

B. PACKAGE LEAFLET

Package leaflet: Information for the patient

Farydak 10 mg hard capsules
Farydak 15 mg hard capsules
Farydak 20 mg hard capsules
panobinostat

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Farydak is and what it is used for
2. What you need to know before you take Farydak
3. How to take Farydak
4. Possible side effects
5. How to store Farydak
6. Contents of the pack and other information

1. What Farydak is and what it is used for

What Farydak is

Farydak is an anti-cancer medicine that contains the active substance panobinostat, which belongs to a group of medicines called pan-deacetylase inhibitors.

What Farydak is used for

Farydak is used to treat adult patients with a rare type of blood cancer called multiple myeloma. Multiple myeloma is a disorder of plasma cells (a type of blood cell) that grow out of control in the bone marrow.

Farydak blocks the growth of cancerous plasma cells and reduces the number of cancer cells.

Farydak is always used together with two other medicines: bortezomib and dexamethasone.

If you have any questions about how Farydak works or why you have been given it, ask your doctor or pharmacist.

2. What you need to know before you take Farydak

Do not take Farydak:

- if you are allergic to panobinostat or any of the other ingredients of this medicine (listed in section 6).
- if you are breast-feeding

Warnings and precautions

Follow all your doctor's instructions carefully.

Talk to your doctor or pharmacist before taking Farydak:

- if you have liver problems or have ever had liver disease.
- if you have heart or heartbeat problems, such as irregular heartbeat or a condition called long QT syndrome.
- if you have a bacterial, viral or fungal infection.
- if you have gastrointestinal problems such as diarrhoea, nausea or vomiting.
- if you have blood clotting problems (coagulation disorder).

Tell your doctor or pharmacist straight away during treatment with Farydak:

- if you notice any signs of a gastrointestinal problem.
- if you notice any signs of a liver problem.
- if you notice any signs of an infection.
- if you notice any signs of a heart problem.

The list of associated symptoms is provided in section 4, Possible side effects.

Your doctor may need to change your dose, temporarily stop or completely stop your treatment with Farydak in case you experience side effects.

Monitoring during your treatment with Farydak

You will have regular blood tests during treatment with Farydak. These are to:

- check how well your liver is working (by measuring your blood levels of bilirubin and transaminase, which are substances made by the liver).
- check the amounts of certain cells of your blood (white blood cells, red blood cells, platelets).
- check the amount of electrolytes (such as potassium, magnesium, phosphate) in your body.
- check how well your thyroid and pituitary gland are working (by measuring your blood levels of thyroid hormones).

Your heart rate will also be checked using a machine that measures the electrical activity of the heart (called an ECG).

Children and adolescents

Farydak is not to be used in children or adolescents under 18 years of age.

Other medicines and Farydak

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, such as vitamins or herbal supplements, because they might interact with Farydak.

In particular tell your doctor or pharmacist if you are taking any of the following medicines:

- medicines used to treat infections, including fungal infections (such as ketoconazole, itraconazole, voriconazole or posaconazole) and some bacterial infections (such as antibiotics like clarithromycin or telithromycin). Medicines used to treat tuberculosis, such as rifabutin or rifampicin.
- medicines used to stop seizures or fits (anti-epileptics such as carbamazepine, pherphenazine, phenobarbital or phenytoin).
- medicines used to treat HIV, such as ritonavir or saquinavir.
- medicines used to treat depression, such as nefazodone.
- St. John's wort, a herbal medicine used to treat depression.
- medicines to prevent blood clotting called anti-coagulants, such as warfarin or heparin.
- medicines used to treat cough, such as dextromethorphan.
- medicines used to treat irregular heartbeat, such as amiodarone, disopyramide, procainamide, quinidine, propafenone or sotalol.
- medicines that may have an unwanted effect on the heart (called QT prolongation), such as chloroquine, halofantrine, methadone, moxifloxacin, bepridil or pimozide.
- medicines used to treat hypertension, such as metoprolol or nebivolol.
- medicines used to treat severe mental health problems, such as risperidone.
- medicines used to treat breast cancer, such as tamoxifen.

- medicines used to treat nausea and vomiting such as dolasetron, granisetron, ondansetron or tropisetron; these may also have an unwanted effect on the heart (QT prolongation).
- atomoxetine, a medicine used to treat attention deficit hyperactivity disorder.

These medicines should be used with care or may need to be avoided during your treatment with Farydak. If you are taking any of these medicines, your doctor might prescribe a different medicine for you during your treatment with Farydak.

