INFLECTRA™▼ (INFLIXIMAB): SCREENING SHEET

This checklist provides guidance for the screening and selection of patients.
It highlights the contraindications and identified risks of treatment with INFLECTRA™.

1.0 Patient data

1.1 Patient name:.....

1.2 Date of birth:..... 1.3 Weight: .....

1.4 Diagnosis: ☐ Rheumatoid Arthritis ☐ Ankylosing Spondylitis ☐ Psoriatic Arthritis ☐ Crohn's Disease ☐ Ulcerative Colitis ☐ Plaque Psoriasis

2.0 Contraindications

	YES	NO
2.1 For the patient named above, is there any known hypersensitivity to:		
i) The active ingredient infliximab or other murine proteins?		
ii) Any one of the other ingredients? *(sucrose, polysorbate 80, sodium dihydrogen phosphate monohydrate, disodium phosphate dihydrate)*		
2.2 Does the patient currently have active tuberculosis (TB) or other severe infections such as sepsis, abscesses or opportunistic infections?		
2.3 Does the patient have moderate or severe cardiac insufficiency (NYHA III/IV)?		

All questions in section 2 must be answered NO.

3.0 Screening

	YES	NO
3.1 Is the patient known to have any of the following:		
Risk of Hepatitis B (HBV) infection or known HBV infection?		
Chronic or recurrent infection(s)?		
Present or past history of malignant disease?		
Ulcerative colitis (UC), with an increased risk for dysplasia or colon cancer (e.g. patients with long-term UC or primary sclerosing cholangitis), or with present or past history of dysplasia or colon cancer?		
Mild cardiac insufficiency?		
Severe asthma or a history of heavy smoking?		
A demyelinating disease (e.g. multiple sclerosis or Guillain-Barré-syndrome)?		
Liver dysfunction?		
3.2 Are any surgical procedures *(including dental)* scheduled for the patient?		
3.3 Has the patient visited regions where TB, fungal or other infections are endemic?		
3.4 Has the patient been vaccinated recently with live vaccines? *Please check vaccination status. If required, perform vaccinations with live vaccines **prior to** initiation of anti-TNF therapy. The concurrent administration of live vacines with INFLECTRA™ is not recommended.*		

3.0 Screening cont.		
	YES	NO
3.5 Does the patient wish to have children? *Women of childbearing potential must use adequate contraception to prevent pregnancy and continue its use for at least 6 months after the last INFLECTRA™ treatment.*		
3.6 Is the patient pregnant or breast-feeding? *INFLECTRA™ is not recommended during pregnancy. Women must not breast-feed during and for at least 6 months after INFLECTRA™ treatment. At least 6 months after birth should elapse before giving live vaccines to infants exposed in utero to infliximab.*		
3.7 ***Rheumatology:*** Is the patient receiving anakinra or abatacept?		
3.8 ***Plaque psoriasis:*** Is there a history of extensive immunosuppressive therapy or prolonged PUVA (psoralen + UVA) treatment?		
3.9 ***Gastroenterology:*** Is there combination therapy with azathioprine or 6-MP scheduled, or has the patient been treated with azathioprine or 6-MP, immediately prior to the intended *INFLECTRA™* therapy?		

Questions 3.1 to 3.9: If one or more of these questions are answered YES, consultation with the patient's treating physician is required.

	YES	NO
3.10 Has a TB screening (medical history/chest X-ray) and tuberculin skin test or tuberculosis blood test been performed according to current guidance?		
Test:	Date:	

	YES	NO
3.11 If latent tuberculosis has been diagnosed, has anti-tuberculosis therapy been initiated prior to anti-TNF therapy?		
3.12 Has the patient been comprehensively informed about the effect and administration of the drug; has the patient alert card been discussed with the patient, and will it be given to the patient at the time of the first dose of INFLECTRA™?		
3.13 Has the patient been informed about the importance of recording brand name and batch number for every infusion?		
3.14 Has the patient been informed about potential side effects and instructed to contact the physician in case there are any indications of severe infection or tuberculosis (such as persistent cough, wasting/ weight loss, mild fever) or haematological reactions (e.g. persistent fever, bruising, bleeding, pallor)?		

Questions 3.10 to 3.14 must be answered YES.

INFLECTRA™ (INFLIXIMAB): SAFETY INFORMATION FOR PRESCRIBING PHYSICIANS

Infliximab may be associated with serious, potentially life-threatening adverse reactions that must be prevented, or identified and treated as early as possible.

