Remsima® Infliximab

HEALTHCARE CELLTRION

Patient Screening Sheet for Infliximab Therapy

This screening sheet is intended for use by any healthcare professional who is assessing patients being considered for infliximab therapy.
Before initiating treatment with infliximab, please answer the questions below.
Full details of the contra-indications and risks associated with infliximab therapy can be found in the Summary of Product Characteristics (SPC). Please read the SPC before prescribing.

1. Patient Data

1-1. Patient's name :

1-2. Date of birth : (DD/MM/YYYY)

1-3. Height : cm **1-4.** Weight : kg

1-5. Indication for infliximab :

- ☐ Rheumatoid Arthritis
- ☐ Ankylosing Spondylitis
- ☐ Psoriatic Arthritis
- ☐ Crohn's Disease
- ☐ Ulcerative Colitis
- ☐ Psoriasis
- ☐ Paediatric Crohn's Disease
- ☐ Paediatric Ulcerative Colitis

2. Checklist Contraindications

If the answer to any question in Section 2 is Yes, infliximab is contra-indicated in this patient (see Section 4.3 of the SPC).

2-1. Does the patient have known hypersensitivity to the active ingredient infliximab or other murine proteins?

☐ Yes, please specify _____ ☐ No _____

2-2. Does the patient have known hypersensitivity to one of the other ingredients (sucrose, polysorbate 80, sodium dihydrogen phosphate monohydrate, disodium phosphate dihydrate)?

☐ Yes, please specify _____ ☐ No _____

2-3. Does the patient currently have active tuberculosis (TB) or other severe infections such as sepsis, abscesses or opportunistic infections?

☐ Yes, please specify _____ ☐ No _____

2-4. Does the patient have moderate or severe cardiac insufficiency [New York Heart Association (NYHA) III/IV]?

☐ Yes, please specify _____ ☐ No _____

3. Checklist Screening

Questions 3-1 to 3-14: if one or more questions are answered by Yes, refer to Section 4.4 of the SPC and consult the treating physician.
Questions 3-15 to 3-18: these concern important pre-treatment screening (see Section 4.4 of the SPC) and safety information that should be given to patients.

3-1. Does the patient have Hepatitis B virus (HBV) carrier status or active HBV infection (see Sections 4.4 and 4.8 of the SPC)?

☐ Yes, please specify _____ ☐ No _____

3-2. Is there another chronic or recurrent infection known (see Sections 4.4 and 4.8 of the SPC)?

☐ Yes, please specify _____ ☐ No _____

3-3. Has the patient recently travelled to any region where TB or invasive fungal infections, such as histoplasmosis, coccidioidomycosis or blastomycosis, are endemic (see Sections 4.4 and 4.8 of the SPC)?

☐ Yes, please specify _____ ☐ No _____

3-4. Is there any present or past history of malignant disease (see Sections 4.4 and 4.8 of the SPC)?

☐ Yes, please specify _____ ☐ No _____

3-5. Is there any present or past history of dysplasia or colon cancer, or is there an increased risk (e.g. patients with long-term ulcerative colitis) (see Section 4.4 of the SPC)?

☐ Yes, please specify _____ ☐ No _____

3. Checklist Screening

Questions 3-1 to 3-14: if one or more questions are answered by Yes, refer to Section 4.4 of the SPC and consult the treating physician.
Questions 3-15 to 3-18: these concern important pre-treatment screening (see Section 4.4 of the SPC) and safety information that should be given to patients.

3-6. Is the patient known to have mild cardiac insufficiency (NYHA I/II) (see Sections 4.4 and 4.8 of the SPC)?

☐ Yes, please specify _____ ☐ No _____

3-7. Is the patient known to have moderate to severe chronic obstructive pulmonary disease, or a history of heavy smoking (see Sections 4.4 and 4.8 of the SPC)?

☐ Yes, please specify _____ ☐ No _____

3-8. Are there any surgical or dental procedures scheduled (see Section 4.4 of the SPC)?

☐ Yes, please specify _____ ☐ No _____

3-9. Has the patient been vaccinated with live vaccines within the last 8 weeks (see Section 4.4 of the SPC)?

☐ Yes, please specify _____ ☐ No _____

Please check vaccination status, if required perform vaccinations with live vaccines prior to initiation of anti-TNF therapy. In children and adolescents with Crohn's disease it is recommended to perform all vaccinations according to current recommendations prior to initiation of therapy.

3-10. If the patient is of childbearing potential, is she currently using adequate contraception (see Section 4.6 of the SPC)?

☐ Yes, please specify _____ ☐ No _____

3-11. Is the patient pregnant or breast-feeding (see Section 4.6 of the SPC)?

☐ Yes, please specify _____ ☐ No _____

3-12. Is the patient currently receiving treatment with anakinra, abatacept or other biological agents (see Sections 4.4 and 4.5 of the SPC)?

☐ Yes, please specify _____ ☐ No _____

3-13. Psoriasis: Is there a history of extensive immunosuppressive therapy or prolonged psoralen ultraviolet A (PUVA) treatment (see Section 4.4 of the SPC)?

☐ Yes, please specify _____ ☐ No _____

3-14. Gastroenterology: Is there a combination therapy with azathioprine or 6-Mercaptopurine (6-MP) scheduled, or was the patient treated with azathioprine or 6-MP immediately prior to the intended Remsima therapy (see Section 4.4 of the SPC)?

☐ Yes, please specify _____ ☐ No _____

3-15. Was there a TB screening [chest X-ray (date…….) / tuberculin skin test or tuberculosis blood test (date…….)] performed according to current guidance (see Section 4.4 of the SPC)?

☐ Yes, please specify _____ ☐ No, please describe why _____

3-16. If latent TB has been diagnosed, has an anti-TB therapy been initiated prior to anti-TNF therapy (see Section 4.4 of the SPC)?

☐ Yes, please specify _____ ☐ No, please describe why _____

3-17. Has the patient been informed about the possible adverse events during the administration of the drug and has the patient alert card been discussed and handed to the patient before first administration?

☐ Yes, please specify _____ ☐ No, please describe why _____

3-18. Was the patient informed about potential side effects of treatment and instructed to contact the physician if there are any signs of severe infection or TB (such as persistent cough, weight loss, mild fever)?

☐ Yes _____ ☐ No, please describe _____

Reporting of side effects
ADR reporting
Sir Temi Zammit Buildings, Malta Life Sciences Park,
San Gwann SGN 3000, Malta
Email: postlicensing.medicinesauthority@gov.mt
By reporting side effects, you can help provide more information on the safety of this medicine.