



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 June 2020
EMA/64561/2020

Deferasirox Mylan: Measures to avoid medication errors

Doses may differ from other deferasirox products

Educational material will be given to patients and healthcare professionals using Deferasirox Mylan (deferasirox) to alert them that there are different forms of medicines containing deferasirox on the market. Deferasirox Mylan, available as film-coated tablets, is used to remove excessive iron from the blood of patients with beta thalassaemia or other blood disorders that result in excessive iron in the blood.

The educational material will advise that the different deferasirox formulations available in the EU require different dosing: a smaller dose of the film-coated tablets is needed than that of dispersible tablets. If the dose is not adjusted when changing from one type of tablet to another, the patient may receive too little or too much of the medicine.

Information for patients

- Deferasirox Mylan film-coated tablets have been introduced.
- In the EU, medicines containing deferasirox are available as film-coated tablets and dispersible tablets marketed under different names. Both are taken once a day, preferably at the same time each day. A smaller dose of the film-coated tablets is needed than of the dispersible tablets.
- Whereas the dispersible tablets have to be taken on an empty stomach 30 minutes before food, the film-coated tablets can be taken on an empty stomach or with a light meal.
- Your doctor will have worked out the dose of Deferasirox Mylan you need. The dose depends on your weight, the amount of iron in your blood, how well your liver and kidneys work and the number of blood transfusions you receive.
- Read the package leaflet and other information you have been given with your tablets. It has important information about your treatment and how to take the medicine. If you have any questions about your treatment, contact your doctor, pharmacist or nurse.
- You will be given a handbook about these tablets and how to take them.

Information for healthcare professionals

- Deferasirox Mylan (deferasirox) film-coated tablets will be available in the EU in addition to film-coated tablets and dispersible tablets already marketed under other names.



- Bioavailability of deferasirox from film-coated tablets is higher than from dispersible tablets and the strength of film-coated tablets is correspondingly lower. Film-coated tablets containing 90, 180 and 360 mg are equivalent to dispersible tablets containing 125, 250 and 500 mg, respectively.
- The summary of product characteristics and the guide for healthcare professionals on Deferasirox Mylan contains important information on its use.
- Patients prescribed Deferasirox Mylan should be issued with a handbook about the tablets and how to take them.
- The following table describes the differences between the two formulations:

	Film-coated tablets	Dispersible tablets
Strength	90 mg, 180 mg and 360 mg	125 mg, 250 mg and 500 mg
When to take tablets	Once daily, may be taken on an empty stomach or with a light meal	Once daily, must be taken on an empty stomach, at least 30 minutes before food
How to take tablets	Swallowed whole with some water or crushed and sprinkled on soft food (e.g. yogurt or apple sauce)	Dispersed in water, orange juice or apple juice. Not to be chewed or swallowed whole
Dose range (adults and children)	7–28 mg/kg daily, rounded to the nearest whole tablet size	10–40 mg/kg daily, rounded to the nearest whole tablet size

More about the medicine

Deferasirox Mylan is a medicine used to treat chronic iron overload (an excess of iron in the body) in patients with beta thalassaemia or other blood disorders in which patients do not have enough normal haemoglobin in the blood. These patients develop have high levels of iron in the blood because of blood transfusions or, sometimes, excess iron absorption from the gut.

Deferasirox Mylan contains the active substance deferasirox which is an 'iron chelator'. This means that it attaches to iron in the body to form a 'chelate' that can be excreted by the body, mainly in the stool. This helps to correct iron overload and prevent the extra iron from damaging organs such as the heart and liver.

More information on Deferasirox Mylan, including its indications in full, can be found on the Agency's website: <https://www.ema.europa.eu/en/medicines/human/EPAR/deferasirox-mylan>