Novartis Oncology

# Physician's reference checklist for Exjade/Jadenu (deferasirox) dosing and biological monitoring

**This document has been reviewed and approved by The Saudi Food and Drug Authority (SFDA).**

**This document highlights important information about requirements for Exjade dosing, dose adjustment and biological monitoring. For complete information about Exjade dosing, dose adjustment and biological monitoring, please refer to Exjade/Jadenu SmPC**

Exjade

Jadenu

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## Chronic transfusional iron overload

**After ~100 ml/kg of packed red blood cells (~20 units) or serum ferritin levels > 1,000 µg/l**
**--> Starting dose: 14 mg/kg/day (FCT)***

In case of starting treatment with deferasirox DT, the starting dose should be adapted. For reference the starting dose for Exjade DT is 20mg/kg/day (see HCP educational materials for more details)

## Non-transfusion dependent thalassemia

**If LIC ≥5 mg Fe/g dw or serum ferritin consistently >800 µg/l**

**--> Starting dose: 7 mg/kg/day (FCT)***

In case of starting treatment with deferasirox DT, the starting dose should be adapted. For reference the starting dose for Exjade DT is 10mg/kg/day (see HCP educational materials for more details)

**Start treatment**

## Biological monitoring

**Serum ferritin:**
- At baseline
- Routine monthly monitoring

**LIC (NTDT patients only):**
- At baseline
- Every 3 months (for pediatrics only, if serum ferritin is ≤800 µg/l)

**Serum creatinine:**
- At baseline in duplicate assessments
- Weekly, in the first month after initiation of deferasirox or after dose modification,
- Routine monthly monitoring

**Creatinine clearance and/or plasma cystatin C:**
- At baseline
- Weekly, in the first month after initiation of deferasirox or after dose modification
- Routine monthly monitoring

**Proteinuria:**
- At baseline
- Routine monthly monitoring

**Hepatic function (serum transaminases, bilirubin, alkaline phosphatase):**
- At baseline
- Every 2 weeks in the first month after initiation of deferasirox or after dose modification
- Routine monthly monitoring

**Body weight and height:**
- At baseline
- Routine yearly monitoring (pediatric patients)

**Auditory and ophthalmic testing (including fundoscopy)**
- At baseline
- Routine yearly monitoring

**Sexual development status (pediatric patients)**
- At baseline
- Routine yearly monitoring

**Concomitant medications to avoid drug interactions (type and concentration as per label)**
- Regularly
- Upon changes of therapy

**Adjust dose during treatment***

**Up-titrate if serum ferritin >2,500 µg/l**
- Increase in increments of 3.5 to 7 mg/kg/day (FCT, **Max dose: 28mg/kg/day**)

**Down-titrate if serum ferritin <2,500 µg/l**
- Decrease in steps of 3.5 to 7mg/kg/day (FCT)
- Closely monitor renal and hepatic function and serum ferritin levels

**Up-titrate if serum ferritin >2,000 µg/l or if LIC ≥7 mg Fe/g dw**
- Increase in increments of 3.5 to 7 mg/kg/day (FCT), **Max dose: 7mg/kg/day for pediatric patients and 14 mg/kg/day in adults**)

**Down-titrate if serum ferritin is ≤2,000 µg/l or if LIC <7 mg Fe/g dw**
- Decrease **to 3.5 to 7 mg/kg/day** (FCT)
- Closely monitor renal and hepatic function and serum ferritin levels

**Interrupt treatment**

- If target serum ferritin level is achieved or when it is consistently <500 µg/l

- If target serum ferritin level is achieved or is consistently **<300 µg/l or if LIC <3 mg Fe/g dw.** ***Re-treatment is not recommended.***

- If after dose reduction, when serum creatinine remains>33% above baseline and/or creatinine clearance < LLN (90 ml/min) that cannot be attributed to other causes
- If there is persistent proteinuria
- If there are abnormalities in levels of tubular markers and/or if clinically indicated**
- If there is a persistent and progressive increase in liver enzymes (serum transaminases) that cannot be attributed to other causes
- If there are disturbances of vision or hearing**
- If there is a development of unexplained cytopenia
- Other§

*Further examples of dose calculation or adjustments are provided in the label. *Note: When switching from deferasirox DT to Jadenu FCT, a lower dose is required. As referenced in SmPC: Due to different pharmacokinetic profiles, a 30% lower dose of Jadenu FCT is needed in comparison to the recommended dose for EXJADE DTs.*

** dose reduction can also be considered
§ refer to the product label for other dose adjustments/interruptions for renal and hepatic abnormalities, metabolic acidosis, SCARs , hypersensitivity reactions.
**FCT**= Film-Coated Tablets; **LIC** = Liver Iron Concentration; **NTDT** = Non-Transfusion Dependent Thalassemia; **DT** = Dispersible Tablets

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**Patient Safety Department Novartis Pharma AG - Saudi Arabia -.**
Toll Free Number: 8001240078
Phone: +966112658100
Fax: +966112658107
Email: adverse.events@novartis.com
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**Saudi Food and Drug Authority National Pharmacovigilance Center**
Unified Contact Center: 19999
Email: npc.drug@sfda.gov.sa
Or by online: https://ade.sfda.gov.sa

NOVARTIS

Novartis Saudi Ltd. “Novartis”
Laysen Valley, king Khaled road, Building Number: 7892, West Umm Al Hamam District. Riyadh, KSA.
P.O. Box 12329
Riyadh, Saudi Arabia
Tel.: +966112658100
Fax: +966112658107