NOVARTIS

FRAIZERON® (secukinumab)

150 mg Powder for solution for injection

Basic Succinct Statement (BSS)

Code: BSS RD 21 Mar 19 v2; APPR 12 Oct 20
This material is only meant for Healthcare Professionals

Fraizeron®

Important note: Before prescribing, consult full prescribing information.

Presentation:

Secukinumab. Powder for solution for subcutaneous injection containing 150 mg of secukinumab.

Indications:

♦ Plaque psoriasis:
Fraizeron is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.

♦ Psoriatic arthritis:
Fraizeron, alone or in combination with methotrexate (MTX), is indicated for the treatment of active psoriatic arthritis in adult patients when the response to previous disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate.

♦ Ankylosing spondylitis
Fraizeron is indicated for the treatment of active ankylosing spondylitis in adults who have responded inadequately to conventional therapy.

Dosage and administration:

♦ Plaque psoriasis:
The recommended dose is 300 mg by subcutaneous injection with initial dosing at weeks 0, 1, 2, 3, and 4 followed by monthly maintenance dosing. Each 300 mg dose is given as two subcutaneous injections of 150 mg. For some patients, a dosage of 150mg may be acceptable.

♦ Psoriatic Arthritis:
The recommended dose is 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3, and 4 followed by monthly maintenance dosing. Based on clinical response, the dose can be increased to 300 mg.
For patients who are anti-TNF-alpha inadequate responders (IR) or patients with concomitant moderate to severe plaque psoriasis, the recommended dose is 300 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3, and 4 followed by monthly maintenance dosing starting at Week 4. Each 300 mg dose is given as two subcutaneous injections of 150 mg.

♦ Ankylosing spondylitis

The recommended dose is 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3, and 4 followed by monthly maintenance dosing. Based on clinical response, the dose can be increased to 300 mg.

Contraindications:

♦ Fraizeron is contraindicated in patients who have/had severe hypersensitivity reactions reaction to the active substance or to any of the excipients.

Warnings and precautions:

♦**Infections**: Caution in patients with chronic or history of recurrent infection. If a patient develops a serious infection, the patient should be closely monitored and Fraizeron should not be administered until the infection resolves. Anti-tuberculosis therapy should be considered prior to initiation of Fraizeron in patients with latent tuberculosis. Fraizeron should not be given to patients with active tuberculosis.

♦**Inflammatory bowel disease:** Patients with active inflammatory bowel disease (e.g. Crohn's disease and ulcerative colitis) treated with Fraizeron should be followed closely.

♦**Hypersensitivity reactions**: Rare cases of anaphylactic reactions have been observed during clinical trials. Administration of Fraizeron should be discontinued immediately and appropriate therapy initiated if an anaphylactic or other serious allergic reaction occurs.

♦**Vaccinations:** Fraizeron should not be given concurrently with live vaccines.

Pregnancy, lactation, females and males of reproductive potential

Pregnancy: Fraizeron should be used during pregnancy only if the benefits clearly outweigh the potential risks.

Lactation: Caution should be exercised when Fraizeron is administered to a woman who is breast-feeding.

Adverse drug reactions:

Very common (≥10%):

Upper respiratory tract infections (nasopharyngitis, upper respiratory tract infection, rhinitis, pharyngitis, sinusitis, tonsillitis).

Common (≥1 to <10%):

Oral herpes, diarrhea, urticaria, rhinorrhea.

Uncommon (≥0.1 to <1%):

Oral candidiasis, neutropenia, tinea pedis, conjunctivitis.

Frequency not known:

Mucosal and cutaneous candidiasis

Interactions:

Live vaccines should not be given concurrently with Fraizeron.

In a study in subjects with plaque psoriasis, no interaction was observed between secukinumab and midazolam (CYP 3A4 substrate).