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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 department)
Email to: npc.drug@sfda.sa
Fax: +966-11-2057662
Online: http://ade.sfda.gov.sa/
Or you can contact company scientific office at:
Email to: GCC-PV2@its.jnj.com
Fax: +966-11-2153190

All the information contained within this booklet is taken from the Stelara® European summary of product characteristics. Date: March 2014

Patients

Which patients are suitable for Stelara® treatment?

Stelara® is indicated for the treatment of active psoriatic arthritis in adult patients when the response to previous non-biological disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate.

Stelara® can be used alone or in combination with methotrexate (MTX).

Contraindications to Stelara® are hypersensitivity to the active substance and/or associated excipients and clinically important or active infection (e.g. active tuberculosis).

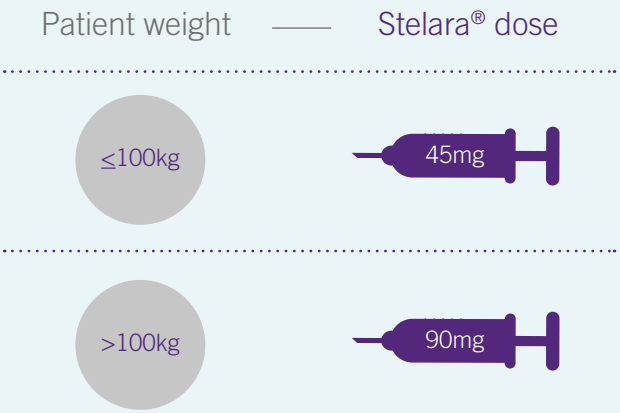
Dosing

What is the recommended dose of Stelara® in psoriatic arthritis?

- Stelara® treatment is initiated with two 45mg doses, one at Week 0 and one at Week 4
- Maintenance injections are then required once every 12 weeks
- Dose may be adjusted to 90mg for patients weighing >100kg.

Are there any dose adjustments for specific patient populations?

- No dose adjustment is needed for elderly patients (≥65 years)
- Stelara® has not been studied in patients with renal and hepatic impairment; therefore no dose recommendations can be made
- The safety and efficacy of Stelara® in children younger than 18 years of age have not yet been established; no data are available.



An injection of Stelara® is required at Week 0, Week 4 and every 12 weeks thereafter

Consideration should be given to discontinuing treatment in patients who have shown no response up to 28 weeks of treatment.

Please refer to the SmPC for complete information on the safety profile of Stelara®.

Administration

How is Stelara® administered?

Stelara® is administered by **subcutaneous injection**. Where possible, areas of skin that are affected by psoriasis should not be used as injection sites.

Can my patients self-administer Stelara®?

Stelara® may be self-injected following suitable training in subcutaneous injection techniques.

Patients should be instructed to inject the full amount of Stelara® according to directions provided in the package leaflet. There is also a step-by-step instruction booklet on how to self-inject within the Stelara® patient initiation pack.

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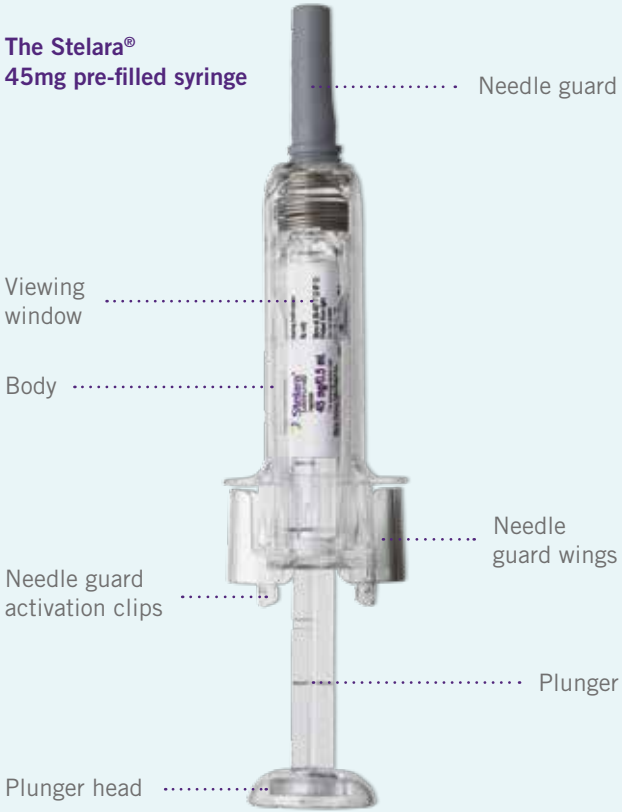
Stelara® is available in a pre-filled syringe with a needle guard for added convenience and safety.



Special warnings and precautions for use

Infections and malignancies

Does Stelara® increase the risk of infection?

