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Daclizumab Injection

pronounced as (da kliz' ue mab)

Notice:

Daclizumab injection is no longer available. If you are currently using daclizumab, you should call your doctor to discuss switching to another treatment.

IMPORTANT WARNING:

Daclizumab may cause serious or life-threatening liver damage. The risk of liver damage may be increased in people taking other medications known to cause liver damage, and in people who already have liver disease. Tell your doctor if you have or ever had liver problems or hepatitis. Your doctor may tell you not to use daclizumab injection. Tell your doctor and pharmacist about all the medications you are taking so they can check whether any of your medications may increase the risk that you will develop liver damage during your treatment with daclizumab. Your doctor will monitor you for signs of liver problems during and for 6 months after your treatment with daclizumab. If you experience any of the following symptoms, call your doctor immediately: nausea, vomiting, extreme tiredness, unusual bleeding or bruising, lack of energy, loss of appetite, pain in the upper right part of the stomach, yellowing of the skin or eyes, dark-colored urine, or flu-like symptoms.

Daclizumab may cause serious immune system disorders (conditions that occur when the immune system attacks healthy cells in the body). Tell your doctor if you have or have ever had skin problems, including eczema or psoriasis. If you experience any of the following symptoms, call your doctor immediately: redness, itching, or scaling of the skin; swollen glands in the neck, armpits, or groin; diarrhea; bloody stools; stomach pain; or any new, unexplained symptom affecting any part of your body.

Because of the risks with this medication, daclizumab injection is available only through a special restricted distribution program. A program has been set up by the manufacturer of daclizumab to be sure that people do not use daclizumab injection without the necessary monitoring called the Zinbryta Risk Evaluation and Mitigation Strategies (REMS) Program. Your doctor and your

pharmacist must be registered with the Zinbryta REMS program. Ask your doctor for more information about this program and how you will receive your medication.

Keep all appointments with your doctor and the laboratory. Your doctor will order certain tests before, during, and for 6 months after your final dose to check your body's response to daclizumab injection.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with daclizumab injection and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>]) to obtain the Medication Guide.

Talk to your doctor about the risk(s) of receiving daclizumab injection.

Why is this medication prescribed?

Daclizumab is used to prevent episodes of symptoms and slow the worsening of disability in people who have relapsing-remitting forms (course of disease where symptoms flare up from time to time) of multiple sclerosis (MS; a disease in which the nerves do not function properly and people may experience weakness, numbness, loss of muscle coordination, and problems with vision, speech, and bladder control). Daclizumab is usually used by people who were not helped by at least two other medications for MS. Daclizumab is in a class of medications called immunomodulators. It is thought to work by decreasing inflammation and decreasing the action of immune cells that may cause nerve damage.

How should this medicine be used?

Daclizumab comes as a solution (liquid) in a prefilled syringe to inject subcutaneously (under the skin). It is usually injected once a month. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Use daclizumab exactly as directed. Do not use more or less of it or use it more often than prescribed by your doctor.

You will receive your first dose of daclizumab in your doctor's office. After that, you can inject daclizumab yourself or have a friend or relative perform the injections. Before you use daclizumab yourself the first time, read the written instructions that come with it. Ask your doctor or pharmacist to show you or the person who will be injecting the medication how to inject it.

You can inject daclizumab in the back of your upper arms, stomach area, or your thighs. Do not inject your medication into skin that is irritated, bruised, reddened, infected, scarred, or tattooed.

Never reuse or share needles or prefilled syringes of medication. Throw away used syringes in a puncture-resistant container. Talk to your doctor or pharmacist about how to dispose of the puncture-resistant container.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before using daclizumab injection,

- tell your doctor and pharmacist if you are allergic to daclizumab, any other medications, or any of the ingredients in daclizumab injection. Ask your pharmacist or check the Medication Guide for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you have or have ever had tuberculosis or if you have an infection. Also, tell your doctor if you have or ever had depression or if you have ever thought about or attempted suicide.
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while using daclizumab, call your doctor.
- you should know that you may become depressed or suicidal (thinking about harming or killing yourself or planning or trying to do so) while you are using daclizumab injection. You, your family, or your caregiver should call your doctor right away if you experience any of the following symptoms: new or worsening depression, talking or thinking about wanting to hurt yourself or end your life, or any other unusual changes in behavior or mood. Be sure that your family or caregiver knows which symptoms may be serious so they can call the doctor if you are unable to seek treatment on your own.
- do not have any vaccinations during your treatment with daclizumab or up to 4 months after your final dose without talking to your doctor.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

If you miss a dose of daclizumab injection, inject your missed dose as soon as you remember it. However, if it is more than 2 weeks after your missed dose, skip the missed dose and continue your regular dosing schedule. Do not inject a double dose to make up for a missed dose. Call your doctor if you miss a dose and have questions about what to do.

What side effects can this medication cause?

Daclizumab injection may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- acne
- mouth pain

Some side effects can be serious. If you experience any of these symptoms or those listed in the IMPORTANT WARNING section, and call your doctor immediately or get emergency medical treatment:

- rash
- hives
- itching
- difficulty breathing or swallowing
- swelling of the eyes, face, mouth, tongue, or throat
- new or worsening depression
- changes in mood or behavior
- thinking about harming or killing yourself or planning or trying to do so
- runny nose, coughing, sore throat, fever, chills, and other signs of infection
- difficulty urinating
- pain when urinating
- seizures

Daclizumab may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the carton it came in, tightly closed, and out of reach of children. Store daclizumab in the refrigerator but do not freeze it. If you accidentally freeze the medication, you should discard that syringe. Daclizumab may be kept at room temperature for up to 30 days but should be protected from light. Daclizumab should not be put back into the refrigerator after it has been stored at room temperature.

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and

young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>]. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

What other information should I know?

Before having any laboratory test, tell your doctor and the laboratory personnel that you are using daclizumab injection.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Zinbryta[®]
- Zenapax[®]†

† This branded product is no longer on the market. Generic alternatives may be available.

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