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 to assist in assessing patients being considered for Infliximab therapy.
Before treating patients with infliximab therapy, please, consider to complete all questions below.

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. Diagnosis :

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

2. Checklist Contraindications

Questions 2-1 to 2-4: have to be answered by No

2-1. Is there any hypersensitivity known in this patient to the active ingredient infliximab or other murine proteins?

☐ Yes, please specify _____ ☐ No _____

2-2. Is there any hypersensitivity known in this patient 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 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, consultation with the treating physician is required.
Questions 3-17 to 3-20: have to be answered by Yes.

3-1. Is there a risk of Hepatitis B virus (HBV) infection or does the patient have a known HBV infection?

☐ Yes, please specify _____ ☐ No _____

3-2. Is there another chronic or recurrent infection known?

☐ Yes, please specify _____ ☐ No _____

3-3. Did the patient sojourn in regions where fungal, tuberculosis (TB) or other infections are endemic?

☐ Yes, please specify _____ ☐ No _____

3-4. Is there any present or past history of malignant disease?

☐ 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)?

☐ Yes, please specify _____ ☐ No _____

3-6. Is the patient known to have mild cardiac insufficiency?

☐ Yes, please specify _____ ☐ No _____

3. Checklist Screening

Questions 3-1 to 3-16: If one or more questions are answered by Yes, consultation with the treating physician is required.
Questions 3-17 to 3-20: have to be answered by Yes.

3-7. Is the patient known to have severe asthma or heavy nicotine consumption?

☐ Yes, please specify _____ ☐ No _____

3-8. Is the patient known to have a demyelinising disease (e.g. multiple sclerosis or Guillain-Barré-syndrome)?

☐ Yes, please specify _____ ☐ No _____

3-9. Is there any surgical procedure (also dental) scheduled?

☐ Yes, please specify _____ ☐ No _____

3-10. Has the patient been recently vaccinated with live vaccines within 8 weeks?

☐ 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 patients known to have liver dysfunction?

☐ Yes, please specify _____ ☐ No _____

3-12. Does the patient wish to have children (inadequate contraception)?

☐ Yes, please specify _____ ☐ No _____

3-13. Is the patient pregnant or breast-feeding?

☐ Yes, please specify _____ ☐ No _____

3-14. Rheumatology: Does the patient receive Anakinra or Abatacerpt?

☐ Yes, please specify _____ ☐ No _____

3-15. Plaque psoriasis: Is there a history of extensive immunosuppressive therapy or prolonged psoralen ultraviolet A (PUVA) treatment?

☐ 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?

☐ Yes, please specify _____ ☐ No _____

3-17. Was there a TB screening (chest X-ray (date…) / tuberculin skin test or tuberculosis blood test (date…) performed according to current guidance?

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

3-18. In case latent tuberculosis has been diagnosed, has an anti-tuberculosis therapy been initiated prior to anti-TNF therapy?

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

3-19. Has the patient been comprehensively informed about the effect on the administration of the drug; has the infusion scheduler been discussed and is it handed to him/her before first application?

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

3-20. Was the patient informed about potential side effects and instructed to contact the physician in case there are any indications of e.g. severe infection or tuberculosis (such as persistent cough, decline, weight loss, mild fever) or haematological reactions (e.g. persistent fever, haematoma, haemorrhage, pallor)?

☐ Yes _____ ☐ No, please specify _____