Remsima (Infliximab)

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

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/M/YYYY)

1-3. Hight: cm 1-4. Weight: kg

1-5: Indication for infliximab:

☐ Rheumatoid Arthritis ☐ Ankylosing Spondylitis ☐ Psoriatic Arthritis

☐ Crohn's Disease ☐ Ulcerative Colitis ☐ Psoriasis

☐ Pediatric Crohn's Disease ☐ Pediatric Ulcerative Colitis

2. Checklist Contraindications

If the answer to any question in Section 2 is Yes, infliximab is contraindicated 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 3-16: if one or more questions are answered by Yes, refer to Section 4.4 of the SPC and consult the treating physician.
Questions 3-17 to 3-20: 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

3-6. Is the patient known to have mild cardiac insu-ciency (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. Is there present or past history of any demyelinating disease (e.g. multiple sclerosis or Guillain-Barré-syndrome) (see Section 4.4 of the SPC)?

☐ Yes, please specify ☐ No

3-9. Are there any surgical or dental procedures scheduled (see Section 4.4 of the SPC)?

☐ Yes, please specify ☐ No

3-10. 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.

3-11. Is the patient known to have liver dysfunction (see Sections 4.4 and 4.8 of the SPC)?

☐ Yes, please specify ☐ No

3-12. If the patient is of childbearing potential, is she currently using adequate contraception (see Section 4.6 of the SPC)?

☐ Yes, please specify ☐ No

3-13. Is the patient pregnant or breast-feeding (see Section 4.6 of the SPC)?

☐ Yes, please specify ☐ No

3-14. 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

3-15. 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

3-16. 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

3-17. Was a TB screening [chest X-ray (date……)/tuberculin skin test or TB blood test (date……)] performed according to current guidance (see Section 4.4 of the SPC)?

☐ Yes, please specify ☐ No

3-18. 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

3-19. 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

3-20. 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) or hematological reactions (e.g. persistent fever, hematoma, hemorrhage, pallor)?

☐ Yes, please specify ☐ No

Reporting of side effects

Patient safety is a top priority for JPI. JPI is committed to continuously monitor the safety and tolerability of its therapies, and to keep close communication with health authorities and healthcare professionals in order to provide them with accurate information about any potential risks associated with the use of its products. You can assist for monitoring the safety of Remsima® (Infliximab) by reporting suspected adverse events associated with the use of Remsima® to:

Saudi Food and Drug Authority
National Pharmacovigilance and Drug Safety Center
Toll-free Phone: 19999 Email: npc.drug@sfda.gov.sa
Website: https://ade.sfda.gov.sa/ Fax: +966-11-205-7662.
Or; Qualified Person for Pharmacovigilance
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