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

Adverse events should be reported.

Reporting forms and information can be found at <a href="www.mhra.gov.uk/yellowcard">www.mhra.gov.uk/yellowcard</a> 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 <a href="mailto:cdr.drugsafety.europe@sunpharma.com">cdrugsafety.europe@sunpharma.com</a> or online through the pharmacovigilance intake (PVI) tool at <a href="www.sunpharma.com/adverse-event-reporting">www.sunpharma.com/adverse-event-reporting</a>

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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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)\* Start treatment 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)\*

#### 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

#### **Biological 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:

- · Atbaseline
- · Routine monthly monitoring

#### Hepatic function (serum transaminases, bilirubin, alkaline phosphatase):

- Atbaseline
- Every 2 weeks in the first month after initiation of deferasirox or after dose modification
- · Routine monthly monitoring

#### Body weight and height:

- Atbaseline
- Routine yearly monitoring in paediatric patients

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

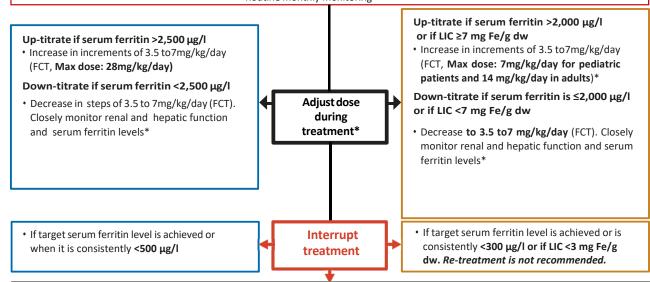
- At baseline
- · Routine yearly monitoring

#### <u>Sexual development status</u> (pediatric 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) 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.