

Novartis Oncology

Physician's reference checklist for Exjade[®] (deferasirox) dosing and biological monitoring

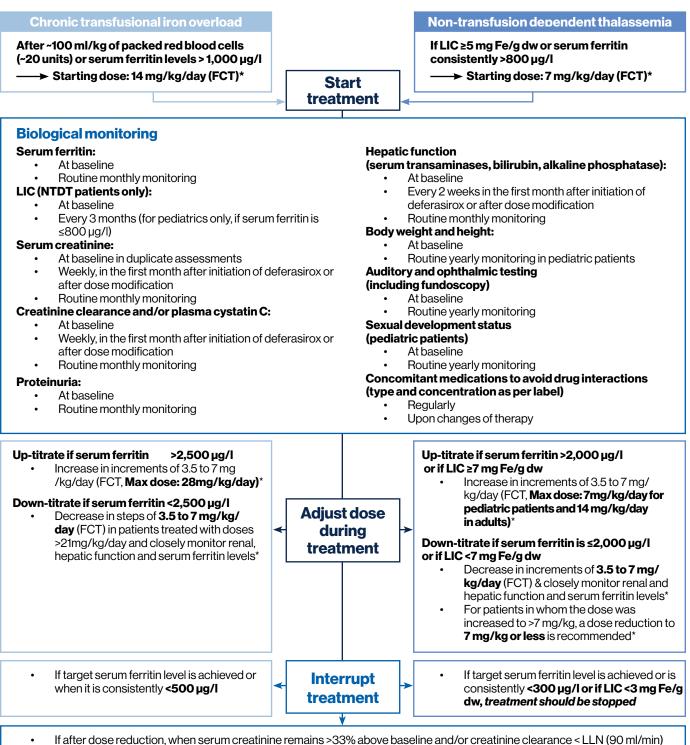
▼This medicinal product is subject to additional monitoring. Reporting suspected adverse reactions of the medicinal product is important to Novartis and the HPRA. It allows continued monitoring of the benefit/risk profile of the medicinal product. All suspected adverse reactions should be reported via HPRA Pharmacovigilance, website: www.hpra.ie. Adverse events could also be reported to Novartis preferably via www.report.novartis.com or by email: drugsafety.dublin@novartis.com or by calling 01 2080 612.

This document highlights the main information about requirements for Exjade dosing, dose adjustment and biological monitoring. For complete information about Exjade dosing, dose adjustment and biological monitoring, please refer to Exjade SmPC, which is available at www.medicines.ie.



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- that cannot be attributed to another cause
- 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 SmPC. Note: When switching from deferasirox DT to Exjade FCT, a lower dose is required. As referenced in SmPC: Due to different pharmacokinetic profiles, a 30% lower dose of EXJADE FCT is needed in comparison to the recommended dose for deferasirox DTs.

"Dose reduction can also be considered.

[§]Refer to the SmPC for other dose adjustments/interruptions for renal and hepatic abnormalities, metabolic acidosis, SCARs, hypersensitivity reactions.

FCT= Film-Coated Tablets; LIC = Liver Iron Concentration; NTDT = Non-Transfusion Dependent Thalassemia; LLN = lower limit of the normal range



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