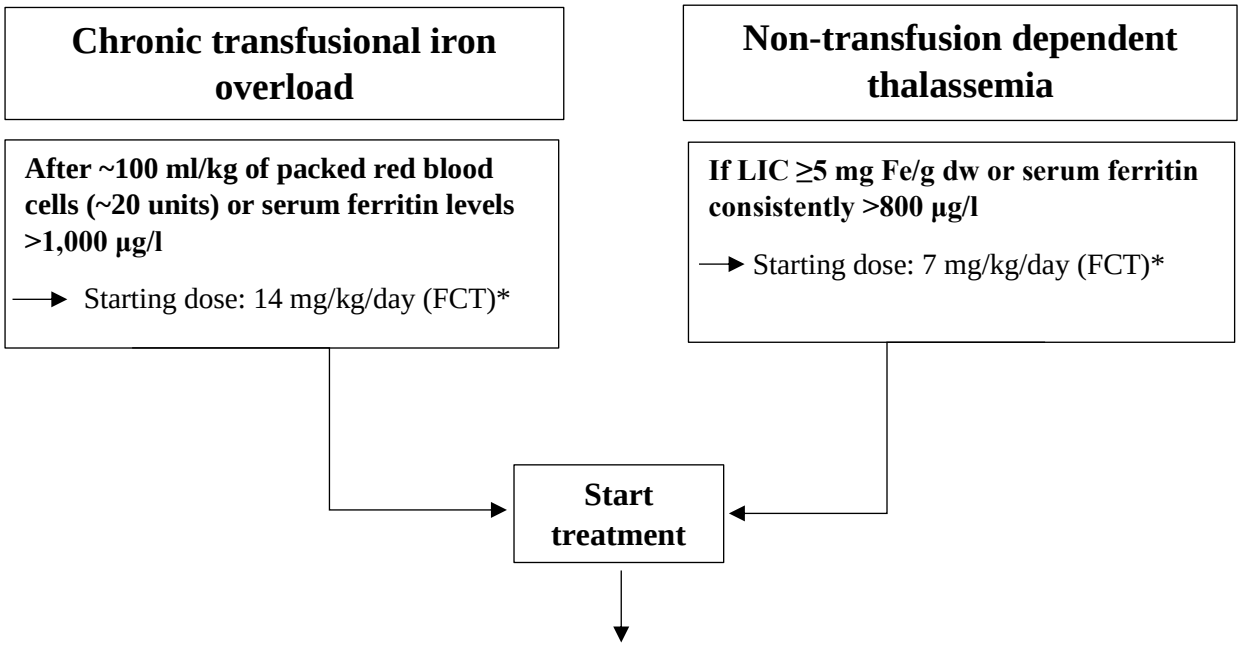
Physician’s reference checklist for Deferasirox Abdi (deferasirox) dosing and biological monitoring

Adverse events should be reported.

Reporting forms and information can be found at www.mhra.gov.uk/yellowcard

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

For more information refer to the Deferasirox Abdi SmPC (www.mhra.gov.uk)



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

<u>Auditory and ophthalmic testing (including fundoscopy)</u>

- At baseline
- Routine yearly monitoring

<u>Sexual development status (pediatric patients)</u>

- At baseline
- Routine yearly monitoring

<u>Concomitant medications to avoid drug interactions (type and concentration as per label)</u>

- Regularly
- Upon changes of therapy

Adjust dose during treatment

Up-titrate if serum ferritin >2,500 µg/l

- Increase in increments of 3.5 to7 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 7mg/kg/day (FCT) or 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 to7 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 to7 mg/kg/day (FCT) 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)
- 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)
- 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.

[$] 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