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Daklinza (Daclatasvir)

The active substance of Daklinza – Daclatasvir was approved for use in Europe on August 22, 2014. It was developed by the Bristol-Myers Squibb (USA) company. On June 24, 2015, Daklinza was approved by the FDA as a remedy to be used for treatment of hepatitis C of genotype 3 in the United States.

- **ActiveIngredient:**
 - **DosageForm:**
 - **Dosage:**
 - **Indications:**
 - **Manufacturer:**
 - **Storage:**
 - **Market Price:**
 - **Drug Status:**
-

Description

General Information The history of the therapy of viral hepatitis C started about 15 years ago with the advent of antiviral drugs – interferon and ribavirin, which afterwards became the standard of treatment. Proper and timely treatment using those substances made it was possible to achieve a full recovery. The active substance of Daklinza – Daclatasvir was approved for use in Europe on August 22, 2014. It was developed by the Bristol-Myers Squibb (USA) company. On June 24, 2015, Daklinza was approved by the FDA as a remedy to be used for treatment of hepatitis C of genotype 3 in the United States. Daklatasvir / Daklinza is an innovative solution developed by the Bristol-Myers Squibb pharmaceutical company (USA). Daclatasvir is a special chemical substance – a potent panthenotypic inhibitor of the NS5A non-structural protein replication complex. It has a dual mechanism of action – it prevents the reproduction of the hepatitis C virus (suppresses the replication of viral RNA) of any of the six known and most common human genotypes directly inside the infected hepatocyte and blocks the assembly of the viral particles (virions). Owing to straight directional action of the remedy the HCV virus ceases to enter the bloodstream from infected cells, and therefore stops spreading to various organs and tissues of the human body as a whole. Generic Daklinza – Daclatasvir in combination with a number of other modern antiviral medications composes various 12-week or 24-week combined treatment regimens for patients suffering from chronic hepatitis C, as well as a scheme of the so-called two-component, completely non-interferon regimen for simultaneous administration with other antiviral medications. According to the official statistics, those patients who have been treated with the discussed substance and passed a complete course of treatment with this drug in combination with some other modern antiviral agent, approximately 12 weeks after the end of therapy in at least 89-95% of cases are showing a sustained viral response. And it is observed regardless of the presence or absence of liver cirrhosis. This information is confirmed by the results of numerous clinical trials on the effectiveness of this agent. The drug showed its high antiviral efficacy in equal measure both among patients who passed treatment for the first time in their life, and among patients with bad experience of antiviral therapy in the past. How to take? The remedy can be bought at a pharmacy by the prescription of a hepatologist, and it should be taken one tablet a day in a dose of at least 60 mg in combination with other modern antiviral agents. It is not recommended to chew or break the tablet into several parts. It should be swallowed completely, washing down with a small amount of liquid. Reception of the pills is not depended to the time of eating, so you can take the pill directly during, before or after meals. A specific schedule of taking the drug should be prescribed only by the doctor-

hepatologist. What is Daklinza? Daklinza, known generically as daclatasvir, is an antiviral medication used in combination with other drugs to treat chronic hepatitis C virus (HCV) infection. It's part of a class of medications known as NS5A inhibitors. How does Daklinza work? Daklinza works by inhibiting the NS5A protein, which is essential for HCV replication. This disrupts the virus's life cycle, preventing it from multiplying and spreading in the body. What types of HCV can Daklinza treat? Daklinza is effective against multiple genotypes of the hepatitis C virus, often used in combination therapy for the most effective treatment across various HCV genotypes. What are the common side effects of Daklinza? Common side effects of Daklinza include headache, fatigue, nausea, and diarrhea. When taken in combination with other HCV medications, other side effects may occur. How is Daklinza taken? Daklinza is taken orally as a tablet, usually once a day. It should be taken at the same time each day, with or without food, according to the prescription from a healthcare provider. Can Daklinza cure hepatitis C? When used as part of a combination therapy, Daklinza has shown high cure rates for hepatitis C, leading to a sustained virologic response which is considered a cure for the infection. Is Daklinza safe for people with liver problems? Daklinza is generally safe for people with mild to moderate liver problems, but it may not be suitable for those with severe liver impairment. A healthcare provider will assess the suitability based on individual liver function. Can Daklinza be used in combination with other HCV medications? Yes, Daklinza is usually used in combination with other hepatitis C medications, such as sofosbuvir, for more effective treatment, depending on the HCV genotype and patient health factors. Are there any medications or foods to avoid while taking Daklinza? Certain medications may interact with Daklinza, so it's important to inform your healthcare provider about all medications you are taking. Avoiding grapefruit and grapefruit juice is also recommended, as they can interact with Daklinza. How should Daklinza be stored? Daklinza should be stored at room temperature, away from light and moisture. Keep the medication in its original container and out of reach of children and pets.

