



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Measures to avoid medication errors with Exjade

Educational material to raise awareness of dose variation between different types of tablets

Educational material will be given to patients and healthcare professionals using Exjade (deferasirox), following the introduction of a film-coated tablet to the already authorised dispersible tablet. Exjade is a medicine used to remove excessive iron from the blood of patients with beta thalassemia or other blood disorders which result in excessive iron in the blood.

The education material will advise that the doses for the two types of Exjade tablets are different. A smaller dose is needed of the new film-coated tablets compared to that of the dispersible tablet. The patient may receive too little or too much of the medicine if the dose is not correct when changing from one type of tablet to another.

The two types of tablets can be easily distinguished by their shape, and the design of the outer cartons and blisters.

Both types of tablets will be available for some time, which will allow doctors to switch patients from dispersible tablets to film-coated tablets. After this time, Exjade dispersible tablets will no longer be marketed. Healthcare professionals will be notified of the planned date for removing the dispersible tablets from the market.

Information for patients

- Exjade film-coated tablets have been introduced.
- The dispersible tablets and the new film-coated tablets are to be taken once a day, preferably at the same time each day.
- 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 Exjade you need. The dose depends on your weight, the amount of iron in your blood, how well your liver and kidneys work and the amount of blood transfusions you receive.
- Exjade dispersible tablets will not be available in the future. If you are switching from dispersible tablets to the new film-coated tablets, you will need a smaller dose. The doctor will tell you how much of the new tablet you need to take.



- 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 with information on the two types of tablets and how to take them.

Information for healthcare professionals

- Exjade (deferasirox) is now available as film-coated tablets in addition to the already authorised dispersible tablets.
- Both types of tablets will be available for a limited period to allow doctors to switch patients from the dispersible tablets to the film-coated tablets. After this time Exjade dispersible tablets will no longer be marketed.
- Bioavailability of film-coated tablets is higher than of the 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.
- To avoid errors, prescriptions for Exjade must specify the type of formulation (dispersible tablets or film-coated tablets), the prescribed dose in mg/kg/day, and the calculated dose per day with the strength of film-coated or dispersible tablets.
- The summary of product characteristics and the educational materials on the use of Exjade should be followed because they give important information on its use.
- The following table describes the differences between the two formulations:

	Film-coated tablets	Dispersible tablets (to be discontinued)
Description and strength	Oval, blue tablets containing 90 mg (light blue), 180 mg (medium blue) and 360 mg (dark blue)	Round, white tablets containing 125 mg, 250 mg and 500 mg (all white)
Excipient: lactose	Does not contain lactose	Contains lactose
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

Exjade is a medicine used to treat chronic iron overload (an excess of iron in the body) in patients with beta thalassemia or other blood disorders in which patients do not have enough normal haemoglobin in the blood.

Exjade 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 Exjade, including its indications in full, can be found on the Agency's website: [ema.europa.eu/Findmedicine/Human medicines/European public assessment reports](http://ema.europa.eu/Findmedicine/Human%20medicines/European%20public%20assessment%20reports).