Generic Name:
Afamelanotide
Trade Name:
Scenesse
Company:
Clinuvel
Notes:

On October 8, FDA approved afamelanotide to increase pain-free light exposure in adult patients with a history of phototoxic reactions from erythropoietic protoporphyria. Erythropoietic protoporphyria is a rare disorder caused by mutations leading to impaired activity of ferrochelatase, an enzyme involved in heme production. The decrease in ferrochelatase activity leads to an accumulation of protoporphyrin IX (PPIX) in the body. Light reaching the skin can react with PPIX, causing intense skin pain and skin changes, such as redness and thickening.

Afamelanotide, a melanocortin-1 receptor agonist, increases the production of eumelanin in the skin independent of exposure to sunlight or artificial light sources. It is an implant that is administered subcutaneously.

Common adverse effects are implant site reaction, nausea, oropharyngeal pain, cough, fatigue, skin hyperpigmentation, dizziness, melanocytic nevus, respiratory tract infection, somnolence, nonacute porphyria. and skin irritation.

Afamelanotide should be administered by a health professional who is proficient in the S.C. implantation procedure and has completed the applicant-provided training. The drug may induce skin darkening, and a full body skin examination is recommended for patients twice a year. In addition, patients are encouraged to maintain sun protection measures during treatment to prevent phototoxic reactions related to erythropoietic protoporphyria.

Medication Monitor Categories:
New Drug Approvals