

Therapeutic indication:

Simponi belongs to a group of medicines called ‘TNF blockers’. It is used **in adults** for the treatment of the following **inflammatory** diseases:

- Rheumatoid arthritis
- Psoriatic arthritis
- Axial spondyloarthritis, including ankylosing spondylitis and non radiographic axial spondyloarthritis
- Ulcerative colitis

In children weighing at least 40 kg, Simponi is used for the treatment of polyarticular juvenile idiopathic arthritis.

Simponi works by blocking the action of a protein called ‘tumour necrosis factor alpha’ (TNF α). This protein is involved in **inflammatory** processes of the body, and blocking it can reduce the **inflammation** in your body

Rheumatoid arthritis is an inflammatory disease of the joints. If you have active rheumatoid arthritis you will first be given other medicines. If you do not respond well enough to these medicines, you may be given Simponi which you will take in combination with another medicine called methotrexate to:

- . Reduce the signs and symptoms of your disease.
- . Slow down the damage to your bones and joints.
- . Improve your physical function.

Dose:

Rheumatoid arthritis, psoriatic arthritis, and axial spondyloarthritis, including ankylosing spondylitis and non radiographic axial spondyloarthritis:

- The recommended dose is 50 mg (the content of 1 pre filled pen) given once a month, on the same date each month.
- Talk to your doctor before taking your fourth dose. Your doctor will determine if you should continue Simponi treatment.
 - If you weigh more than 100 kg, the dose might be increased to 100 mg (the content of 2 pre filled pens) given once a month, on the same date each month.
- Polyarticular juvenile idiopathic arthritis:
- The recommended dose is 50 mg given once a month, on the same date each month.
- Talk to your child’s doctor before your child takes their fourth dose. Your child’s doctor will determine if they should continue Simponi treatment.
- Ulcerative colitis

Initial treatment	Usually use this medicine. A starting dose of 200 mg (the contents of 4 pre-filled pens) followed by 100 mg (the contents of 2 pre-filled pens) 2 weeks later.
Maintenance treatment	<ul style="list-style-type: none"> • In patients weighing less than 80 kg, 50 mg (the contents of 1 pre filled pen) 4 weeks after your last treatment, then every 4 weeks thereafter. Your doctor may decide to prescribe 100 mg (the contents of 2 pre-filled pens), depending on how well Simponi works for you. • In patients weighing 80 kg or more, 100 mg (the contents of 2 pre filled pens) 4 weeks after your last treatment, then every 4 weeks thereafter.

Contraindications:

- Do not use Simponi:
- If you are allergic (hypersensitive) to golimumab or any of the other ingredients of this medicine .
- If you have tuberculosis (TB) or any other severe infection.
- If you have moderate or severe heart failure.
- If you are not sure if any of the above applies to you, talk to your doctor, pharmacist or nurse before using Simponi.

Warnings and precautions:

- Talk to your doctor, pharmacist or nurse before using Simponi.
- Infections
- Tell your doctor straight away if you already have or get any symptoms of infection, during or after your treatment with Simponi. Symptoms of infection include fever, cough, shortness of breath, flu like symptoms, diarrhoea, wounds, dental problems or a burning feeling when urinating.
- You may get infections more easily while using Simponi.
- Infections may progress more rapidly and may be more severe. In addition, some previous infections may reappear.
- Tuberculosis (TB)
- Tell your doctor straight away if symptoms of TB appear during or after your treatment. Symptoms of TB include persistent cough, weight loss, tiredness, fever or night sweats.
- Cases of TB have been reported in patients treated with Simponi, in rare occasions even in patients who have been treated with medicines for TB. Your doctor will test you to see if you have TB. Your doctor will record these tests on your Patient Reminder Card.
- It is very important that you tell your doctor if you have ever had TB, or if you have been in close contact with someone who has had or has TB.
- If your doctor feels that you are at risk of TB, you may be treated with medicines for TB before you begin using Simponi.
- Hepatitis B virus (HBV)
- Tell your doctor if you are a carrier or if you have or have had HBV before you are given Simponi.
- Tell your doctor if you think you might be at risk of contracting HBV
- Your doctor should test you for HBV
- Treatment with TNF blockers such as Simponi may result in reactivation of HBV in patients who carry this virus, which can be life threatening in some cases.

Invasive fungal infections

If you have lived in or travelled to an area where infections caused by specific type of fungi that can affect the lungs or other parts of the body (called histoplasmosis, coccidioidomycosis, or blastomycosis), are common, tell your doctor straight away. Ask your doctor if you don’t know if these fungal infections are common in the area in which you have lived or travelled.

Cancer and lymphoma

Tell your doctor if you have ever been diagnosed with lymphoma (a type of blood cancer) or any other cancer before you use Simponi.

