

Important Safety Information

Contraindications

SIMPONI® (golimumab) is contraindicated in patients with:

- Hypersensitivity to the active substance or excipients
- Active tuberculosis (TB) or other severe infections such as sepsis, and opportunistic infections
- Moderate or severe heart failure (NYHA Class III/IV)

Before treatment

The Patient Alert Card for SIMPONI provides safety information to the patient. It should be given and explained to all patients.

Patients must show the Alert Card to any doctor involved in their treatment, during and for up to 6 months after treatment with SIMPONI.

Before initiating therapy with SIMPONI, patients should be screened for:

- TB: active and latent disease. Patients with active TB should not be treated. If latent TB is detected, appropriate treatment should be started prior to therapy with SIMPONI.
- (Prior) hepatitis B virus (HBV) infection: The value of antiviral therapy to prevent HBV reactivation in patients treated with TNF antagonists is unknown. For patients who test positive, consultation with a physician with expertise in the treatment of HBV is recommended, and these patients should be closely monitored for reactivation during treatment.

During treatment

Monitoring should be performed for the following patients treated with SIMPONI:

- All patients for occurring infections, including sepsis and TB
- All patients for new onset or worsening of congestive heart failure
- HBV carrier patients for hepatitis B
- All patients for anaphylactic or other serious allergic reactions
- All patients, particularly those with risk factors for skin cancer, are recommended to undergo periodic skin examinations

There is potential risk of acute injection-related reactions and serious hypersensitivity reactions, including after first administration.

In case of an event, SIMPONI should be stopped and appropriate treatment should be started.

Injections of SIMPONI

- Detailed instructions on how to administer SIMPONI can be found in the package leaflet. Additional materials are available (eg, DVD).
- After proper training, patients may self-inject if their physician determines that this is appropriate.
- The full amount of SIMPONI should be administered at all times. Please report any failure to administer SIMPONI.
- Mild injection site reactions commonly occur. In case of severe reaction(s), SIMPONI should be discontinued.



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