

SUMMARY OF RECOMMENDATIONS*

Monitoring Patients Receiving KYNAMRO®

TIMING	RECOMMENDATION
Prior to initiating treatment	<input type="checkbox"/> Measure transaminases (ALT, AST), alkaline phosphatase, and total bilirubin
During the first year of treatment	<input type="checkbox"/> Instruct patients to report symptoms of possible liver problems <input type="checkbox"/> Conduct liver-related tests monthly (ALT and AST, at minimum)
After the first year of treatment	<input type="checkbox"/> Instruct patients to report symptoms of possible liver problems <input type="checkbox"/> Conduct liver-related tests at least every 3 months (ALT and AST, at a minimum)
If liver enzyme elevations are observed:	<ul style="list-style-type: none"> • If elevations in ALT or AST levels $\geq 3X$ and $< 5X$ ULN are observed, confirm elevation with a repeat measurement within 1 week. If confirmed, withhold dosing, obtain additional liver-related tests if not already measured (such as total bilirubin, alkaline phosphatase, and INR) and investigate to identify the probable cause • If elevations in ALT or AST levels $\geq 5X$ ULN are observed, withhold dosing, obtain additional liver-related tests if not already measured (such as total bilirubin, alkaline phosphatase, and INR) and investigate to identify the probable cause • If resuming KYNAMRO after transaminases resolve to $< 3X$ ULN, consider monitoring liver-related laboratory tests more frequently
For patients with:	<ul style="list-style-type: none"> • Persistent or clinically significant elevations in transaminases • Transaminase elevations accompanied by clinical symptoms of liver injury, increases in bilirubin $\geq 2X$ ULN, or active liver disease • Clinically significant liver toxicity
Discontinue treatment with KYNAMRO and investigate to identify the probable cause	
*Please see the Prescribing Information for more information.	
Report all suspected adverse events associated with KYNAMRO. Please contact Genzyme at 1-800-745-4447 or the FDA at 1-800-FDA-1088 (332-1088) or www.fda.gov/medwatch .	

