

Package leaflet: Information for the patient

Daklinza 30 mg film-coated tablets

Daklinza 60 mg film-coated tablets

daclatasvir

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Daklinza is and what it is used for
2. What you need to know before you take Daklinza
3. How to take Daklinza
4. Possible side effects
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6. Contents of the pack and other information

1. What Daklinza is and what it is used for

Daklinza contains the active ingredient daclatasvir. It is used to treat adults with hepatitis C, an infectious disease that affects the liver, caused by the hepatitis C virus.

This medicine works by stopping the hepatitis C virus from multiplying and infecting new cells. This lowers the amount of hepatitis C virus in your body and removes the virus from your blood over a period of time.

Daklinza must always be used together with other medicines against hepatitis C infection and must never be used by itself.

It is very important that you also read the package leaflets for the other medicines that you will be taking with Daklinza. If you have any questions about your medicines, please ask your doctor or pharmacist.

2. What you need to know before you take Daklinza

Do not take Daklinza

- if you are allergic to daclatasvir or any of the other ingredients of this medicine (listed in section 6 of this leaflet)
- if you are taking (by mouth or other ways that affect the whole body) any of the following medicines
 - phenytoin, carbamazepine, oxcarbazepine or phenobarbital, used to treat epileptic seizures
 - rifampicin, rifabutin or rifapentine, antibiotics used to treat tuberculosis
 - dexamethasone, a steroid used to treat allergic and inflammatory diseases
 - medicines containing St. John's wort (*Hypericum perforatum*, a herbal preparation).

These medicines lower the effect of Daklinza and may result in your treatment not working. If you take any of these medicines, tell your doctor immediately.

Since Daklinza must always be used in combination with other medicines against hepatitis C infection, please make sure that you read the "Do not take" section of the package leaflets for these medicines. If you are unsure of any information in the package leaflets, please contact your doctor or pharmacist.

Warnings and precautions

Talk to your doctor or pharmacist before taking Daklinza.

Tell your doctor if any of the following applies:

- you have an infection with the human immunodeficiency virus (HIV) or a hepatitis B infection
- you have had, or are waiting to have a liver or another organ transplant
- your liver is damaged and not functioning properly (decompensated liver disease)

Children and adolescents

Daklinza is not recommended for patients below 18 years of age. Daklinza has not yet been studied in children and adolescents.

Other medicines and Daklinza

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because Daklinza may affect the way some medicines work. In addition some medicines may affect the way Daklinza works. Your doctor may need to adjust the dose of Daklinza or you may not be able to take Daklinza with certain medicines.

Do not take Daklinza if you are taking any of the following medicines:

- phenytoin, carbamazepine, oxcarbazepine or phenobarbital, used to treat epileptic seizures
- rifampicin, rifabutin or rifapentine, antibiotics used to treat tuberculosis
- dexamethasone, a steroid used to treat allergic and inflammatory diseases
- medicines containing St. John's wort (*Hypericum perforatum*, a herbal preparation).

These medicines lower the effect of Daklinza so your treatment will not work. If you take any of these medicines, tell your doctor immediately.

Tell your doctor if you take any of the following medicines:

- atazanavir/ritonavir, darunavir/ritonavir, lopinavir/ritonavir, etravirine, nevirapine, efavirenz or any medicine combined with cobicistat, used to treat HIV infection
- boceprevir or telaprevir, used to treat hepatitis C infection
- clarithromycin, telithromycin or erythromycin, used to treat bacterial infections
- dabigatran etexilate, used to to prevent blood clots
- ketoconazole, itraconazole, posaconazole or voriconazole, used to treat fungal infections
- digoxin, used to treat irregular heart beats
- verapamil, diltiazem, nifedipine or amlodipine, used to decrease blood pressure
- rosuvastatin, atorvastatin, fluvastatin, simvastatin, pitavastatin or pravastatin, used to lower blood cholesterol
- oral contraceptives

With some of these medicines, your doctor may need to adjust your dose of Daklinza.

Pregnancy and contraception

Tell your doctor if you are pregnant, think you may be pregnant or are planning to become pregnant. If you become pregnant, stop taking Daklinza and tell your doctor immediately.

If you are pregnant you must not take Daklinza.

If you can become pregnant, use effective contraception during and for 5 weeks after your treatment with Daklinza.

Daklinza is sometimes used together with ribavirin. Ribavirin can harm your unborn baby. It is therefore very important that you (or your partner) do not become pregnant during this treatment.

Breast-feeding

It is not known whether Daklinza passes into human breast milk. You should not breastfeed during treatment with Daklinza.