Like all immunosuppressants, Stelara® may have the potential to increase the risk of infections and reactivate latent infections. Caution should therefore be exercised when considering the use of Stelara® in patients with a chronic infection or a history of recurrent infection.

Can Stelara® be used in patients with active or latent tuberculosis infection?

Prior to initiating treatment with Stelara®, patients should be evaluated for tuberculosis infection. Stelara® must not be given to patients with active tuberculosis and treatment of latent tuberculosis infection should be initiated prior to administering Stelara®.

Patients receiving Stelara® should be monitored closely for signs and symptoms of active tuberculosis during and after treatment.

Does Stelara® increase the risk of malignancy?

Immunosuppressants like Stelara® have the potential to increase the risk of malignancy. Some patients who received Stelara® in clinical studies developed cutaneous and non-cutaneous malignancies. Therefore, caution should be exercised when considering the use of Stelara® in patients with a history of malignancy.

Exercise caution when considering Stelara® for your patients with a history of infection or malignancy, perform TB screening prior to initiating Stelara® and carefully monitor patients during and after treatment.

Special warnings and precautions for use

Vaccinations and other medications

Can I continue giving Stelara® treatment if my patient requires a vaccination?

Live viral or live bacterial vaccines [such as Bacillus of Calmette and Guérin (BCG)] should not be given concurrently with Stelara®.

Patients receiving Stelara® may receive concurrent inactivated or non-live vaccinations.

Before a live viral or live bacterial vaccination, treatment with Stelara® should be withheld for at least 15 weeks after the last dose and can be resumed a minimum of 2 weeks after vaccination.

Can Stelara® be administered alongside other immunosuppressive therapy?

Caution should be exercised when considering concomitant use of other immunosuppressants with Stelara® or when transitioning from other immunosuppressive biologics.

In psoriatic arthritis studies, concomitant MTX use did not appear to influence the safety or efficacy of Stelara®.

Can Stelara® be administered with other drugs used to treat psoriatic arthritis?

The pharmacokinetics of Stelara® are not affected by the concomitant use of MTX, NSAIDs and oral corticosteroids, or by prior exposure to anti-TNFα agents.

Adverse events

What adverse events (AEs) are commonly associated with Stelara® ?

The most common AEs (>5%) in the psoriasis and psoriatic arthritis clinical studies with Stelara® were:

- Nasopharyngitis
- Headache
- Upper respiratory tract infection.

Most AEs were considered to be mild and did not necessitate discontinuation of study treatment.

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Experience from clinical studies and post-marketing activities have shown that injection site reactions with Stelara® are uncommon (<1% of patients).

Hypersensitivity reactions

Serious hypersensitivity reactions such as anaphylaxis and angioedema have been reported, in some cases several days after treatment. If an anaphylactic or other serious hypersensitivity reaction occurs, appropriate therapy should be initiated and Stelara® should be discontinued immediately.

Can Stelara® be given to patients with latex sensitivity?

The needle cover in the pre-filled syringe is manufactured from dry natural rubber (a derivative of latex), which may cause allergic reactions in individuals sensitive to latex.

Storage and handling

How should Stelara® be stored/handled?

- Store Stelara® in a refrigerator (2ºC-8ºC); do not freeze
- Keep the pre-filled syringe in the outer carton to protect from light
- Allow Stelara® to reach room temperature before administration (this takes approximately half an hour)
- Do not shake the solution in the syringe
- Do not use Stelara® if the solution is discoloured or cloudy. Stelara® may contain a few small translucent or white particles of protein – this is normal for proteinaceous solutions
- Dispose of any solution remaining in the syringe after use; do not reuse.

Stelara® has a shelf life of 2 years.

Treatment checklist

Could my patient be suitable for Stelara® treatment?

- ☑ Adult (18 years or older)
- ☑ Active psoriatic arthritis
- ☑ Inadequate response to DMARD therapy

Are there any screening tests that I need to do?

- ☑ Tuberculosis
- ☑ Active infection

Other screening tests/suitability checks which may be carried out if appropriate include:

- ☑ Chronic or active infection (e.g. salmonella, non-tuberculosis mycobacteria)
- ☑ Malignancies
- ☑ Pregnancy test
- ☑ Latex allergy
- ☑ Vaccination history
- ☑ Concomitant medication

What does my patient need to know?

- ☑ Risk of reactivation of latent tuberculosis and information about tuberculosis screening according to local guidance
- ☑ Risk of serious infections, including salmonella, tuberculosis and other mycobacterial infections
- ☑ Risk of hypersensitivity reactions including latex allergy
- ☑ Potential risk of malignancies
- ☑ How to self-administer if appropriate
- ☑ Contraception
- ☑ Live vaccination avoidance

Before initiating Stelara®, you will need to carry out a number of screening tests and inform the patient of potential risks and how to seek medical advice if they occur.