Brand Name: Mircera
Generic: methoxy polyethylene glycol epoetin beta
Type: monoclonal antibody
Year Accepted/Phase: 2007

Mechanism:

methoxy polyethylene glycol epoetin beta is a continuous erythropoietin receptor activator (CERA) that binds to and activates the erythropoietin receptor. Its polyethylene glycol (PEG) moiety extends its half-life, allowing for less frequent dosing compared to traditional erythropoiesis-stimulating agents (ESAs).

Chemical Structure: N/A

Indication:

Mircera is indicated for the treatment of anemia associated with chronic kidney disease (CKD) in both dialysis and non-dialysis patients.

Clinical trials:

MAXIMA Trial (Phase III)
Pubmed: https://pubmed.ncbi.nlm.nih.gov/24824768/
Purpose: Compare the efficacy and safety of Mircera administered once every two weeks versus epoetin (three times weekly) in CKD patients on dialysis.
Dates: Results published in 2007.
Results: Mircera was shown to be as effective as epoetin in maintaining hemoglobin levels within the target range. The study demonstrated that Mircera could be administered less frequently (every two weeks) with comparable efficacy and safety to more frequently administered epoetin.
Impact: These findings supported the use of Mircera as a convenient, less frequently dosed alternative to traditional ESAs for CKD patients on dialysis.

PROTOS Trial (Phase III)
Pubmed: https://pubmed.ncbi.nlm.nih.gov/17699476/
Purpose: Assess the efficacy and safety of Mircera for the treatment of anemia in CKD patients not on dialysis.
Dates: Results published in 2007.
Results: Mircera was effective in maintaining hemoglobin levels within the target range, similar to darbepoetin alfa administered every two weeks. Mircera allowed for less frequent dosing (once every four weeks) compared to darbepoetin.
Impact: This trial expanded the potential use of Mircera to CKD patients not on dialysis, offering a less frequent dosing regimen and improving patient convenience.

ARCTOS Trial (Phase III)
Pubmed: https://pubmed.ncbi.nlm.nih.gov/18287255/
Purpose: Evaluate the efficacy and safety of Mircera in CKD patients not on dialysis previously treated with darbepoetin alfa or epoetin.
Dates: Results published in 2007.
Results: The trial demonstrated that patients previously treated with darbepoetin alfa or epoetin could be successfully switched to Mircera, maintaining stable hemoglobin levels with less frequent dosing (every two or four weeks). Safety profiles were similar between treatment groups.
Impact: This study supported the use of Mircera as a suitable alternative for patients transitioning from other ESAs, with the benefit of reduced dosing frequency.

MAINTAIN Trial (Phase III)
Pubmed: https://pubmed.ncbi.nlm.nih.gov/37207300/
Purpose: Compare the efficacy and safety of Mircera versus darbepoetin alfa in maintaining hemoglobin levels in CKD patients on dialysis.
Dates: Results published in 2008.
Results: Mircera was as effective as darbepoetin alfa in maintaining target hemoglobin levels, with comparable safety profiles. Mircera's less frequent dosing schedule (every two or four weeks) was well-tolerated and provided effective anemia management.
Impact: The findings reinforced the suitability of Mircera for anemia management in CKD patients on dialysis, offering the advantage of reduced dosing frequency.