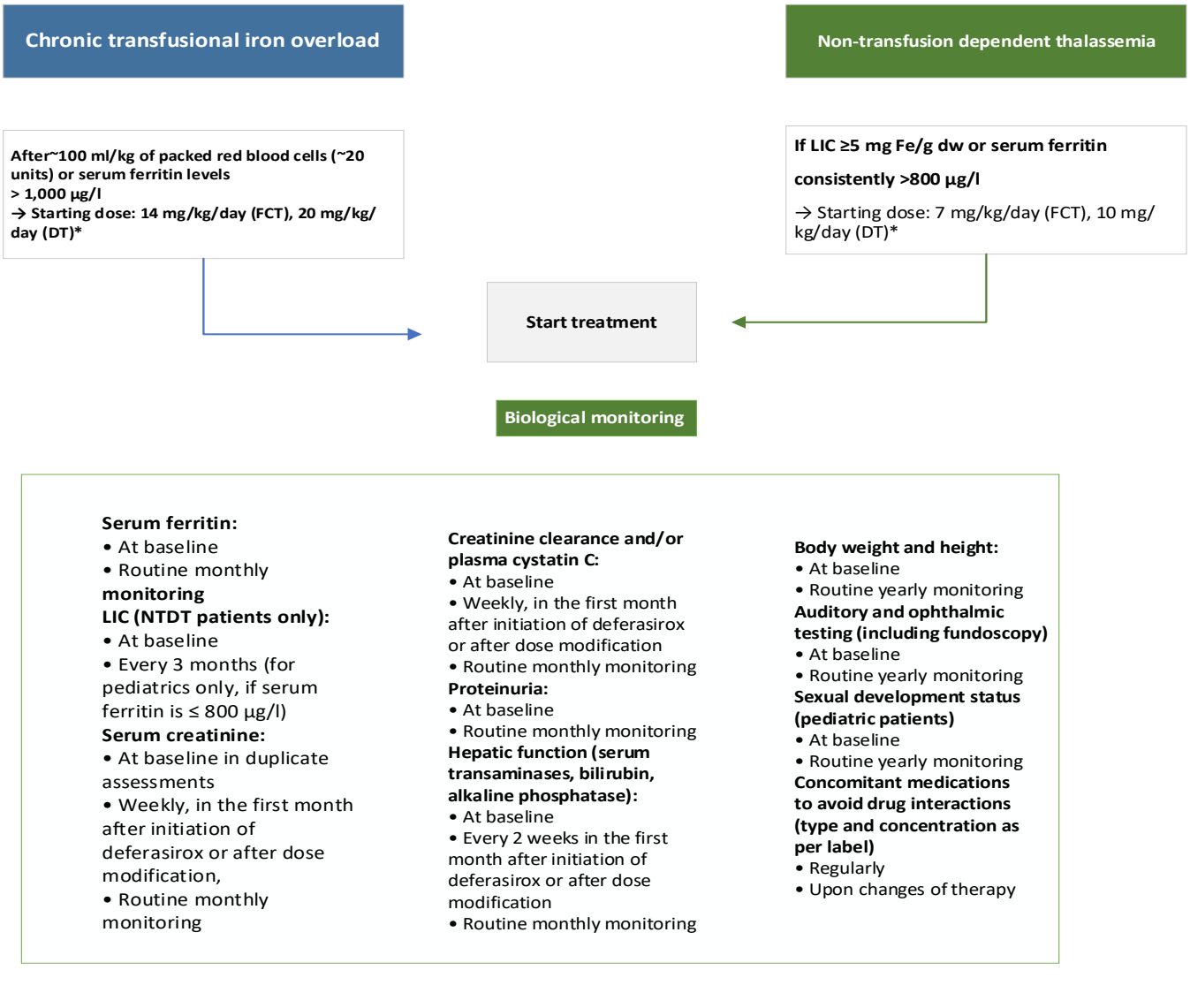
Physician's reference checklist for Toxefro® (Deferasirox) dosing and biological monitoring

Toxefro® 250 mg Dispersible Tablets
Toxefro® 500 mg Dispersible Tablets
Toxefro® 90mg F.C Tablets
Toxefro® 180mg F.C Tablets
Toxefro® 360mg F.C Tablets

www.mspharma.com


Chronic transfusional iron overload
Non-transfusion dependent thalassemia
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), 20 mg/kg/day (DT)*
If LIC ≥5 mg Fe/g dw or serum ferritin consistently >800 µg/l
→ Starting dose: 7 mg/kg/day (FCT), 10 mg/kg/day (DT)*
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
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
Up-titrate if serum ferritin >2,500 µg/l
• Increase in increments of 3.5 to 7 mg/kg/day (FCT, Max dose: 28mg/kg/day), or 5 to 10 mg/kg/day (DT, Max dose: 40 mg/kg/day)
Down-titrate if serum ferritin <2,500 µg/l
• Decrease insteps of 3.5 to 7 mg/kg/day (FCT), or 5to 10 mg/kg/day (DT) 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 7 mg/kg/day (FCT, Max dose: 7mg/kg/day for pediatric patients and 14 mg/kg/day in adults), or 5 to 10 mg/kg/day (DT, Max dose: 10mg/kg/day for pediatric patients and 20mg/kg/day for adults)*
Down-titrate if serum ferritin is ≤2,000 µg/l or if LIC <7 mg Fe/g dw
• Decrease to 3.5 to 7 mg/kg/day (FCT), or 5 to 10 mg/kg/day (DT) or closely monitor renal and hepatic function and serum ferritin levels*
• If target serum ferritin level is achieved or when it is consistently <500 µg/l
Interrupt treatment
• 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 (90 ml/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; **DT** = Dispersible Tablets; **LIC** = Liver Iron Concentration; **NTDT** = Non-Transfusion Dependent Thalassemia

Call for reporting:

Additional copies of the materials can be obtained by contacting MS pharma for pharmaceuticals.
Report suspected adverse drug reactions associated with Toxefro® (Deferasirox) by contacting:

Pharmacovigilance Department at MS Pharma:

- Email: pharmacovigilance@mspharma.com
- Website: www.mspharma.com
- Phone No: + 966112790122 Ext. 6013

The National Pharmacovigilance Center (NPC): (Saudi food and drug authority)

- Email: npc.drug@sfda.gov.sa
- Call Center: 19999
- Website: https://ade.sfda.gov.sa/
- QR Code