Novartis Oncology

Physician's reference checklist for Exjade®▼ (deferasirox) dosing and biological monitoring

▼This medicinal product is subject to additional monitoring. Reporting suspected adverse reactions of the medicinal product is important to Novartis and the HPRA. It allows continued monitoring of the benefit/risk profile of the medicinal product. All suspected adverse reactions should be reported via HPRA Pharmacovigilance, website: www.hpra.ie. Adverse events could also be reported to Novartis preferably via www.report.novartis.com or by email: drugsafety.dublin@novartis.com or by calling 01 2080 612.

This document highlights the main 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 SmPC, which is available at www.medicines.ie.

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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)***

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)***

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 in 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 7 mg/kg/day** (FCT) in patients treated with doses >21mg/kg/day and closely monitor renal, 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 in increments of **3.5 to 7 mg/kg/day** (FCT) & closely monitor renal and hepatic function and serum ferritin levels*
- For patients in whom the dose was increased to >7 mg/kg, a dose reduction to **7 mg/kg or less** is recommended*

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, *treatment should be stopped***

- If after dose reduction, when serum creatinine remains >33% above baseline and/or creatinine clearance < LLN (90 ml/min) that cannot be attributed to another cause
- If there is a 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 SmPC. *Note: When switching from deferasirox DT to Exjade FCT, a lower dose is required. As referenced in SmPC: Due to different pharmacokinetic profiles, a 30% lower dose of EXJADE FCT is needed in comparison to the recommended dose for deferasirox DTs.*

**Dose reduction can also be considered.

§Refer to the SmPC 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; **LLN** = lower limit of the normal range

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