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

Adverse events should be reported to the MAH.

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

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://www.medicines.org.uk/emc).

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)* Start treatment 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

<u>Creatinine clearance and/or plasma</u> <u>cystatin C</u>:

- · At baseline
- Weekly, in the first month after initiation of deferasirox or after dose modification
- · Routine monthly monitoring

Proteinuria:

- At baseline
- · Routine monthly monitoring

<u>Hepatic function (serum transaminases, bilirubin, alkaline phosphatase):</u>

- 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)

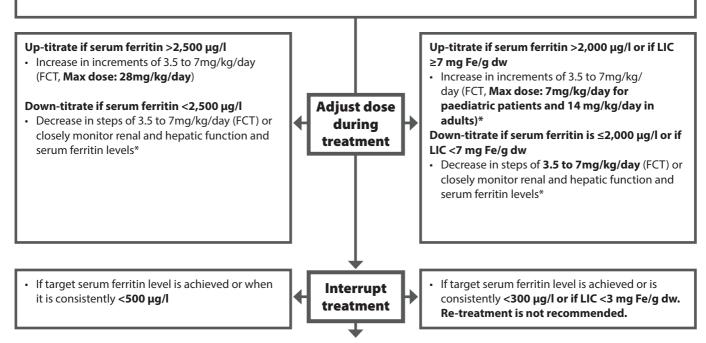
- · At baseline
- Routine yearly monitoring

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

- · At baseline
- · Routine yearly monitoring

Concomitant medications to avoid drug interactions (type and concentration as per label)

- Regularly
- · Upon changes of therapy



- 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 Thalassaemia

MHRA Approval 11.02.2022 Version 1