

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

Sarcoidosis/sarcoid-like reactions

Sarcoidosis/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.

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Any suspected adverse reaction can be reported to the Medicines Authority. Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and posted to Medicines Authority Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gżira GŻR 1368, MALTA, or sent by email to postlicensing.medicinesauthority@gov.mt

August 2013
MALTA/13/270


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

INFLECTRA™ SCREENING SHEET

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

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

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