Physician's reference checklist for Deferasirox▼ dosing and biological monitoring

Adverse events should be reported.

Please report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme, via the Yellow Card website www.mhra.gov.uk/yellowcard, the free Yellow Card app available in Apple App Store or Google Play Store. Alternatively, you can call 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

By reporting suspected adverse drug reactions, you can help provide more information on the safety of this medicine.

Healthcare Professionals may also report any adverse events associated with the use of Deferasirox to Northumbria Pharma, by phone on 01740 618611.

If you have any question about the product, please contact Medical Information on +44 (0)1740 618611 or by email at ukmedinfo@northumbriapharma.com

Approved by MHRA [to be completed upon approval]

This document highlights important information about requirements for Deferasirox▼ dosing, dose adjustment and biological monitoring. For more information refer to the Deferasirox SmPC (to be completed upon registration**)**

Pharmathen
Innovation inspired by life

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 7mg/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 to7mg/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 to7 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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