Maximum Maintenance Dose of Mircera

This article responds to your request for information on the maximum maintenance dose of Mircera® (methoxy polyethylene glycol-epoetin beta) for the treatment of patients with anemia associated with chronic kidney disease. This response was developed according to the principles of evidence-based medicine and contains data from clinical trials.

Maintenance dose recommendations

Mircera dose is adjusted based on hemoglobin level changes and the patient's individual target level (Table 1). Dose adjustments should not be made more frequently than once a month. Roche does not have a recommendation for the maximum dose of Mircera.

Table 1. Mircera dose adjustments based on Hb level changes

If the Hb level increases	then Mircera dose may be...	If the Hb level continues to increase
by <1.0 g/mL (0.621 mmol/L) per month	increased by ~25% monthly until the individual target Hb level is reached.	
by >2.0 g/dL (1.24 mmol/L) per month	decreased by ~25%.	interrupt therapy until Hb level decreases by ~0.35 g/dL (0.22 mmol/L) per week. Restart dose at ~25% below the previous dose.
and is approaching 12 g/dL (7.45 mmol/L)	decreased by ~25%.	interrupt therapy until Hb level decreases by ~0.35 g/dL (0.22 mmol/L) per week. Restart dose at ~25% below the previous dose.

Maximum maintenance dose used in clinical studies

In a randomized open-label multi-center controlled study evaluating the efficacy and safety of subcutaneous Mircera for the maintenance treatment of anemia in patients with chronic kidney disease who are on dialysis, the highest dose administered was

- 2,300 µg or ~45 µg/kg in a female patient (51.0 kg)
- 5,129 µg or ~56 µg/kg in a male patient (90.2 kg).[1,2]

Clinical considerations for potential lack of efficacy with the current dose

The most common reasons for incomplete response to ESAs are iron deficiency and inflammatory disorders.[3] Other conditions that may compromise effectiveness of ESA therapy are

- chronic blood loss
- bone marrow fibrosis
- severe aluminum overload due to treatment of renal failure
- folic acid or vitamin B12 deficienies, and
- hemolysis.

Precaution related to Pure Red Cell Aplasia

If all conditions listed above are excluded and the patient has a sudden drop of hemoglobin associated with reticylocytopenia and anti-erythopoietin antibodies, examination of the bone marrow for the diagnosis of Pure Red Cell Aplasia (PRCA) should be considered.[4] If PRCA is diagnosed, Mircera therapy should be discontinued and patients should not be switched to another ESA.

References

1. Roche Internal Clinical Study Report (BA16740). Accessed on 12 Jul 2023.

2. A Study of Subcutaneous Mircera for the Treatment of Anemia in Dialysis Patients. ClinicalTrials.gov Identifier: NCT00077623. Accessed August 10, 2023. .
https://classic.clinicaltrials.gov/ct2/show/NCT00077623

3. NKF-KDOQI Clinical Practice Guidelines for Anemia of Chronic Kidney Disease: update 2000. Am J Kidney Dis 2001;37:S182-238. https://www.ncbi.nlm.nih.gov/pubmed/11229970

4. Roche Internal Regulatory Document. Accessed 12 Jul 2023.