



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

27 November 2015  
EMA/599292/2015

## Compliance card to be given to patients using Farydak

Compliance card will ensure correct use and avoid medication errors

Each patient treated with the cancer medicine Farydak (panobinostat) will receive a compliance card to ensure the safe and effective use of the medicine and to reduce the risk of medication errors.

Farydak is used for the treatment of multiple myeloma, a cancer of a type of blood cells called plasma cells. It is given by mouth in 21-day treatment cycles on days 1, 3, 5, 8, 10 and 12. Farydak is always used together with the medicines bortezomib and dexamethasone. These medicines are given according to a specific schedule but not always on the same day as Farydak, which may lead to medication errors.

Confusion about the day that treatment is due may lead to over- or under-dosing of the medicine. Overdose can result in side effects such as diarrhoea, nausea and vomiting whereas under-dosing may result in a lack of effect. Patients will therefore be given a compliance card that will help them remember when their treatment is due.

### Information for patients and carers

- Farydak is a medicine used for the treatment of multiple myeloma, a cancer of a type of blood cells called plasma cells.
- Farydak is given together with bortezomib and dexamethasone in 21-day treatment cycles.
- Because this is a complex schedule, every patient will be given the below compliance card containing a table describing what medicines to take for each day of the cycle.



**CYCLES 1-8 (BORTEZOMIB TWICE WEEKLY)**

Start Date: \_\_\_\_\_ Prescribed Dose of FARYDAK® (panobinostat):  10mg  15mg  20mg

Week 1		Week 2		Week 3 (Rest)	
Day of the week and date (dd/mm)	Mark EACH accordingly	Day of the week and date (dd/mm)	Mark EACH accordingly	Day of the week and date (dd/mm)	Mark EACH accordingly
	F + B + D <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		F + B + D <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>		No dose <input type="checkbox"/>
	D <input type="checkbox"/>		D <input type="checkbox"/>		No dose <input type="checkbox"/>
	F <input type="checkbox"/>		F <input type="checkbox"/>		No dose <input type="checkbox"/>
	B + D <input type="checkbox"/> <input type="checkbox"/>		B + D <input type="checkbox"/> <input type="checkbox"/>		No dose <input type="checkbox"/>
	F + D <input type="checkbox"/> <input type="checkbox"/>		F + D <input type="checkbox"/> <input type="checkbox"/>		No dose <input type="checkbox"/>
	No dose <input type="checkbox"/>		No dose <input type="checkbox"/>		No dose <input type="checkbox"/>
	No dose <input type="checkbox"/>		No dose <input type="checkbox"/>		No dose <input type="checkbox"/>

This is the approved dosing schedule for FARYDAK. Please follow your doctor's instructions carefully.

F FARYDAK   
 D Dexamethasone   
 B Bortezomib (Velcade®)

**DO NOT** take any medication(s) on your off days or on your off week

- The compliance card includes a box for each medicine which the patients should mark when they take a dose.
- The compliance card will help patients remember when their treatment is due.
- Patients should bring the compliance card to each doctor's visit.
- If patients take more capsules than they should they should contact their doctor straight away. If patients forget a dose and if it is less than 12 hours since they were due to take it they should take it as soon as they remember. If more than 12 hours have passed patients should skip the dose. Patients should tell their doctor about any doses they have missed during a 21-day cycle of treatment.
- In case of any questions about the treatment, patients should speak to their doctor or pharmacist.

### Information for healthcare professionals

- Before prescribing or dispensing Farydak, patients should be given a compliance card to help them remember when their treatment is due.
- The compliance card contains a table describing the treatment regimen for each day of the cycle with space for the patient to mark when they took their dose.
- Patients should be informed to bring the compliance card to each doctor's visit.
- Patients should be informed of how to act if a too high dose is taken or if doses are missed

---

**More about the medicine**

Farydak is a cancer medicine used to treat patients with multiple myeloma (a cancer of the bone marrow). It is used with two other medicines, bortezomib and dexamethasone, in adults whose disease has come back or has gotten worse after at least two previous treatments, including bortezomib and at least one immunomodulatory medicine (medicine that acts on the immune system).

More information on Farydak can be found on the Agency's website: [ema.europa.eu/Find/medicine/Human\\_medicines/European\\_public\\_assessment\\_reports](http://ema.europa.eu/Find/medicine/Human_medicines/European_public_assessment_reports)