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

Dear Healthcare Professional,

This is an introductory notification letter from Novartis informing you of a new formulation of deferasirox film coated tablets under the new trade name Jadenu®. The two formulations (film-coated tablets and dispersible tablets) have the same active ingredient (deferasirox) with a comparable pharmacokinetic profile.

- Jadenu film-coated tablets are a strength-adjusted formulation of deferasirox, with higher bioavailability compared to Exjade® dispersible tablets.
- Jadenu film-coated tablets are available in two strengths: 180 mg, and 360 mg. Both formulations can be differentiated by name, tablet form, colour, size and packaging.
- Jadenu film-coated tablets are dosed and administered differently from Exjade dispersible tablets. 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. A dose conversion table is included below.

Information on Jadenu film-coated tablets

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.
- The Jadenu ovaloid, biconvex film-coated tablets are available in three strengths: 180mg (medium blue), and 360mg (dark blue)
- The Jadenu film-coated tablet dose range is 7 to 28 mg/kg of patient body weight; with the dose calculated based on patient weight and rounded to the nearest whole tablet.
- The recommended initial daily dose of Jadenu film-coated tablets is 14mg/kg body weight (equivalent to Exjade dispersible tablets 20mg/kg body weight).
- Dose modifications of Jadenu for safety or efficacy should be in steps of 3.5 or 7 mg/kg body weight
- Jadenu film-coated tablets should be swallowed whole with some water. For patients who are unable to swallow whole tablets, film-coated tablets may be crushed and administered by sprinkling the full dose onto soft food, e.g. yogurt or applesauce (pureed apple). The dose should be immediately and completely consumed, and not stored for future use. The film-coated tablets may be taken on an empty stomach or with a light meal.
- 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.

- To avoid dosing errors, it is important that the prescription specify both the type of formulation (dispersible tablet or film-coated tablet) and the prescribed dose in mg/kg/day.

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

Exjade dispersible tablets	Jadenu film-coated tablets
Strengths: 250mg, 500mg (round, white tablets)	Strengths: 180mg, 360mg (oval, blue tablets)
Dispersible tablets	Film-coated tablets
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
Disperse tablets in water, orange juice, or apple juice. Dispersible tablets must not be chewed or swallowed whole.	Tablets can be swallowed whole with some water or crushed and administered by sprinkling onto soft food (e.g. yogurt or apple sauce).
Contains lactose	Does not contain lactose

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

Exjade dispersible tablets	Jadenu film-coated tablets
Dose range: 10-40mg/kg; calculated and rounded to the nearest whole tablet size.	Dose range: 7-28mg/kg; calculated and rounded to the nearest whole tablet size.
Dose adjustment: increments of 5-10mg/kg	Dose adjustment: increments of 3.5-7mg/kg
Exjade therapeutic dose range: 10mg/kg 20mg/kg 30mg/kg 40mg/kg (max. recommended dose)	Jadenu therapeutic dose range: 7mg/kg 14mg/kg 21mg/kg 28mg/kg (max. recommended dose)
Calculated dose example for 50kg patient receiving Exjade 30mg/kg: 30mg/kg * 50kg = 1500mg/day Three (3) 500mg tablets	Calculated dose example for 50kg patient receiving Jadenu 21mg/kg: 21mg/kg * 50kg = 1050mg/day Three (3) 360mg tablets

Further information

Therapeutic indication

Exjade and Jadenu are indicated for the same patient populations:

Exjade and Jadenu are indicated for the treatment of chronic iron overload due to blood transfusions (transfusional hemosiderosis) in adult and pediatric patients (aged 2 years and over).

Exjade and Jadenu are also indicated for the treatment of chronic iron overload in patients with non-transfusion-dependent thalassemia syndromes aged 10 years and older

Monitoring as per local label

- Jadenu causes rises in serum creatinine in some patients
- Jadenu causes rises in serum transaminases in some patients

Test	Frequency
Serum ferritin	Prior to therapy. Monthly
Serum creatinine and/or creatinine clearance	In duplicate prior to therapy. Weekly during first month of therapy and during first month after dose modification. Monthly thereafter.
Proteinuria	Monthly
Serum transaminases, bilirubin, alkaline phosphatase	Prior to therapy. Every 2 weeks during first month of therapy. Monthly thereafter.
Auditory and ophthalmic testing	Prior to therapy. Annually thereafter.
Body weight and height	Annually in paediatric patients.

Call for reporting

- Detailed information on the new formulation can be found in the enclosed label and Package Leaflet.

Reporting suspected adverse 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 reactions online to the Scientific Centre of Drug and Medical Technology Expertise after academician E. Gabrielyan of MoH of RA via www.pharm.am or call the hotline numbers: (+374 0) 20 05 05 and (+374 96) 22 05 05..

Company contact point
Asteria LLC, Nairi Zaryan 72/3 Street. Telephone:+37411519070.

e-mail: drugsafety.cis@novartis.com.

Annexes
Local label and Package Leaflet are available on official site Scientific center of medicine and medical technology expertise of Ministry of Health of Republic of Armenia:
http://pharm.cals.am/pharm/drug_images/index.php