Driving and using machines

Some patients have reported dizziness, difficulty concentrating, and vision problems while taking Daklinza with other medicines for their hepatitis C infection. If you have any of these side effects, do not drive or use any tools or machines.

Daklinza contains lactose

If you have been told by your doctor that you have an intolerance to some sugars (e.g. lactose), talk to your doctor before taking Daklinza.

3. How to take Daklinza

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Recommended dose

The recommended dose is **one tablet once a day** of Daklinza 60 mg. Swallow the tablet whole. Do not chew or crush the tablet as it has a very unpleasant taste. Daklinza can be taken with or without a meal.

Some other medicines can interact with Daklinza, affecting the levels of Daklinza in your body. If you are taking any of these medicines, your doctor may decide to change your daily dose of Daklinza to ensure that the treatment is safe and effective for you.

Since Daklinza must always be used with other medicines against hepatitis C infection, please read the package leaflets for these medicines. If you have any questions, ask your doctor or pharmacist.

How long to take Daklinza

Make sure you take Daklinza for as long as your doctor has told you to take it.

The duration of your treatment with Daklinza will be either 12 or 24 weeks. The duration of your treatment will depend on whether you have previously received treatment for your hepatitis C infection, the condition of your liver, and what other medicines you will take with Daklinza. You may have to take your other medicines for different lengths of time.

If you take more Daklinza than you should

If you accidentally take more Daklinza tablets than your doctor recommended, contact your doctor at once or contact the nearest hospital for advice. Keep the tablet blister with you so that you can easily describe what you have taken.

If you forget to take Daklinza

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

If you do miss a dose:

- and you notice within 20 hours of the time you usually take Daklinza, you must take the tablet as soon as possible. Then take the next dose at your usual time.
- and you notice 20 hours or more after the time you usually take Daklinza, wait and take the next dose at your usual time. Do not take a double dose (two doses close together).

If you stop taking Daklinza

It is important that you continue to take Daklinza during the whole treatment period. Otherwise the medicine may not work against the hepatitis C virus. **Do not stop taking Daklinza unless your doctor told you to stop.**

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

When Daklinza is used together with sofosbuvir (with or without ribavirin), the following side effects have been reported.

Very common (may affect more than 1 in 10 people):

- headache, nausea (feeling sick), fatigue

Common (may affect up to 1 in 10 people):

- decreased appetite
- difficulty sleeping
- dizziness
- migraine
- shortness of breath
- hot flush
- itching, dry skin, unusual hair loss or thinning, rash
- diarrhoea, upper abdominal pain, constipation, excessive gas in the stomach or bowel, heartburn, vomiting
- cough, nasal congestion (blocked nose), dry mouth
- joint pain, aching or tender muscles, not caused by exercise
- depression, anxiety, irritability
- reduction in red blood cells (anaemia)

When Daklinza is used together with peginterferon alfa and ribavirin the reported side effects are the same as those listed in the package leaflets for these medicines. The most common of these side effects are listed below.

Very common (may affect more than 1 in 10 people):

- decreased appetite
- difficulty sleeping
- headache
- shortness of breath
- nausea
- fatigue
- flu-like illness, fever
- itching, dry skin, unusual hair loss or thinning, rash
- diarrhoea
- cough
- joint pain, aching or tender muscles, not caused by exercise, unusual weakness
- irritability
- reduction in red blood cells (anaemia), reduction in white blood cells

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Daklinza

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Daklinza contains

- The active substance is daclatasvir. Each film-coated tablet contains 30 mg or 60 mg daclatasvir (as dihydrochloride)
- The other ingredients are
 - *Tablet core:* anhydrous lactose (see section 2), microcrystalline cellulose, croscarmellose sodium, silicon dioxide (E551) and magnesium stearate
 - *Film-coating:* hypromellose, titanium dioxide (E171), macrogol 400, indigo carmine aluminum lake (E132), yellow iron oxide (E172)

What Daklinza looks like and contents of the pack

Daklinza 30 mg: the film-coated tablet is green, biconvex, pentagonal shape with "BMS" debossed on one side and "213" on the other side.

Daklinza 60 mg: the film-coated tablet is light green, biconvex, pentagonal shape with "BMS" debossed on one side and "215" on the other side.

Daklinza 30 mg film-coated tablets are available in packs of 28 tablets in non-perforated calendar blisters and perforated unit dose blisters.

Daklinza 60 mg film-coated tablets are available in packs of 28 tablets in non-perforated calendar blisters and perforated unit dose blisters.

Not all packages may be marketed in your country.

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This leaflet was last revised in August 2014.

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu>.