- If you use Simponi or other TNF blockers, your risk for developing lymphoma or another cancer may increase.
- Patients with severe rheumatoid arthritis and other inflammatory diseases, who have had the disease for a long time, may be at higher than average risk of developing lymphoma.
- There have been cases of cancers, including unusual types, in children and teenage patients taking TNF blocking agents, which sometimes resulted in death.
- On rare occasions, a specific and severe type of lymphoma called hepatosplenic T cell lymphoma has been observed in patients taking other TNF blockers. Most of these patients were adolescent or young adult males. This type of cancer has usually resulted in death. Almost all of these patients had also received medicines known as azathioprine or 6 mercaptopurine. Tell your doctor if you are taking azathioprine or 6 mercaptopurine with Simponi.
- Patients with severe persistent asthma, chronic obstructive pulmonary disease (COPD), or are heavy smokers may be at increased risk for cancer with Simponi treatment. If you have severe persistent asthma, COPD or are a heavy smoker, you should discuss with your doctor whether treatment with a TNF blocker is appropriate for you.
- Some patients treated with golimumab have developed certain kinds of skin cancer. If any changes in the appearance of the skin or growths on the skin occur during or after therapy, tell your doctor.

Heart failure

Tell your doctor straight away if you get new or worsening symptoms of heart failure. Symptoms of heart failure include shortness of breath or swelling of your feet.

- New and worsening congestive heart failure has been reported with TNF blockers, including Simponi. Some of these patients died.
- If you have mild heart failure and you are being treated with Simponi, you must be closely monitored by your doctor.

Nervous system disease

- Tell your doctor straight away if you have ever been diagnosed with or develop symptoms of a demyelinating disease such as multiple sclerosis. Symptoms may include changes in your vision, weakness in your arms or legs or numbness or tingling in any part of your body. Your doctor will decide if you should receive Simponi.

Operations or dental procedures

- Talk to your doctor if you are going to have any operations or dental procedures.
- Tell your surgeon or dentist performing the procedure that you are having treatment with Simponi by showing them your Patient Reminder Card.

Autoimmune disease

Tell your doctor if you develop symptoms of a disease called lupus. Symptoms include persistent rash, fever, joint pain and tiredness.

- On rare occasions, people treated with TNF blockers have developed lupus.

Blood disease

- In some patients the body may fail to produce enough of the blood cells that help your body fight infections or help you to stop bleeding. If you develop a fever that does not go away, bruise or bleed very easily or look very pale, call your doctor right away. Your doctor may decide to stop treatment.
- If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using Simponi.

Vaccinations

- Talk to your doctor if you have had, or are due to have a vaccine.
- You should not receive certain (live) vaccines while using Simponi.
- Certain vaccinations may cause infections. If you received Simponi while you were pregnant, your baby may be at higher risk for getting such an infection for up to approximately six months after the last dose you received during pregnancy. It is important that you tell your baby’s doctors and other health care professionals about your Simponi use so they can decide when your baby should receive any vaccine.

Talk to your child’s doctor regarding vaccinations for your child. If possible, your child should be up to date with all vaccinations before using Simponi.

Children and adolescents

- Simponi is not recommended for children weighing less than 40 kg with polyarticular juvenile idiopathic arthritis or in children and adolescents younger than 18 years for any other condition.

Pregnancy and breast feeding

- Talk to your doctor before using Simponi if:
- You are pregnant or are planning to become pregnant while using Simponi. The effects of this medicine in pregnant women are not known. The use of Simponi in pregnant women is not recommended. If you are being treated with Simponi, you must avoid becoming pregnant by using adequate contraception during your treatment and for at least 6 months after the last Simponi injection.
- Before starting breast feeding, your last treatment with Simponi must be at least 6 months ago. You must stop breast feeding if you are to be given Simponi.
- If you received Simponi during your pregnancy, your baby may have a higher risk for getting an infection. It is important that you tell your baby’s doctors and other health care professionals about your Simponi use before the baby receives any vaccine (for more information see section on vaccination).
- If you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

- Simponi has minor influence on your ability to drive and use tools or machines. Dizziness may however occur after you take Simponi. If this happens, do not drive or use any tools or machines.

Possible Side Effects:

Very common side effects (may affect more than 1 in 10 people):

- Upper respiratory tract infections, sore throat or hoarseness, runny nose

Common side effects (may affect up to 1 in 10 people):

- Abnormal liver tests (increased liver enzymes) found during blood tests done by your doctor
- Feeling dizzy
- Headache
- Feeling numb or having a tingling feeling
- Superficial fungal infections
- Abscess
- Bacterial infections (such as cellulitis)
- Low red blood cell counts
- Low white blood cell counts
- Positive blood lupus test
- Allergic reactions
- Indigestion
- Stomach pain
- Feeling sick (nausea)
- Flu
- Bronchitis
- Sinus infection
- Cold sores
- High blood pressure
- Fever
- Asthma, shortness of breath, wheezing
- Stomach and bowel disorders which include inflammation of the stomach lining and colon which may cause fever
- Pain and ulcers in the mouth
- Injection site reactions (including redness, hardness, pain, bruising, itching, tingling and irritation)
- Hair loss
- Rash and itching of the skin
- Difficulty sleeping
- Depression
- Feeling weak
- Bone fractures
- Chest discomfort
- Serious infection including (TB , bacterial infections including blood infections & pneumonia , severe fungal infections and other opportunistic infections)

Always read the full prescribing information. Healthcare professionals are asked to report any suspected adverse reactions to Egyptian pharmacovigilance center (EPVC). Ministry of Health Simponi Leaflet approval date 6-12-2020.

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