

Simponi (golimumab)

WHAT IS IT?

Simponi (also known by its generic name golimumab) is a biologic medication approved in April 2009 by the US Food and Drug Administration (FDA) for the treatment of moderate to severe psoriatic arthritis. It is also approved for treating rheumatoid arthritis and ankylosing spondylitis (arthritis affecting the spine).

HOW DOES IT WORK?

Golimumab blocks excess tumor necrosis factor-alpha (TNF-alpha), a “chemical messenger” in the immune system that signals other cells to cause inflammation. There is too much TNF-alpha in the joints of people with certain types of arthritis.

TNF-alpha can also lead to increased immune system activity through the activation of T cells. T cells are a type of white blood cell in the body; in psoriatic arthritis, once T cells are mistakenly activated, they can trigger inflammation and other immune responses. Simponi helps lower the amount of TNF-alpha, thus interrupting the inflammatory cycle of psoriatic arthritis and leading to the improvement in symptoms for many people who take it.

WHO CAN TAKE IT?

Golimumab is prescribed for adults with moderate to severe active psoriatic arthritis.

WHO SHOULD NOT TAKE IT?

- People with active infections or with a history of recurrent infections.
- Children—the medication has not been approved for children.

Caution is advised for the elderly, due to the already increased risk of infection for this age group. The impact of golimumab on pregnant women or developing fetuses is not known, nor is it known if the medication passes into breast milk in nursing women. If you are pregnant or planning to become pregnant, talk to your doctor.

HOW IS IT USED?

Patients take golimumab at home by giving themselves an injection under the skin, similar to diabetes patients who give themselves insulin injections. The recommended dose for patients with psoriatic arthritis is 50 mg once a month. Simponi is designed to be taken continuously to maintain improvement.

The medication can be prescribed by itself or in combination treatment with methotrexate, a systemic medication prescribed for psoriasis and psoriatic arthritis. In clinical studies, people taking golimumab in combination with methotrexate for psoriatic arthritis experienced more disease improvement than patients taking Simponi or methotrexate alone.

SIDE EFFECTS

The most common side effects are:

- Upper respiratory infection
- Nausea
- Abnormal liver tests
- Injection site reactions
- High blood pressure
- Bronchitis
- Dizziness
- Flu

These side effects were generally mild and did not cause most patients to stop taking golimumab. These happened most often after the first dose and may decrease after additional doses.

EFFECTIVENESS

Arthritis severity score

- Usually determined by examining swelling in and around the joints and taking into consideration joint tenderness, pain, physical function and morning stiffness.
- In clinical trials, about 50 percent of patients saw a 20 percent improvement in arthritis severity scores after one 14-week course.

RISKS

- Golimumab is not recommended for someone with an active infection or a history of recurring infections. Tell your doctor if you have a fever, cough, flu-like symptoms, feel very tired, or have warm, red, or painful skin.
- People should be evaluated for latent TB infections by getting a TB skin test prior to treatment with golimumab. Doctors may also order a chest X-ray before starting treatment. Patients with a positive TB test must be treated before starting golimumab.
- There is the risk of an allergic reaction to this drug. Signs of a serious allergic reaction include a skin rash, a swollen face, or trouble breathing.
- Some people taking a TNF-alpha blocker such as golimumab have reported reactivation of hepatitis B virus. Tell your doctor if you know or think you may be a carrier of hepatitis B. Tell your doctor if you experience signs of hepatitis B infection, such as feeling unwell, poor appetite and tiredness.
- There have been rare reports of central nervous system disorders in association with the use of golimumab.
- In some people taking golimumab, the body may not make enough of the blood cells that help stop bleeding. Tell your doctor if you have a persistent fever, look very pale or bruise or bleed very easily.
- There have been reports of new or worsening heart failure in people taking golimumab. Tell your doctor if you have shortness of breath, sudden weight gain or swelling of your ankles or feet.
- Some individuals developed lupus-like symptoms that decreased after stopping treatment. Tell your doctor if you develop chest pains that do not go away, shortness of breath, joint pain, or a rash on your cheeks or arms that is sensitive to the sun.
- Your risk of getting lymphoma, a type of blood cancer, may increase by taking golimumab.
- There is an increased risk of invasive fungal infections for people who take golimumab. Discuss the use of golimumab with your doctor if you reside in or are if you are planning to travel to regions where fungal infections are common.

For detailed information on side effects and safety, talk to your doctor.

PATIENT ASSISTANCE INFORMATION:

Centocor Ortho Biotech has a special program where patients can get help with insurance issues or find financial assistance if they cannot afford golimumab. Call 1.888.ACCESS.1(1.888.222.3771).

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