Ask your doctor or pharmacist if you are not sure whether your medicine is one of the medicines listed above.

During Farydak treatment, you should also tell your doctor or your pharmacist if you are prescribed another medicine that you have not already been taking.

Farydak with food and drink

You should not eat star fruit, pomegranate or grapefruit or drink pomegranate or grapefruit juice during your treatment with Farydak, as they may increase the amount of the medicine that passes into your blood.

Pregnancy and breast-feeding

Due to the potential risk of death or malformation to the foetus, Farydak should not be taken during:

- Pregnancy

Farydak should not be taken during pregnancy, unless the potential benefit to the mother is greater than the potential risk to the baby. If you are pregnant, think you might be pregnant or plan to become pregnant, ask your doctor for advice. Your doctor will discuss with you the possible risks of taking Farydak during pregnancy.

- Breast-feeding

You must not take Farydak if you are breast-feeding.

Contraception for women and men

Due to the potential risk of death or malformation to the foetus, you should use the following methods of contraception while taking Farydak:

- For women taking Farydak

If you are a sexually active woman, you should have a pregnancy test before starting Farydak treatment and you must use a highly effective method of contraception during treatment with Farydak. You must also use this for three months after you have stopped taking Farydak. Your doctor will discuss with you which is the best method for you to use. If you use a hormonal contraceptive you must also use a barrier method of contraception (such as condom or diaphragm) in addition.

- For men taking Farydak

If you are a sexually active man, you should use condoms during treatment with Farydak. You should also do this for six months after you have stopped taking Farydak. If your partner is able to become pregnant she should also use a highly effective method of contraception during your treatment and for six months after. Tell your doctor straight away if your partner becomes pregnant while you are taking Farydak or during the six months following your treatment with Farydak.

Driving and using machines

Farydak may have a minor influence on the ability to drive and use machines. If you feel dizzy while taking this medicine, do not drive a vehicle or use any tools or machines.

3. How to take Farydak

Always take this medicine exactly as your doctor has told you. Check with your doctor or your

pharmacist if you are not sure.

How much to take

- Farydak is taken over 21 days (2 weeks on and 1 week off) – this is called a treatment cycle.
- You do not take the medicine every day.
- Based on the recommendation of your doctor, the dose of Farydak is either 20 mg or 15 mg or 10 mg, to be taken once a day on days 1, 3, 5, 8, 10 and 12 of the 21-day cycle.
- Do not take Farydak in Week 3.
- After Week 3 you start a new cycle again as shown in Tables 1 and 2 below.
Please refer to Table 1 for cycles 1 to 8 and Table 2 for cycles 9-16.

Table 1 Recommended schedule for taking Farydak in combination with bortezomib and dexamethasone (cycles 1-8)

Cycles 1-8 (3-week cycles)	Week 1 Days						Week 2 Days						Week 3
Farydak	1		3		5		8		10		12		Rest period
Bortezomib	1			4			8			11			Rest period
Dexamethasone	1	2		4	5		8	9		11	12		Rest period

Table 2 Recommended schedule for taking Farydak in combination with bortezomib and dexamethasone (cycles 9-16).

Cycles 9-16 (3-week cycles)	Week 1 Days						Week 2 Days						Week 3
Farydak	1		3		5		8		10		12		Rest period
Bortezomib	1						8						Rest period
Dexamethasone	1	2					8	9					Rest period

Your doctor will tell you exactly how many capsules of Farydak you need to take. Do not change the dose without talking to your doctor.

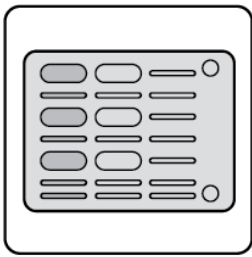
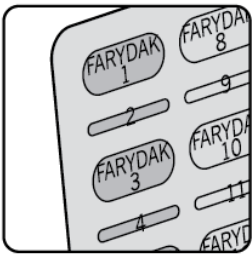
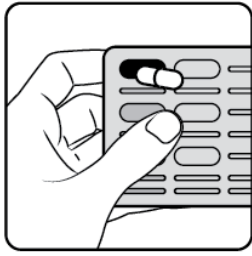
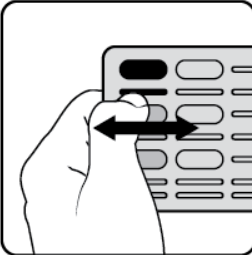
Take Farydak once a day at the same time each day only on the scheduled days.

