NOVARTIS

Our ref :

Date :

09/10/2018

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التاريخ : ٠٠١٧١٩
١٨-١٠-٠٢٨٧

٢٩ / محرّم /١٤٤٠هـ

Jadenu® film-coated tablets (deferasirox): new formulation, new posology, and new method of administration: risk of medication error

Dear Healthcare Professional,

Novartis, in association with the Saudi Food and Drug Authority (SFDA), would like to inform you of a new film-coated tablet formulation of deferasirox:

Jadenu® film-coated tablets (deferasirox) 90 mg, 180 mg, and 360 mg

The current formulation of deferasirox, Exjade dispersible tablets, and the new formulation, Jadenu film-coated tablets, have the same active ingredient, and the same indications (see Therapeutic Indications section below). In order to minimize the risk of medication error due to prescriptions written by generic name that do not specify either the formulation or the strength, Novartis reminds you of the relevant differences between the film-coated tablet and dispersible tablet:

Summary

Jadenu film-coated tablets – important information:

- Dosed and administered differently from Exjade dispersible tablets – Jadenu film-coated tablets are a strength-adjusted formulation of deferasirox, with higher bioavailability compared to Exjade dispersible tablets
- Available in three strengths: 90 mg, 180 mg, and 360 mg
- The dose range is 7 to 28 mg/kg of patient body weight; dose modifications for safety or efficacy should be in steps of 3.5 or 7 mg/kg
- The two formulations are differentiated by tablet form, color, size and packaging

Switching from Exjade dispersible tablets to Jadenu film-coated tablets:

- When switching from one formulation to another, a dose conversion must be calculated (please see below dose conversion table)

To avoid dosing errors, it is important that the prescription specifies the type of formulation (dispersible tablet or film-coated tablet), the prescribed dose in mg/kg/day, and the calculated total dose per day with strength of film-coated or dispersible tablets.

Further information

- A new posology and new method of administration must be applied when switching patients between dispersible tablets and film-coated tablets of deferasirox. Jadenu film-coated tablets are a strength-adjusted formulation of deferasirox with higher bioavailability compared to dispersible tablets

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مكتب شركة نوفارتس كونسلتنغ إي جي المكتب العلمي
ترخيص وزارة التجارة رقم ٣

الرياض
ص.ب :١٦٠٣٢
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تلفون : ٨٨٨٢ ٤٦٥
تليفاكس : ٨١٢٧ ٤٦٤

جدة
ص.ب : ٨٦٤٠
جدة : ٢١٤٩٢
تلفون : ٥٦٦٦ ٦٦٩
تليفاكس: ٣٥٣٤ ٦٦٣

الدمام
ص.ب : ٦٥٠٣
الدمام : ٣١٤٥٢
تلفون :٣١٧٤ ٨٣٤
تليفاكس : ٤٢٠٠ ٨٣٤

Important differences between the dispersible tablets and the film-coated tablets

	CURRENT FORMULATION	NEW FORMULATION
	EXJADE DISPERSIBLE TABLETS	**JADENU** FILM-COATED TABLETS
Strengths	125 mg, 250 mg, 500 mg	90 mg, 180 mg, 360 mg
Packaging		
Description of tablets	Round, white tablets available in three strengths: 125 mg (white), 250 mg (white), 500 mg (white) *(Tablets shown are not actual size)* 	Ovaloid, biconvex available in three strengths: 90 mg (light blue), 180 mg (medium blue), and 360 mg (dark blue) *(Tablets shown are not actual size)* 
Administration	Dispersible tablets should be mixed in water, orange juice, or apple juice. Dispersible tablets must not be chewed or swallowed whole.	Film-coated tablets can be swallowed whole with some water. Film-coated tablets can be crushed and administered by sprinkling onto soft food such as yogurt or applesauce (pureed apple). The dose should be immediately and completely consumed, and not stored for future use.
	Must be taken on an empty stomach, at least 30 minutes before food	May be taken on an empty stomach or with a light meal
	Contains lactose	Does not contain lactose

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Dose conversion between the dispersible tablets and the film-coated tablets

When converting the patient's prescription to Jadenu film-coated tablets, the dose of the film-coated tablets should be 30% lower than the dose of dispersible tablets, rounded to the nearest whole tablet.

	CURRENT FORMULATION EXJADE DISPERSIBLE TABLETS	NEW FORMULUATION Jadenu FILM-COATED TABLETS
Dose range	**10 to 40 mg/kg/day** Calculated and rounded to the nearest whole tablet size.	**7 to 28 mg/kg/day** Calculated and rounded to the nearest whole tablet size.
Recommended initial daily dose	20 mg/kg/day (TIO) 10 mg/kg/day (NTDT)	14 mg/kg/day (TIO) 7 mg/kg/day (NTDT)
Dose adjustment	Increments of 5-10 mg/kg	Increments of 3.5-7 mg/kg
Therapeutic dose range	Exjade dispersible tablets • 10 mg/kg/day • 20 mg/kg/day • 30 mg/kg/day • 40 mg/kg/day	Jadenu film-coated tablets • 7 mg/kg/day • 14 mg/kg/day • 21 mg/kg/day • 28 mg/kg/day
Calculated dose example for 50 kg patient receiving	Exjade dispersible tablets TIO: 20 mg/kg/day: 20 mg/kg * 50 kg = 1000 mg/day Two (2) 500 mg tablets NTDT: 10 mg/kg/day: 10 mg/kg * 50 kg = 500 mg/day One (1) 500 mg tablet	Jadenu film-coated tablets TIO: 14 mg/kg/day: 14 mg/kg * 50 kg = 700 mg/day Two (2) 360 mg/tablets NTDT: 7 mg/kg/day: 7 mg/kg * 50 kg = 350 mg/day One (1) 360 mg tablet

TIO, transfusional iron overload; NTDT, non-transfusion-dependent thalassaemia.

Please share this information with relevant colleagues and health care professionals.

Therapeutic indication

The new formulation is indicated for the same patient populations as the current formulation:

Jadenu film-coated tablets are indicated for the treatment of chronic iron overload due to frequent blood transfusions (≥7 ml/kg/month of packed red blood cells) in patients with beta thalassaemia major aged 6 years and older.

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Jadenu film-coated tablets also are indicated for the treatment of chronic iron overload due to blood transfusions when deferoxamine therapy is contraindicated or inadequate in the following patient groups:

- In paediatric patients with beta thalassaemia major with iron overload due to frequent blood transfusions (≥7 ml/kg/month of packed red blood cells) aged 2 to 5 years
- In adult and paediatric patients with beta thalassaemia major with iron overload due to infrequent blood transfusions (<7 ml/kg/month of packed red blood cells) aged 2 years and older
- In adult and paediatric patients with other anaemias aged 2 years and older

Jadenu film-coated tablets also are indicated for the treatment of chronic iron overload requiring chelation therapy when deferoxamine therapy is contraindicated or inadequate in patients with non-transfusion-dependent thalassaemia syndromes aged 10 years and older.

Please refer to the Summary of Product Characteristics (SmPC) for a complete description of the product.

Call for reporting

- As per the SmPC black triangle, doctors are prompted to report serious ADRs and certain selected ADRs

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse drug reactions.

Reporting suspected adverse drug reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse drug reactions **via the national reporting system.**

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Yours faithfully,

Malak Alowais
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تليفاكس : ٨١٢٧ ٤٦٤	تليفاكس: ٣٥٣٤ ٦٦٣	تليفاكس : ٤٢٠٠ ٨٣٤