Physician’s reference checklist for Deferasirox (deferasirox) dosing and biological monitoring

Adverse events should be reported.
Reporting forms and information can be found at www.mhra.gov.uk/yellowcard.
Adverse events should also be reported to Torrent Pharma UK Ltd via email to:
Medinfo.Torrent@apcerls.com or by telephoning Torrent Medical Information team on 0800 0885 366

This document highlights important information about requirements for Deferasirox.
(deferasirox) dosing, dose adjustment and biological monitoring.

For more information refer to the Deferasirox SmPC: https://torrentpharmauk.healthcare/deferasirox

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 Deferasirox is 20mg/kg/day (see HCP educational materials for more details)

Non-transfusion dependent thalassaemia

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 Deferasirox is 10mg/kg/day (see HCP educational materials for more details)

Treatment Start

Biological Monitoring

Serum ferritin:
- At baseline
- Routine monthly monitoring

LIC (NTDT patients only):
- At baseline
- Every 3 months (for paediatrics 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 (paediatric 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 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/ granules) or 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 7mg/kg/ day (FCT/ granules Max dose: 7mg/kg/day for paediatric 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 steps of 3.5 to 7mg/kg/day (FCT/ granules) or 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. Note: When switching from Deferasirox DT to Deferasirox FCT/granules, a lower dose is required. As referenced in SmPC: Due to different pharmacokinetic profiles, a 30% lower dose of Deferasirox FCT/Granules is needed in comparison to the recommended dose for Deferasirox DTs.

** 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 Thalassaemia; DT= Dispersible tablets