how you are told to by your healthcare provider.
- Do not change your dose unless you are told to by your healthcare provider.
- Do not stop taking DAKLINZA without first talking with your healthcare provider.
- Take DAKLINZA one time each day with or without food.
- If you miss a dose, call your healthcare provider or pharmacist. It is important that you do not miss or skip doses of DAKLINZA during treatment.
- If you take too much DAKLINZA, call your healthcare provider or go to the nearest hospital emergency room right away.

What are the possible side effects of DAKLINZA?

DAKLINZA can cause serious side effects, including:

- **Hepatitis B virus reactivation.** See “What is the most important information I should know about DAKLINZA?”

DAKLINZA in combination with sofosbuvir and amiodarone may cause serious side effects, including:

- **Slow heart rate (bradycardia).** DAKLINZA combination treatment with sofosbuvir may result in slowing of the heart rate (pulse) along with other symptoms when taken with amiodarone, a medicine used to treat certain heart problems. Get medical help right away if you take amiodarone with sofosbuvir and DAKLINZA and get any of the following symptoms:
 - fainting or near-fainting
 - weakness
 - chest pain
 - dizziness or lightheadedness
 - tiredness
 - confusion
 - not feeling well
 - shortness of breath
 - memory problems

The most common side effects of DAKLINZA when used in combination with sofosbuvir include:

- headache
- tiredness

The most common side effects of DAKLINZA when used in combination with sofosbuvir and ribavirin include:

- headache
- tiredness
- low red blood cell count (anemia)
- nausea

These are not all the possible side effects of DAKLINZA.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store DAKLINZA?

- Store DAKLINZA at room temperature between 68°F and 77°F (20°C and 25°C).

Keep DAKLINZA and all medicines out of the reach of children.

General information about the safe and effective use of DAKLINZA

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use DAKLINZA for a condition for which it was not prescribed. Do not give DAKLINZA to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about DAKLINZA that is written for health professionals.

What are the ingredients in DAKLINZA?

Active ingredient: daclatasvir

Inactive ingredients: anhydrous lactose, microcrystalline cellulose, croscarmellose sodium, silicon dioxide, magnesium stearate, and Opadry green. Opadry green contains hypromellose, titanium dioxide, polyethylene glycol 400, FD&C blue #2/indigo carmine aluminum lake, and yellow iron oxide.

Manufactured for: Bristol-Myers Squibb Company, Princeton, NJ 08543, USA

Product of Ireland

DAKLINZA is a trademark of Bristol-Myers Squibb Company. For more information, go to www.patientsupportconnect.com or call 1-844-442-6663.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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