Side Effects In the process of treatment of a patient with chronic hepatitis C using the remedy containing main active substance Daclatasvir in combination with other direct antiviral drugs or in combination with pegylated interferons-alpha and ribavirin, the following undesirable effects or side effects were registered: tendency to dizziness, temporary aggravation of visual dysfunctions and attention disorder. In such cases, hepatologists recommend avoiding long-term driving of the vehicle. Patients receiving a combination treatment which includes mentioned substance may also face insomnia, skin rashes, temporary loss of appetite, increased irritability, mild anemia, dry skin, and minor joint pain. Common side effects include: Headache Diarrhea nausea Fatigability Increase in ALT Increase in ACT Precaution We have to ask patients to pay special attention at the fact that this medication in no case and under no circumstances should be used in monotherapy – this remedy is prescribed only in combination with one or more other antiviral drugs. Before buying and taking this medication, each patient should carefully read the list of contraindications, among which the following are most important: individual hypersensitivity to Daclatasvir and / or any of the auxiliary chemical components which may be included into the original preparation; age of the patient under 18 years – the efficacy and safety of this agent have not been studied in this category of patients with chronic hepatitis C; decompensated cirrhosis of liver (more than 8 points on the scoring scale of severity of liver cirrhosis); pregnancy of any term and period of active lactation; deficiency of lactose in the patient's body, lactose intolerance, glucose-galactose malabsorption. individual intolerance of the main or accompanying components of a medication. In addition, this remedy should be used with some caution when the patient is diagnosed with HCV-associated liver cirrhosis of the Child-A functional class. **THE MEDICATION SHOULD BE TAKEN WITH CAUTION BY:** patients who have cirrhosis of the liver. In this case, the course of treatment is carried out under the strict control of the hepatologist; women of childbearing age (the effect of the substance on reproductive performance has not been studied). In this case it is mandatory to use contraceptives during treatment. patients who has liver transplantation in anamnesis. In this case also the treatment is carried out under the strict control and supervision of a hepatologist. **Overdose** Symptoms of overdose were not described. There were no unforeseen side effects registered in Phase I of clinical trials, when applying the substance in healthy volunteers at doses up to 100 mg for a period of up to 14 days or a single dose of up to 200 mg. There is no antidote to Daclatasvir. Treatment in case of overdose should consist of general supportive measures, including monitoring the vital signs and monitoring the clinical state of the patient. Due to the high binding of Daclatasvir to plasma proteins, the dialysis is not recommended in case of O.D. **Interactions** In view of the fact that Daklinza is used as a part of combined treatment regimens, it is necessary to learn possible interactions with each of the solutions included into the

treatment scheme. When prescribing concomitant therapy, the most conservative recommendations should be observed. Daclatasvir is a substrate of the CYP3A4 isoenzymes, so moderate and strong inducers of the CYP3A4 isoenzymes may reduce the level of substance in the plasma as well as its therapeutic effect. Strong inhibitors of the isoenzyme CYP3A4 can increase the serum concentration of this solution. Daclatasvir is also a substrate for transport P-glycoprotein (P-gp), but the combined use of agents which affect only P-gp properties (without simultaneous effect on the CYP3A isoenzyme) is not sufficient to produce a clinically significant effect on Daclatasvir plasma concentration. Also it is an inhibitor of P-gp, the organic anion transporting polypeptide (OATP) 1B1 and 1B3 and the breast cancer resistance protein (BCRP). The use of this medication may increase the systemic effect of solutions which are substrates of the P-glycoprotein or the organic anion transporting polypeptide 1B1 / 1B3 or BCRP, which may increase or prolong their therapeutic effect and enhance undesirable phenomena. Daklinza should not be used as a monotherapy. Among more than 2,000 patients enrolled in clinical trials of combination therapy with Daklinza, 372 patients had compensated cirrhosis (class A according to the Child-Pugh scale). Differences in the safety and efficacy of therapy among patients with compensated cirrhosis and patients without cirrhosis were not observed. The safety and efficacy of Daklinza in patients with decompensated cirrhosis has not been established. It is not necessary to change the dose of Daklinza in patients with a weak (class A according to the Child-Pugh scale), moderate (class B according to the Child-Pugh scale) or severe (class C according to the Child-Pugh scale) liver function abnormality. Studies of the possible effect of the use of the drug on the ability to drive vehicles and work with mechanisms have not been performed. If the patient experiences dizziness, impaired attention, blurred vision, or decreased visual acuity, which may affect the ability to concentrate, than the individual should refrain from motor vehicle driving. There is a large number of positive reviews about Daklinza, which could be found both on the Internet and from infectious disease physician. This substance is a real breakthrough in the field of medicine, since earlier there was practically no chance to get rid of such a terrible disease as hepatitis C. Reviews Please, find below some feedback from patients, who treated hepatitis C with Daklinza: Alex: I want to share my history of healing from hepatitis C and inspire hope to all who are desperate. In 2008 I was diagnosed with this terrible disease of 1b genotype. From 2009 to 2011 I used Intron A (72 weeks), but with no positive result. In May 2015 I started a 24-week course of treatment in combination with other non-interferon drugs. As a result, on the 14th day of treatment course the PCR test gave a negative result, which lasts until now. I feel much better. Tanya: Two years ago I was shocked with diagnosed hepatitis C. Then the doctor recommended a three-month treatment regimen with this preparation in combination with another drug. Today, I am very grateful to this person, because the properl treatment helped me to get rid of the virus. Thomas: My doctor told me about the effectiveness of this drug, so, despite its price, I decided to take it. I was fortunate enough to buy the preparation much cheaper – and I took several packages, immediately for the entire course of treatment. I can say that it was worth it – during the therapy the laboratory indicators improved significantly. After the course of treatment, the traces of the virus in the blood disappeared and I am absolutely healthy.

Side Effects

Uses

Interactions

Other Details
