Physician's reference checklist for Deferasirox dosing and biological monitoring

Adverse events should be reported.
Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
Adverse events should also be reported to SUN Pharma via t Drugsafety Europe <drugsafety.europe@sunpharma.com> or online through the pharmacovigilance intake (PVI) tool at www.sunpharma.com/adverse-event-reporting

If you have a question about the product, please contact Medical Information on Tel: *0208 848 5052 or by email at medinfoeurope@sunpharma.com*.

This document highlights important information about requirements for deferasirox dosing, dose adjustment and biological monitoring. For more information refer to the deferasirox SmPC.

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Approved on:

Version 1

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 paediatric 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). 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 (90ml/min) that cannot be attributed to other causes.
- 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 label.

**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; **DW** = Dry Weight **LIC** = Liver Iron Concentration; **NTDT** = Non-Transfusion Dependent Thalassemia

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