IXIFI (Infliximab)

This document has been reviewed and approved by the Saudi Food and Drug Authority (SFDA).

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 contraindications and risks associated with infliximab therapy can be found in the Local Prescribing Information (SPC).[1]
Please read the SPC before prescribing.

1. Patient Data

1-1. Patient's name: _____

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

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

1-5: Indication for infliximab:[1]

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

PP-IFX-SAU-0036

Reference:
1. Ixifi Summary of Product Characteristics, Saudi Arabia, December 2023.

Version Number: 1
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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?[1]

☐ Yes, please specify ☐ No

2-2. Does the patient have known hypersensitivity to one of the other ingredients (sucrose, polysorbate 80, succinic acid, disodium succinate hexahydrate)?[1]

☐ Yes, please specify ☐ No

2-3. Does the patient currently have active tuberculosis (TB) or other severe infections with chronic or recurrent infection, have been exposed to tuberculosis, a history of an opportunistic infection, resided or traveled in areas of endemic tuberculosis or endemic mycoses, such as histoplasmosis, coccidioidomycosis, or blastomycosis; or with underlying conditions that may predispose them to infection?[1]

☐ Yes, please specify ☐ No

2-4. Does the patient have moderate or severe heart failure [New York Heart Association (NYHA) III/IV]?[1]

☐ 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)?[1]

☐ Yes, please specify ☐ No

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3-2. Is there another chronic or recurrent infection known (See Sections 4.4 and 4.8 of the SPC)?[1]

☐ Yes, please specify ☐ No

3-3. Has the patient recently resided or traveled 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)?[1]

☐ 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)?[1]

☐ Yes, please specify ☐ No

3-5. Is the patient known to have long-term (greater than 1 year) ulcerative colitis (See Section 4.4 of the SPC)?[1]

☐ Yes, please specify ☐ No

3-6. Is the patient known to have mild heart failure (NYHA I/II) (See Section 4.8 of the SPC)?[1]

☐ 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)?[1]

☐ Yes, please specify ☐ No

3-8. Is there present or past history of any central nervous system demyelinating disease (See Section 4.4 of the SPC)?[1]

☐ Yes, please specify ☐ No

3-9. Is the patient currently receiving warfarin, cyclosporine, or theophylline (See Section 4.5 of the SPC)?[1]

☐ Yes, please specify ☐ No

3-10. Has the patient been vaccinated with live vaccines as per current vaccination guidelines (See Section 4.4 of the SPC)?[1]

☐ Yes, please specify ☐ No

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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.[1]

3-11. Is the patient known to have liver dysfunction (See Sections 4.4 and 4.8 of the SPC)?[1]

☐ Yes, please specify ☐ No

3-12. Has the patient received infliximab during the latter parts of pregnancy (See Sections 4.4 and 4.6 of the SPC)?[1]

☐ Yes, please specify ☐ No

3-13. Is the patient pregnant or breastfeeding (See Section 4.6 of the SPC)?[1]

☐ 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)?[1]

☐ Yes, please specify ☐ No

3-15. Psoriasis: Is there a history of chronic exposure immunosuppressive therapy or prolonged psoralen ultraviolet A (PUVA) treatment (See Section 4.4 of the SPC)?[1]

☐ 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 infliximab therapy (See Section 4.4 of the SPC)?[1]

☐ Yes, please specify ☐ No

3-17. Was a TB screening [tuberculin skin test (date……)] performed according to current guidance (See Section 4.4 of the SPC)?[1]

☐ 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)?[1]

☐ Yes, please specify ☐ No

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3-19. Has the patient been informed about the possible risks and benefits of treatment prior to initiating therapy?[1]

☐ 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 (such as fever, chills, weight loss, and fatigue) or TB or signs and symptoms suggestive of blood dyscrasias or infection (e.g., persistent fever)?[1]

☐ Yes, please specify ☐ No

3-21. Does the patient develop symptoms suggestive of a lupus-like syndrome (See Sections 4.4 and 4.8 of the SPC)?[1]

☐ Yes, please specify ☐ No

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To Report Side Effects:

The National Pharmacovigilance Center (NPC)

SFDA Call Center: 19999
E-mail: npc.drug@sfda.gov.sa
Website: http://ade.sfda.gov.sa/

Pharmacovigilance Department in the Company
E-mail: SAU.AEReporting@pfizer.com

For extra copies, please send an email with your contact details and the required amount to SAU.AEReporting@pfizer.com

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