Taking this medicine

- Swallow the capsules whole with a glass of water.
- The medicine can be taken with or without food.
- Do not chew or crush the capsules.

If you vomit after you swallow the Farydak capsules, do not take any more capsules until your next scheduled dose.

How to use the Farydak blister

	One Farydak blister = 3 weeks = 1 cycle
	The days of the cycle are numbered on the blister. Take Farydak on days 1, 3 and 5 and on days 8, 10 and 12.
	Push the Farydak capsule through the pocket on days 1, 3 and 5 of week 1 and days 8, 10 and 12 of week 2.
	On days when you do not have to take Farydak, including the rest period in week 3, scratch the relevant empty cavities with your finger nail to help you keep track of your medicine schedule.

How long to take Farydak

Keep taking Farydak for as long as your doctor tells you. This is a long-term treatment with 16 cycles (48 weeks). Your doctor will monitor your condition to see if the treatment is working. If you have questions about how long to take Farydak, talk to your doctor or pharmacist.

If you take more Farydak than you should

If you accidentally take more capsules than you should, or if someone else accidentally takes your medicine, talk to a doctor or go to a hospital straight away. Take the pack and this leaflet with you. You may need medical treatment.

If you forget to take Farydak

- If it is less than 12 hours since you should have taken the medicine, take the missed dose as soon as you remember. Then continue taking the medicine as normal.
- If it is more than 12 hours since you should have taken the medicine, skip the missed dose. Then continue taking the medicine as normal.

Do not take a double dose to make up for a forgotten dose.

Never take a missed dose of Farydak on one of the “off” days when no Farydak dose is planned.

Tell your doctor about all the doses that you have missed during any 21-day cycle of treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects could be serious

STOP taking Farydak and seek medical help immediately if you experience any of the following:

- difficulty in breathing or swallowing, swelling of the face, lips, tongue or throat, severe itching of the skin, with a red rash or raised bumps (potential signs of an allergic reaction)
- severe headache, feeling weak or paralysis of limbs or face, difficulty speaking, sudden loss of consciousness (potential signs of nervous system problems such as bleeding or swelling in the skull or brain)
- fast breathing, feeling dizzy
- sudden and crushing chest pain, feeling tired, irregular heartbeat (potential signs of a heart attack)
- coughing up blood, oozing of bloody fluid from the nose (signs of bleeding in the lungs)
- vomiting blood, black or bloody stools, passage of fresh blood through the anus, usually in or with stools (signs of gastrointestinal bleeding)
- difficulty in breathing with blueness around the mouth, which could lead to loss of consciousness (sign of serious lung problems)
- fever, chest pain, increased heart rate, decreased blood pressure, shortness of breath or rapid breathing (signs of blood poisoning, which is also known as sepsis)
- chest pain or discomfort, changes in heartbeat (faster or slower), palpitations, light-headedness, fainting, dizziness, blue discolouration of your lips, shortness of breath, swelling of lower limbs or skin (signs of heart problems)

Tell a doctor or a pharmacist straight away if you notice any of these side effects:

- stomach or abdominal pain, nausea, diarrhoea, vomiting, black or bloody stools, constipation, heartburn, swelling or bloating of the abdomen (signs of a gastrointestinal problem)
- new or worsening symptoms such as cough with or without mucus, fever, difficult or painful breathing, wheezing, pain in chest when breathing, shortness of breath or, difficulty breathing, pain or burning feeling when passing urine, exaggerated sense of needing to pass urine, blood in urine (signs of an infection in the lungs or urinary tract)
- fever, sore throat, or mouth ulcers due to infections (signs of a low level of white blood cells)
- sudden bleeding or bruising underneath the skin (signs of low level of blood platelets)
- diarrhoea, abdominal pain, fever (signs of an inflamed colon)
- light-headedness, particularly when standing up (a sign of low blood pressure)
- feeling thirsty, low urine output, weight loss, dry flushed skin, irritability (signs of dehydration)
- swollen ankles (a sign of a low level of albumin in the blood which is known as hypoalbuminaemia)
- feeling tired, itching, yellowing of the skin and whites of the eyes, nausea or vomiting, loss of appetite, pain on the right side of your stomach, dark or brown urine, bleeding or bruising more easily than normal (signs of a liver problem)
- severely decreased urine output, swelling of the legs (signs of a kidney problem)
- muscle weakness, muscle spasms, unusual heartbeat (signs of changes in the level of potassium in the blood)

Other possible side effects

If any of the side effects below becomes severe, tell your doctor, or your pharmacist.

