

MEDICATION GUIDE
FARYDAK® (FAYR-ah-dak)
(panobinostat) capsules

What is the most important information I should know about FARYDAK?

FARYDAK can cause serious side effects, including:

- **Diarrhea** is common with FARYDAK and can be severe. Tell your healthcare provider right away if you have abdominal (stomach) cramps, loose stool, diarrhea, or if you feel like you are becoming dehydrated. Your healthcare provider may prescribe medicines to help prevent or treat these side effects. Taking or using stool softeners or laxative medicines may worsen diarrhea, talk to your healthcare provider before taking or using these medicines. Your healthcare provider will do regular tests to check the levels of fluid and electrolytes in your blood during treatment with FARYDAK.
- **Heart problems.** FARYDAK can cause severe heart problems which can lead to death. Your risk of heart problems may be increased if you have a condition called “long QT syndrome” or other heart problems. Your healthcare provider will do blood tests to check your electrolytes and do an electrocardiogram (ECG) tests before and during treatment with FARYDAK. Call your healthcare provider and get emergency medical help right away if you have any of the following symptoms of heart problems:
 - chest pain
 - faster or slower heart beat
 - palpitations (feel like your heart is racing)
 - feel lightheaded or faint
 - dizziness
 - blue colored lips
 - shortness of breath
 - swelling in your legs
- **Bleeding.** FARYDAK can cause severe bleeding which can lead to death. It may take you longer than usual to stop bleeding while you are taking FARYDAK. Your healthcare provider will check your platelet counts before you start FARYDAK and during your treatment with FARYDAK. Tell your healthcare provider right away if you get any of the following signs of bleeding:
 - blood in your stools or black stools (look like tar)
 - pink or brown urine
 - unexpected bleeding or bleeding that is severe or that you cannot control
 - vomit blood or vomit looks like coffee grounds
 - cough up blood or blood clots
 - increased bruising
 - feeling dizzy or weak
 - confusion
 - change in your speech
 - headache that lasts a long time

What is FARYDAK?

FARYDAK is a prescription medicine used, in combination with bortezomib and dexamethasone, to treat people with a type of cancer called multiple myeloma after at least 2 other types of treatment have been tried.

It is not known if FARYDAK is safe and effective in children.

What should I tell my healthcare provider before taking FARYDAK?

Before you take FARYDAK, tell your healthcare provider about all of your medical conditions, including if you:

- have diarrhea
- have heart problems
- have a history of bleeding problems
- have an infection. You should not take FARYDAK if you have an infection.
- have liver problems
- are pregnant or plan to become pregnant. FARYDAK can harm your unborn baby. You should not become pregnant during treatment with FARYDAK.
- If you become pregnant while taking FARYDAK, or think you may be pregnant, tell your healthcare provider right away.
 - Females who are able to become pregnant should use effective birth control during treatment with FARYDAK and for at least 3 months after the last dose of FARYDAK.
 - Males who are sexually active should use a condom during treatment with FARYDAK and for at least 6 months after the last dose of FARYDAK.
- are breastfeeding or plan to breastfeed. It is not known if FARYDAK will pass into your breast milk. You and your healthcare provider should decide if you will take FARYDAK or breastfeed. You should not do both.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take FARYDAK?

- Take FARYDAK exactly as your healthcare provider tells you to take it.
- Your healthcare provider will tell you how much FARYDAK to take and when to take it.
- Your healthcare provider may change your dose or stop treatment temporarily if you have side effects. Do not change your dose or stop taking FARYDAK without first talking with your healthcare provider.
- Take FARYDAK 1 time on each scheduled day at about the same time.
- FARYDAK can be taken with or without food.
- FARYDAK capsule should be swallowed whole with a cup of water. **Do not open, crush, or chew FARYDAK.**
- Avoid contact of the powder in the FARYDAK capsules. If you accidentally get powder from the FARYDAK capsule on your skin, wash the area with soap and water. If you accidentally get powder from the FARYDAK capsule in your eyes, flush your eyes with water.
- If you miss a dose of FARYDAK, take it as soon possible, up to 12 hours after the time the dose should have been taken.
- If you vomit after taking FARYDAK, do not take another capsule. Stay on your dosing schedule and take your next dose as usual.
- If you take too much FARYDAK, call your healthcare provider.

What should I avoid while taking FARYDAK?

- Avoid eating star fruit, pomegranate or pomegranate juice, and grapefruit or grapefruit juice while taking FARYDAK. These foods may affect the amount of FARYDAK in your blood.

What are the possible side effects of FARYDAK?

FARYDAK may cause serious side effects, including:

- See “What is the most important information I should know about FARYDAK?”
- **Low blood cell counts** are common with FARYDAK and can be severe. Your healthcare provider will check your blood counts before you start FARYDAK and during your treatment with FARYDAK.
 - Low platelet count (thrombocytopenia) can cause unusual bleeding or bruising under your skin.
 - Low white cell count (neutropenia) can cause you to get infections.
 - Low red blood cell count (anemia) may make you feel weak, tired, or you may get tired easily, you look pale, or you feel short of breath.
- **Infections.** There is an increased risk of infection while taking FARYDAK. Contact your healthcare provider right away if you have a fever or have any signs of an infection:
 - sweats or chills
 - cough
 - flu-like symptoms
 - shortness of breath
 - blood in your phlegm
 - sores on your body
 - warm or painful areas on your body
 - feeling very tired
- **Liver problems** (hepatotoxicity). Your healthcare provider should do blood tests to check your liver before you start taking FARYDAK and if you have symptoms of liver problems while you take FARYDAK. Call your healthcare provider right away if you have the following symptoms of liver problems:
 - feel tired or weak
 - loss of appetite
 - dark amber colored urine
 - upper abdominal (stomach) pain
 - yellowing of your skin or the white of your eyes

The most common side effects of FARYDAK include tiredness, nausea, swelling in your arms or legs, decreased appetite, fever, and vomiting.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away. These are not all of the possible side effects of FARYDAK. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store FARYDAK?

- Store FARYDAK between 68°F to 77°F (20°C to 25°C). Store blister pack in original carton to protect from light.

Keep FARYDAK and all medicines out of the reach of children.

General information about the safe and effective use of FARYDAK

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use FARYDAK for a condition for which it was not prescribed. Do not give FARYDAK to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about FARYDAK that is written for health professionals.

What are the ingredients in FARYDAK?**Active ingredient:** panobinostat**Inactive ingredients:** magnesium stearate, mannitol, microcrystalline cellulose, and pre-gelatinized starch**Capsule shell contains:** gelatin, FD&C Blue 1 (10 mg capsules), yellow iron oxide (10 mg and 15 mg capsules), red iron oxide (15 mg and 20 mg capsules), and titanium dioxide

Distributed by: Novartis Pharmaceuticals Corporation, East Hanover, New Jersey 07936
For more information, go to www.FARYDAK.com or call 1-844-FARYDAK (1-844-327-9325).

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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