PATIENT & CAREGIVER EDUCATION

Pegvaliase

This information from UpToDate® Lexidrug™ explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US

Palynziq

Brand Names: Canada

Palynziq

Warning

- Allergic reactions have happened during treatment with this drug. Sometimes, these have been life-threatening. Some reactions happened as late as 4 years after treatment started. Cases were seen within 1 hour after the injection, but have also happened up to 48 hours after the dose. A healthcare provider will watch you closely for at least 60 minutes after your first dose. If needed, a healthcare provider may need to watch you closely for other doses as well.
- Get medical help right away if you have any chest pain; dizziness or passing out; fast heartbeat; flushing; not able to control urine or stools; rash, itching, or raised bumps on the skin; swelling of your face, lips, eyes, or tongue; tightness in the chest or throat; trouble breathing or wheezing; very upset stomach, throwing up, or diarrhea; or any other bad effects.
- Your doctor will give you another drug (epinephrine) to use in case of an allergic reaction. Keep it with you at all times while taking this drug. Be sure you know how and when to use it. Get medical help right away after using epinephrine.
- Your doctor may tell you to have an adult nearby in case you have an allergic reaction. If this is needed, be sure that person watches you closely when you use a dose and for at least 60 minutes after your dose. Be sure they know where epinephrine is stored and how to give it if needed.
- Your doctor will tell you how to take this drug. Be sure you know how much to take, how often to take this drug, and how to store this drug. If your doctor does not tell you how to use this drug or if you are not sure how to use it, talk with your doctor.

What is this drug used for?

- It is used to treat phenylketonuria (PKU).

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.

This drug may interact with other drugs or health problems.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Avoid driving and doing other tasks or actions that call for you to be alert until you see how this drug affects you.
- Have patient safety card with you at all times.
- Have blood work checked as you have been told by the doctor. Talk with the doctor.
- Follow the diet plan that your doctor told you about.
- Skin reactions that spread on the skin are common with this drug and have lasted for at least 14 days. These reactions have included itching, rash, and redness. Skin reactions could also be a sign of an allergic reaction. Talk with the doctor about which skin reactions to call about right away.
- This drug may cause harm to the unborn baby if you take it while you are

pregnant.

- If you get pregnant while taking this drug or within 1 month after your last dose, call your doctor right away.
- Tell your doctor if you are breast-feeding. You will need to talk about any risks to your baby.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Infections have happened where this drug was given. Sometimes the infections were severe. Some needed treatment in the hospital, including surgery. Call your doctor right away if you have blisters, scabs, open wounds, or signs of an infection where this drug was given like redness that does not go away, oozing, warmth, swelling, or tenderness.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Irritation where the shot is given.
- Back, muscle, joint, arm, or leg pain.
- Headache.
- Diarrhea, stomach pain, upset stomach, or throwing up.
- Mouth pain.

- Throat pain.
- Cough.
- Feeling tired or weak.
- Anxiety.
- Hair loss.
- Stuffy nose.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

You may report side effects to the FDA at 1-800-332-1088. You may also report side effects at https://www.fda.gov/medwatch.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

- It is given as a shot into the fatty part of the skin in the upper arm, thigh, buttocks, or stomach area.
- Other drugs may be given before this drug to help avoid side effects.
- Do not give into skin within 2 inches (5 cm) of the belly button.
- If you will be giving yourself the shot, your doctor or nurse will teach you how to give the shot.
- Wash your hands before and after use.
- If stored in a refrigerator, let this drug come to room temperature before using it. Leave it at room temperature for at least 30 minutes. Do not heat this drug.
- Do not give into a mole, scar, birthmark, or rash. Do not give into skin that is red, tattooed, irritated, burned, tender, bruised, hard, or damaged.

- Do not give into an infected area of skin.
- Do not shake.
- Do not use if the solution is cloudy, leaking, or has particles.
- This drug is colorless to a faint yellow. Do not use if the solution changes color.
- Move site where you give the shot each time.
- If your dose is more than 1 injection, you may give in the same body part. However, do not give injections within 2 inches (5 cm) of each other.
- Throw away needles in a needle/sharp disposal box. Do not reuse needles or other items. When the box is full, follow all local rules for getting rid of it. Talk with a doctor or pharmacist if you have any questions.

What do I do if I miss a dose?

- Skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.

How do I store and/or throw out this drug?

- Store in a refrigerator. Do not freeze.
- Store in the original container to protect from light.
- If needed, you may store at room temperature.
- If stored at room temperature, throw away any unused drug after 30 days or after the expiration date, whichever comes first.
- Do not put this drug back in the refrigerator after it has been stored at room temperature.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug

take-back programs in your area.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- This drug comes with an extra patient fact sheet called a Medication Guide. Read it with care. Read it again each time this drug is refilled. If you have any questions about this drug, please talk with the doctor, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

Consumer Information Use and Disclaimer

This generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical advice, diagnosis, or treatment of a health care provider based on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care provider for complete information about their health, medical questions, and treatment options, including any risks or benefits regarding use of medications. This information does not endorse any treatments or medications as safe, effective, or approved for treating a specific patient. UpToDate, Inc. and its affiliates disclaim any warranty or liability relating to this information or the use thereof. The use of this information is governed by the Terms of Use, available at

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If you have questions or concerns, contact your healthcare provider. A member of your care team will answer Monday through Friday from 9 a.m. to 5 p.m. Outside those hours, you can leave a message or talk with another MSK provider. There is always a doctor or nurse on call. If you're not sure how to reach your healthcare provider, call 212-639-2000.

For more resources, visit www.mskcc.org/pe to search our virtual library.

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