Educational programme

Important Safety information

Simponi – Golimumab®

janssen
PHARMACEUTICAL COMPANIES
OF Johnson&Johnson

Objectives

- To ensure prescriber awareness of these risks and as well as guidance on the management of them.
- The overall goal of the educational programme is to provide appropriate and accurate educational tools designed to help optimise the benefit-to-risk profile of SIMPONI in the treatment of Rheumatoid arthritis, Psoriatic arthritis, Ankylosing spondylitis.

Approved indications

- Rheumatoid arthritis.
- Ankylosing spondylitis.
- Psoriatic arthritis.

Summary Safety Concerns

- Serious infections including opportunistic infections and TB
- Hepatitis B virus reactivation
- Congestive heart failure
- Serious systemic hypersensitivity (including anaphylactic reaction)
- Skin cancer
- Medication error

Contraindications

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

Hepatitis B virus reactivation

- As observed with the use of other immunosuppressive drugs, the use of TNF-blocking agents, including Simponi, has been associated with reactivation of hepatitis B virus (HBV) in patients who are chronic carriers of the virus (i.e., surface antigen positive).

- Patients should be tested for HBV infection before initiating treatment with immunosuppressant, including Simponi:-
  - For patients who test positive for hepatitis B surface antigen, consultation with a physician with expertise in the treatment of hepatitis B is recommended. Chronic carriers of hepatitis B should be appropriately evaluated and monitored prior to the initiation of, during treatment with, and for several months following discontinuation of Simponi.

Infections

- Bacterial (including sepsis and pneumonia), mycobacterial (tuberculosis), invasive fungal and opportunistic infections, including fatalities, have been reported in patients receiving TNF-blocking agents, including Simponi.

- Patients have frequently presented with disseminated rather than localized disease. Some of these serious infections have occurred in patients on concomitant immunosuppressive therapy that, in addition to their underlying disease, could predispose them to infections.

Tuberculosis

- Patients should be evaluated for tuberculosis risk factors (including close contact with a person with active tuberculosis) and tested for latent tuberculosis infections prior to treatment with SIMPONI.
- Treatment of latent tuberculosis infections should be initiated prior to therapy with SIMPONI.
- Anti-tuberculosis therapy should be considered prior to initiation of SIMPONI in patients with a past history of latent or active tuberculosis in whom an adequate course of treatment cannot be confirmed.
- Tests for latent tuberculosis may yield false negative results, especially in patients who are immunocompromised or severely ill.

Tuberculosis….cont.

- In patients receiving SIMPONI, tuberculosis has frequently presented as disseminated or extra-pulmonary disease. Cases of active tuberculosis have occurred in patients treated with SIMPONI during and after treatment for latent tuberculosis.

- Patients receiving SIMPONI should be monitored closely for signs and symptoms of active tuberculosis, including patients who tested negative for latent tuberculosis, patients who are on treatment for latent tuberculosis, or patients who were previously treated for tuberculosis infection.

- The decision to initiate anti-tuberculosis therapy in these patients should only be made following consultation with a physician with expertise in the treatment of tuberculosis and taking into account both the risk for latent tuberculosis infection and the risks of anti-tuberculosis therapy.

Live vaccines/therapeutic infectious agents

- Patients treated with Simponi may receive concurrent vaccinations, except for live vaccines. In patients receiving anti-TNF therapy, limited data are available on the response to vaccination with live vaccines or on the secondary transmission of infection by live vaccines. Use of live vaccines could result in clinical infections, including disseminated infections.

- Other uses of therapeutic infectious agents such as live attenuated bacteria (e.g., BCG bladder instillation for the treatment of cancer) could result in clinical infections, including disseminated infections.

- It is recommended that therapeutic infectious agents not be given concurrently with Simponi.

Non-live vaccines

- Psoriatic arthritis patients treated with Simponi in one Phase 3 PsA study were able to mount effective B-cell immune responses to pneumococcal polysaccharide vaccine.
- Similar numbers of psoriatic arthritis patients receiving TRADENAME and not receiving Simponi had at least a 2-fold increase in antibody titers.
- The proportions of patients with response to pneumococcal vaccine were lower among Simopni and control-treated patients receiving MTX compared with patients not receiving MTX.
- Overall, the data indicate that Simponi does not suppress the humoral immune response to this vaccine.

Congestive heart failure (CHF)

- Cases of worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers, including Simponi. Some cases had a fatal outcome. Simponi has not been studied in patients with CHF. Simponi should be used with caution in patients with heart failure. If a decision is made to administer Simponi to patients with heart failure, they should be closely monitored during therapy.

- Simponi is Contraindicated in Moderate or severe heart failure (NYHA class III/IV).

- Simponi should be discontinued if new or worsening symptoms of heart failure appear.

Hypersensitivity reactions

- In post-marketing experience, serious systemic hypersensitivity reactions (including anaphylactic reaction) have been reported following Simponi administration. Some of these reactions occurred after the first administration of Simponi. If an anaphylactic or other serious allergic reaction occurs.

- administration of Simponi should be discontinued immediately and appropriate therapy instituted.

Skin cancers

- Melanoma has been reported in patients treated with TNF-blocking agents, including Simponi.

- Periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer.

Missed dose

- If a patient forgets to inject Simponi on the planned date, the forgotten dose should be injected as soon as the patient remembers. Patients should be instructed not to inject a double dose
- For the forgotten dose, the next dose should be administered based on the following guidance:
  - If the dose is less than 2 weeks late, the patient should inject his/her forgotten dose and stay on his/her original monthly schedule.
  - If the dose is more than 2 weeks late, the patient should inject his/her forgotten dose and a new once-monthly schedule should be established from the date of this injection.

Overdose

- In patients weighing more than 100 kg who do not achieve an adequate clinical response after 3 or 4 doses, increasing the dose of Golimumab to 100 mg once a month may be considered, taking into account the increased risk of certain serious adverse drug reaction with the 100 mg dose compared with the 50 mg dose.

- Continued therapy should be reconsidered in patients who show no evidence of therapeutic benefit after receiving 3 to 4 additional doses of 100 mg.

For more information please refer to Summary of product characteristics .

- **Call for reporting:**

Any suspected adverse events should be reported to the national spontaneous reporting system according to the national regulations.

SFDA (National pharmacovigilance and drug safety Center)

Email to: npc.drug@sfda.sa

Fax: +966-11-2057662

Online: http://ade.sfda.gov.sa/

Toll free number: 8002490000

- **Or you can contact company scientific office at:**

Email to: GCC-PV2@its.jnj.com

Fax: +966-11-2153190