

Physician's reference checklist for Exjade (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 EU-SmPC

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/granules)*

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/ granules)*

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

Up-titrate if serum ferritin >2,500 µg/l

- Increase in increments of 3.5 to 7 mg/kg/day (FCT/ granules, 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/ granules)
- Closely monitor renal and hepatic function and serum ferritin levels

Adjust dose during treatment*

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/ granules, 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/ granules)
- Closely monitor renal and hepatic function and serum ferritin levels

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

Interrupt treatment

- 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
- Other⁵

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

** dose reduction can also be considered

⁵ 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; NTD = Non-Transfusion Dependent Thalassemia; DT = Dispersible Tablets

يمكنك الإبلاغ عن أي أعراض جانبية أو شكاوى أو لطلب نسخ إضافية من خلال
شركة نوفارتس - السعودية - قسم سلامة المرضى

الرقم المجاني: 8001240078

الهاتف: ٠٠٩٦٦١١٢٦٥٨١٠٠

الفاكس: ٠٠٩٦٦١١٢٦٥٨١٠٧

الايمل: adverse.events@novartis.com

أو عن طريق الإنترنت: <https://www.report.novartis.com/ar>

الهيئة العامة للغذاء والدواء، المركز الوطني للتبقيظ الدوائي

مركز الاتصال الموحد: 19999

الفاكس: + 966112057662

الايمل: npc.drug@sfd.gov.sa

أو عن طريق الإنترنت: <https://ade.sfda.gov.sa/>

You can report any problem or adverse events or request additional copies of the materials through:

Patient Safety Department Novartis Pharma AG - Saudi Arabia -

Toll Free Number: 8001240078

Phone: +966112658100

Fax: +966112658107

Email: adverse.events@novartis.com

Or by online: <https://report.novartis.com/>

Saudi Food and Drug Authority National Pharmacovigilance Center

Unified Contact Center: 19999

Fax: +966112057662

Email: npc.drug@sfd.gov.sa

Or by online: <https://ade.sfda.gov.sa>

“For extra copies, please contact Novartis as per below contact details”



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