The following guidance provides key information on the identified risks when managing patients for all approved indications.

For full prescribing information please consult the Summary of Product Characteristics.

INFLECTRA™ is a biologic medicinal product. For traceability purposes it is important to record both the brand name and batch number of the product received by the patient wherever possible, particularly in cases of suspected adverse drug reactions (ADRs)

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PRECAUTIONS FOR USE

Congestive heart failure

INFLECTRA™ is contraindicated in patients with moderate or severe heart failure (NYHA class III/IV).

- Patients with mild heart failure (NYHA class I/II)should be closely monitored and INFLECTRA™ must be discontinued if new or worsening symptoms of heart failure occur

Tuberculosis (TB)

There have been reports of active TB in patients receiving infliximab. Before starting treatment with INFLECTRA™, all patients must be evaluated for both active and inactive ('latent') TB.

- If active TB is diagnosed, INFLECTRA™ must not be initiated
- If inactive ('latent') TB is diagnosed, treatment for latent TB must be started with antituberculosis therapy before initiation of INFLECTRA™

Other infections

INFLECTRA™ is contraindicated in patients with severe infections such as sepsis, abscesses and opportunistic infections.

- Patients who develop a new infection while undergoing treatment should be monitored closely
- INFLECTRA™ should be discontinued if patients develop a new serious infection

Serious infections including sepsis (excluding opportunistic infection and TB)

Patients taking tumour necrosis factor (TNF)-blockers, including INFLECTRA™, are more susceptible to serious infections.

- If a patient develops a new serious infection or sepsis, INFLECTRA™ should be discontinued
- Appropriate antimicrobial or antifungal therapy should be initiated until the infection is controlled

Live vaccines/theraputic infectious agents

Use of live vaccines can result in clinical infections.

- The concurrent administration of live vaccines with INFLECTRA™ is not recommended
- At least 6 months following birth should elapse before giving live vaccines to infants exposed *in utero* to infliximab

Hepatitis B (HBV) reactivation

- Patients should be tested for HBV infection before initiating treatment with INFLECTRA™
- Carriers of HBV who require treatment with INFLECTRA™ should be closely monitored for signs and symptoms of HBV reactivation infection throughout therapy and for several months following termination of therapy
- In patients who develop HBV reactivation, INFLECTRA™ should be discontinued and effective anti-viral therapy initiated with appropriate supportive treatment

Malignancy

- All patients with ulcerative colitis who are at increased risk for dysplasia or colon carcinoma (e.g. patients with a long-standing ulcerative colitis or primary sclerosing cholangitis), or who had a prior history of dysplasia or colon carcinoma should be screened for dysplasia at regular intervals before therapy and throughout their disease course. This evaluation should include colonoscopy and biopsies per local recommendations.
- Caution should be exercised when considering the use of INFLECTRA™ in patients with chronic infection or a history of recurrent infections, including concomitant immunosuppressive therapy. Patients should be advised of and avoid exposure to potential risk factors for infection as appropriate.

Serum sickness (delayed hypersensitivity reaction)

Available data suggest an increased risk for delayed hypersensitivity with increasing INFLECTRA™-free interval.

- Patients should be advised to seek immediate medical advice if they experience any delayed adverse event
- If patients are re-treated after a prolonged period, they must be closely monitored for signs and symptoms of delayed hypersensitivity

Haematological reactions

There have been reports of pancytopenia, leucopenia, neutropenia, and thrombocytopenia in patients receiving TNF-blockers, including infliximab.

- All patients should be advised to seek immediate medical attention if they develop signs and symptoms suggestive of blood dyscrasias during treatment with INFLECTRA™ (e.g. persistent fever, bruising, bleeding, pallor)
- Discontinuation of INFLECTRA™ should be considered in patients with confirmed significant haematologic abnormalities

Systemic lupus erythematosus/lupus-like syndrome

- If a patient develops symptoms suggestive of a lupus-like syndrome following treatment with INFLECTRA™ and is positive for antibodies against double-stranded DNA, INFLECTRA™ must be discontinued

THE RISKS IDENTIFIED IN THIS GUIDANCE SHOULD BE DISCUSSED WITH PATIENTS RECEIVING INFLECTRA™. THE MATERIALS BELOW CAN BE USED TO FACILITATE THIS DISCUSSION.

On initiation of treatment with INFLECTRA™, patients should be provided with:

- Patient Alert Card
- Infusion Scheduler

Patient Alert Card

The information highlighted on the Patient Alert Card should be discussed with the patient or carer to ensure understanding.