Very common (may affect more than 1 in 10 people)

- feeling tired (fatigue), pale skin. These could be signs of a low level of red blood cells.
- decreased appetite or weight loss
- difficulty falling or staying asleep (insomnia)
- headache

- feeling dizzy, tired or weak
- vomiting, nausea, upset stomach, indigestion
- swelling of the legs or arms
- reduced blood level of phosphate or sodium

Common (may affect up to 1 in 10 people)

- rash of small fluid-filled blisters, appearing on reddened skin, mouth or gums (signs of a potentially severe viral infection)
- inflamed ear, nose bleed or bleeding in the white of the eye, bruising, inflamed skin caused by infection (rash, red skin, which is also known as erythema)
- abdominal pain, diarrhoea, swelling or bloating of the abdomen (signs of inflamed stomach lining)
- oral thrush (yeast infection of the mouth)
- feeling thirsty, high urine output, increased appetite with weight loss (signs of a high level of sugar in the blood)
- fast weight gain, swelling of hands, ankles, feet or face (signs of water retention)
- reduced level of calcium in the blood, sometimes leading to cramps
- uncontrolled shaking of the body
- palpitations
- clicking, rattling or crackling noise made by the lungs when breathing
- cracked, chapped lips
- dry mouth or changes to your sense of taste
- flatulence
- joint pain or inflammation
- blood in urine (a sign of a kidney problem)
- being unable to control the flow of urine because of loss of or weak bladder control
- chills
- weight gain, feeling tired, hair loss, muscle weakness, feeling cold (signs of an underactive thyroid gland, which is known as hypothyroidism)
- generally feeling unwell
- increased blood level of uric acid
- reduced blood level of magnesium
- increased blood level of the waste product creatinine
- increased blood levels of the liver enzymes alanine aminotransferase (ALT), aspartate aminotransferase (AST) or alkaline phosphatase (ALP).

Uncommon (may affect up to 1 in 100 people)

- red or purple, flat pinhead spots under the skin

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom	Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
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5. How to store Farydak

- Keep this medicine out of the sight and reach of children.
- Do not take this medicine after the expiry date, which is stated on the carton and blister foil.
- Do not store above 30°C.
- Store in the original package in order to protect from moisture.
- Do not take this medicine if you notice any damage to the packaging or if there are any signs of tampering.

- Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Farydak contains

- The active substance of Farydak is panobinostat.
- Each Farydak 10 mg hard capsule contains panobinostat lactate anhydrous equivalent to 10 mg panobinostat. The other ingredients are: magnesium stearate, mannitol, microcrystalline cellulose, pregelatinised starch, gelatin, titanium dioxide (E171), brilliant blue FCF (E133), yellow iron oxide (E172), black iron oxide (E172), propylene glycol (E1520), shellac glaze.
- Each Farydak 15 mg hard capsule contains panobinostat lactate anhydrous equivalent to 15 mg panobinostat. The other ingredients are: magnesium stearate, mannitol, microcrystalline cellulose, pregelatinised starch, gelatin, titanium dioxide (E171), yellow iron oxide (E172), red iron oxide (E172), black iron oxide (E172), propylene glycol (E1520), shellac glaze.
- Each Farydak 20 mg hard capsule contains panobinostat lactate anhydrous equivalent to 20 mg panobinostat. The other ingredients are: magnesium stearate, mannitol, microcrystalline cellulose, pregelatinised starch, gelatin, titanium dioxide (E171), red iron oxide (E172), black iron oxide (E172), propylene glycol (E1520), shellac glaze.

What Farydak looks like and contents of the pack

Farydak 10 mg hard capsules are light green opaque capsules (15.6–16.2 mm) containing white to almost white powder, with radial marking “LBH 10 mg” in black ink on the cap and two radial bands in black ink on the body, provided in blisters.

Farydak 15 mg hard capsules are orange opaque capsules (19.1–19.7 mm) containing white to almost white powder, with radial marking “LBH 15 mg” in black ink on the cap and two radial bands in black ink on the body, provided in blisters.

Farydak 20 mg hard capsules are red opaque capsules (19.1–19.7 mm) containing white to almost white powder, with radial marking “LBH 20 mg” in black ink on the cap and two radial bands in black ink on the body, provided in blisters.

The following pack sizes are available: blister packs containing 6, 12 or 24 capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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