

Eticovo™ (etanercept-ykro) – New biosimilar approval

- On April 25, 2019, the FDA approved Samsung Bioepis' [Eticovo \(etanercept-ykro\)](#), a biosimilar to Amgen's [Enbrel® \(etanercept\)](#).
 - Eticovo is the second FDA-approved biosimilar to Enbrel.
 - Sandoz's [Erelzi™ \(etanercept-szzs\)](#) was the first biosimilar to Enbrel and was approved in 2016. Sandoz's launch plans for Erelzi are pending.
- Eticovo, Erelzi, and Enbrel share the following indications:
 - **Rheumatoid arthritis (RA)**: reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active RA. Eticovo, Erelzi, and Enbrel can be initiated in combination with [methotrexate \(MTX\)](#) or used alone.
 - **Polyarticular juvenile idiopathic arthritis (JIA)**: reducing signs and symptoms of moderately to severely active JIA in patients ages 2 and older.
 - **Ankylosing spondylitis (AS)**: reducing signs and symptoms in patients with active AS.
- Eticovo and Enbrel are also indicated for the following indications:
 - **Psoriatic arthritis (PsA)**: reducing signs and symptoms, inhibiting the progression of structural damage of active arthritis, and improving physical function in patients with PsA. Eticovo and Enbrel can be used with or without MTX.
 - **Plaque psoriasis (PsO)**: treatment of patients 4 years or older with chronic moderate to severe PsO who are candidates for systemic therapy or phototherapy.
- A biosimilar product is a biological agent that is considered highly similar to an already-approved biological drug, known as the reference product. Biological products are generally derived from a living organism and can come from many sources, including humans, animals, microorganisms or yeast.
 - A biosimilar product must show no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products.
 - In addition, a biosimilar product may only be approved for the indication(s) and condition(s) that have been FDA approved for the reference product, and must have the same mechanism(s) of action, route(s) of administration, dosage form(s) and strength(s) as the reference product.
- Eticovo has been approved as a biosimilar, **not** as an interchangeable product.
- Like Enbrel, Eticovo carries a boxed warning regarding serious infections and malignancy.
- Eticovo is contraindicated in patients with sepsis.
- Additional warnings and precautions for Eticovo include neurologic reactions, patients with heart failure, hematologic reactions, hepatitis B reactivation, allergic reactions, immunizations, autoimmunity, immunosuppression, use in Wegener's granulomatosis patients, use with [Kineret® \(anakinra\)](#) or [Orencia® \(abatacept\)](#), and use in patients with moderate to severe alcoholic hepatitis.

- The most common adverse reactions (incidence > 5%) with etanercept use were infections and injection site reactions.
- The recommend dosage of Eticovo for the treatment of adult RA, AS, and PsA is 50 mg subcutaneously (SC) once weekly. For adult PsO, the recommended starting dose is 50 mg twice weekly for 3 months followed by 50 mg once weekly for maintenance.
- The recommended dosage of Eticovo for the treatment of pediatric (patients who weigh \geq 63 kg) PsO or JIA is 50 mg SC once weekly.
 - There is no dosage form for Eticovo that allows weight base dosing for pediatric patients < 63 kg (138 pounds). To achieve pediatric doses other than 50 mg, use other reconstituted etanercept products lyophilized powder.
- Samsung Bioepis' launch plans for Eticovo are pending. Eticovo will be available as a 25 mg/0.5 mL and 50 mg/mL solution in a single-dose prefilled syringe injection.



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