- Prompts patients to inform their doctors straight away of signs of infection or heart problems, either before or during treatment
- Alerts patients that it is important to record brand name and batch number for every infusion

Infusion Scheduler

- Includes space to record the brand name and batch number of each infusion
- Alerts patients to the signs of adverse events that they should tell their doctor about straight away
- Prompts patients to tell their doctors if they have had treatment with infliximab in the past

Demyelinating disorders

- In patients with pre-existing or recent onset of demyelinating disorders, the benefits and risks of anti-TNF treatment should be carefully considered before initiation of INFLECTRA™
- Discontinuation of INFLECTRA™ should be considered if these disorders develop

Hepatosplenic T-cell lymphoma (HSTCL)

A risk for the development of HSTCL in patients treated with INFLECTRA™ cannot be excluded.

- The potential risk for the development of HSTCL with the combination of AZA (azathioprine) or 6-MP (6-mercaptopurine) and infliximab should be carefully considered in patients with Crohn's disease or ulcerative colitis and above all in adolescent or young adult males

Lymphoma (excluding HSTCL)

A risk for the development of lymphomas or other malignancies in patients treated with a TNF- blocking agent cannot be excluded.

- Caution should be exercised when considering INFLECTRA™ for patients with a history of malignancy or when considering continuing treatment in patients who develop a malignancy

Hepatobiliary events

- Patients receiving INFLECTRA™ who have symptoms or signs of liver dysfunction should be evaluated for evidence of liver injury
- If jaundice and/or ALT elevations ≥5 times the upper limit of normal develop(s), INFLECTRA™ should be discontinued, and a thorough investigation of the abnormality should be undertaken

Intestinal and perianal abscess (in Crohn's disease)

- In patients with fistulising Crohn's disease with acute suppurative fistulas, INFLECTRA™ must not be initiated until a source for possible infection, specifically abscess, has been excluded

Sarcoidiosis/sarcoid-like reactions

Sarcoidiosis/sarcoid-like reactions have been observed rarely in patients treated with infliximab.

- If a patient develops symptoms suggestive of a sarcoid-like reaction, further treatment with INFLECTRA™ must not be given

Serious infusion reaction during a re-induction regimen following disease flare

Infliximab has been associated with acute infusion-related reactions, including anaphylactic shock, and delayed hypersensitivity reactions.

- If acute infusion reactions occur, the infusion of INFLECTRA™ must be interrupted immediately

Infusion reactions following re-administration of infliximab:

- In a study in patients with moderate to severe psoriasis the majority of serious infusion reactions occurred during the second infusion at Week 2
- Symptoms included, but were not limited to, dyspnoea, urticaria, facial oedema, and hypotension
- In all cases, infliximab treatment was discontinued and/or other treatment instituted with complete resolution of signs and symptoms

Paediatric malignancy

A risk for the development of malignancies in children and adolescents treated with TNF-blockers, including INFLECTRA™ cannot be excluded. Approximately half of paediatric malignancy cases reported in the post-marketing setting were lymphomas.

Rare post-marketing cases of HSTCL have been reported in patients treated with TNF-blocking agents including infliximab.

- All infliximab cases have occurred in patients with Crohn's disease or ulcerative colitis and the majority were reported in adolescent or young adult males
- All of these patients had received AZA or 6-MP concomitantly with or immediately prior to infliximab
- Potential risk with a combination of AZA or 6-MP and INFLECTRA™ should be carefully considered

Leukaemia

In the post-marketing setting, cases of leukaemia have been reported in patients treated with a TNF-antagonist. There is an increased background risk for lymphoma and leukaemia in rheumatoid arthritis patients with long-standing, highly active, inflammatory disease.

BCG

Pregnant women and mothers should be advised to inform their infants' doctors and other health care professionals of any INFLECTRA™ use during pregnancy, as infants exposed to INFLECTRA™ in utero should not receive a 'live vaccine' such as Bacillus Calmette-Guérin (BCG) within 6 months after birth.

The use of INFLECTRA™ during pregnancy has been associated with very few cases of agranulocytosis or BCG breakthrough infection in the newborn.

Cases involving disseminated BCG infection with fatal outcome following BCG vaccination in infants exposed in utero to infliximab were identified.

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Provides guidance on appropriate screening and selection of patients for all approved indications

INFLECTRA™ SCREENING SHEET

Any suspected adverse reactions can be reported to the Medicines Authority directly via www.medicinesauthority.gov.mt/adrportal

Contact Hospira UK Ltd:
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