

Eldixia[®]

Guselkumab



Description

Eldixia[®] syringe contains guselkumab as an active substance.



Dosage Form

100 mg/1 mL sterile pre-filled syringe for subcutaneous injection



Mechanism of Action

Guselkumab is a human IgG1 monoclonal antibody that selectively binds to IL-23, thereby reducing serum levels of IL-17A, IL-17F, and IL-22. Guselkumab also inhibits the release of proinflammatory cytokines and chemokines.



Labeled Indications

- Moderate to severe plaque psoriasis in adults and pediatric patients 6 years of age and older who also weigh at least 40 kg who are candidates for systemic therapy or phototherapy.
- Active psoriatic arthritis in adults and pediatric patients 6 years of age and older who also weigh at least 40 kg
- Moderately to severely active ulcerative colitis in adults
- Moderately to severely active Crohn's disease in adults



Dosing

The dosing is for the subcutaneous (SubQ) formulation of guselkumab.

Adults

Plaque psoriasis: 100 mg at weeks 0, 4, and then every 8 weeks thereafter.

Psoriatic arthritis: 100 mg at weeks 0, 4, and then every 8 weeks thereafter; may be administered alone or in combination with conventional disease-modifying antirheumatic drugs.

Ulcerative Colitis and Crohn's Disease:

Induction: 400 mg on weeks 0, 4, and 8.

Maintenance: 100 mg every 8 weeks beginning at week 16 **or** 200 mg every 4 weeks beginning at week 12.

Pediatric patients ≥6 years, weighing ≥40 kg

Plaque psoriasis: 100 mg at week 0 and week 4, then 100 mg every 8 weeks thereafter.

Psoriatic arthritis: 100 mg at week 0 and week 4, then 100 mg every 8 weeks thereafter.

may be administered alone or in combination with conventional disease-modifying antirheumatic drugs.



Adverse Reactions

The most frequently reported adverse reactions are:

Gastrointestinal: Abdominal pain (12% to 14%), Immunologic: Antibody development (children, adolescents: 18%; adults: 2% to 11%, neutralizing: 5% to 16%), Infection: Infection (23%; severe infection: ≤2%), and Respiratory: Respiratory tract infection (4% to 38%)



Contraindications

Serious hypersensitivity to guselkumab or any component of the formulation.



Warnings and Precautions

Antibody formation (has not been associated with loss of efficacy), Hepatotoxicity, Hypersensitivity reactions, Infections, and Tuberculosis



Administration

- Eldixia® single-dose pre-filled syringe is administered subcutaneously in the lower abdomen (except for 2 inches around the navel), the front of the thighs, or the back of the upper arms.
- Patients may self-administer after appropriate training in preparation and administration, with appropriate follow-up monitoring.
- Do not inject within 2 inches of the navel or into areas where the skin is tender, bruised, red, hard, thick, scaly, or affected by psoriasis. Avoid areas with scars or stretch marks.
- Administer the 400 mg or 200 mg doses, at separate injection sites.



Storage and Handling

- Keep the Eldixia® pre-filled syringe in the outer carton to protect it from light.
- Store in a refrigerator (2°C-8°C) and avoid freezing.
- Do not use this medicine if it appears cloudy, discolored, or contains large particles.
- Before use, remove the carton from the refrigerator and keep the pre-filled syringe inside the carton to allow it to reach room temperature by waiting for 30 minutes.
- Do not shake.



Reproductive, Pregnancy and Breastfeeding Considerations

Reproduction

Patients who may become pregnant should use effective contraception while using Eldixia® and for at least 12 weeks after the last Eldixia® dose.

Pregnancy

Eldixia® should not be used during pregnancy as the effects of this medicine in pregnant women are not known.

Breastfeeding

The decision to breastfeed during therapy should consider the risk of infant exposure, the benefits of breastfeeding to the infant, and the benefits of treatment to the mother.



Monitoring Parameters

- Evaluate pregnancy status prior to use in patients who could become pregnant.
- CBC and LFT (every 3 to 6 months), complete metabolic panel, C-reactive protein
- Bilirubin and LFT in Crohn's disease or ulcerative colitis indications during the first 16 weeks of treatment and then periodically
- Latent TB (and chest radiograph if positive) and annual testing for TB in high-risk patients
- Hepatitis B and C, HIV screening (baseline) and periodic evaluation of hepatitis B carriers
- Evaluate for infection, malignancy (specifically skin cancer screening), infusion/injection site reactions, lymphadenopathy and symptoms consistent with posterior reversible encephalopathy syndrome or axial polyneuropathy.

References

1. Guselkumab Drug Information- UpToDate [July 2026]
2. Guselkumab Summary of Product Characteristics, Revised: 2026/03
3. Eldixia® Brochure

Eldixia®,

Manufactured by CinnaGen, the first and only Iranian pharmaceutical company with European Union approval