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 after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk profile of the medicinal product. All suspected adverse reactions should be reported to HPRA Pharmacovigilance at www.hpra.ie. Adverse events can also be reported to Novartis preferably at www.novartis.com/report, by emailing 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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