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Panobinostat

pronounced as (pan" oh bin' oh stat)

IMPORTANT WARNING:

Panobinostat may cause severe diarrhea and other serious gastrointestinal (GI; affecting the stomach or intestines) side effects. If you experience any of the following symptoms, call your doctor immediately: stomach cramps; loose stools; diarrhea; vomiting; or dry mouth, dark urine, decreased sweating, dry skin, and other signs of dehydration. Talk to your doctor about what you should do if you develop diarrhea during your treatment with panobinostat. Also talk to your doctor before taking any laxatives or stool softeners while you are taking this medication.

Panobinostat may cause serious or life-threatening heart problems during your treatment. Tell your doctor if you have recently had a heart attack or if you have long QT syndrome (condition that increases the risk of developing an irregular heartbeat that may cause fainting or sudden death), angina (chest pain), or other heart problems. Your doctor will order tests such as an electrocardiogram (ECG; test that records the electrical activity of the heart) before and during your treatment to see if it is safe for you to take panobinostat. If you experience any of the following symptoms, call your doctor immediately: chest pain, rapid, pounding, or irregular heart beat, lightheadedness, feeling faint, dizziness, blue-colored lips, shortness of breath, or swelling of the hands, arms, feet, ankles, or lower legs.

Keep all appointments with your doctor and the laboratory. Your doctor will order certain tests to check your body's response to panobinostat.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with panobinostat 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>]) or the manufacturer's website to obtain the Medication Guide.

Talk to your doctor about the risks of taking panobinostat.

Why is this medication prescribed?

Panobinostat is used in combination with bortezomib (Velcade) and dexamethasone to treat people with multiple myeloma (a type of cancer of the bone marrow) who have already been treated two other medications, including bortezomib (Velcade). Panobinostat is in a class of medications called histone deacetylase (HDAC) inhibitors. It works by killing cancer cells.

How should this medicine be used?

Panobinostat comes as a capsule to take by mouth. It is usually taken with or without food once daily on certain days of a 21-day cycle. The cycle may be repeated for up to 16 cycles. Take panobinostat at around the same time on each scheduled day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take panobinostat exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Swallow the capsules whole with a glass of water; do not crush, chew, or open them. Handle the capsules as little as possible. If you touch a broken panobinostat capsule or the medicine in the capsule, wash that area of your body with soap and water. If the medicine in the capsule gets into your mouth, nose, or eyes, wash it away with plenty of water.

If you vomit after taking panobinostat, do not take another dose. Continue your regular dosing schedule.

Be sure to tell your doctor how you are feeling during your treatment. Your doctor may decrease your dose of panobinostat or stop your treatment for a while or permanently, if you experience side effects of the medication.

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 taking panobinostat,

- tell your doctor and pharmacist if you are allergic to panobinostat, any other medications, or any of the ingredients in panobinostat capsules. 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. Be sure to mention any of the following: amiodarone (Cordarone, Nexterone, Pacerone); antifungals such as itraconazole (Onmel, Sporanox), ketoconazole (Nizoral), posaconazole (Noxafil), and voriconazole (Vfend); atomoxetine (Strattera); bepridil (Vascor; no longer available in the U.S.); boceprevir (Victrelis); carbamazepine (Carbatrol, Tegretol, Teril, others); chloroquine (Aralen); clarithromycin (Biaxin, in PrevPac); conivaptan (Vaprisol); desipramine (Norpramin); dextromethorphan; disopyramide (Norpace); dolasetron (Anzemet); certain medications for HIV such as indinavir (Crixivan), lopinavir/ritonavir (Kaletra), nelfinavir (Viracept), ritonavir (Norvir, in Kaletra, in Viekira Pak), saquinavir (Invirase); methadone (Dolophine, Methadose); metoprolol (Lopressor, Toprol-XL); moxifloxacin (Avelox); nebivolol (Bystolic); nefazodone; ondansetron (Zofran, Zuplenz); perphenazine; pimozide (Orap); phenobarbital; phenytoin (Dilantin, Phenytek); procainamide; quinidine (in Nuedexta); rifampin (Rifadin, Rimactane, in Rifamate, in Rifater); sotalol (Betapace, Sorine, Sotylize); telaprevir (Incivek);

no longer available in U.S.); telithromycin (Ketek); thioridazine; tolterodine (Detrol); and venlafaxine (Effexor). Your doctor may need to change the doses of your medications or monitor you carefully for side effects.

- tell your doctor what herbal products you are taking, especially St John's wort.
- tell your doctor if you have an infection or have or have ever had bleeding problems or liver disease.
- tell your doctor if you are pregnant or plan to become pregnant. Panobinostat may harm the fetus. Use birth control to prevent pregnancy during your treatment with panobinostat and for at least 1 month after the last dose. If you are a man and your partner can become pregnant, you should use a condom while taking this medication and for 90 days after your treatment is completed. Ask your doctor if you have questions about types of birth control that will work for you. If you become pregnant while taking panobinostat, call your doctor immediately.
- tell your doctor if you are breastfeeding. You should not breastfeed while taking panobinostat.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking panobinostat.

What special dietary instructions should I follow?

Do not eat pomegranate, grapefruit or star fruit or drink grapefruit or pomegranate juice while taking this medication.

What should I do if I forget a dose?

If it has been 12 hours or less since you were scheduled to take the dose, take the missed dose as soon as you remember it. If it has been more than 12 hours since your scheduled dose, skip the dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed.

What side effects can this medication cause?

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

- weight loss
- headache

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

- black, tarry, or bloody stools
- bloody vomit or vomited material that looks like coffee grounds
- unusual bruising or bleeding
- pink or brown urine
- blood in phlegm
- confusion
- changes in your speech

- fever, cough, chills, sweating or other signs of infection
- pale skin
- nausea, vomiting, loss of appetite, dark urine, stomach pain, extreme tiredness, lack of energy, or yellowing of skin or white of eyes

Panobinostat 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 container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from light, excess heat and moisture (not in the bathroom).

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.

Symptoms of overdose may include the following:

- diarrhea
- nausea
- vomiting
- decreased appetite

What other information should I know?

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

- Farydak[®]

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