# INFLECTRA™ ▼ (INFLIXIMAB): FOR CHILDREN WITH INFLAMMATORY BOWEL DISEASE (IBD)

## SAFETY INFORMATION

**INFLECTRA™ is indicated for use in:**

### Paediatric Crohn's disease

For treatment of severe, active Crohn's disease, in children and adolescents aged 6 to 17 years, who:

- have not responded to conventional therapy including a corticosteroid, an immunomodulator and primary nutrition therapy; or
- are intolerant to or have contraindications for such therapies

Infliximab has been studied only in combination with conventional immunosuppressive therapy.

### Paediatric ulcerative colitis

For treatment of severely active ulcerative colitis, in children and adolescents aged 6 to 17 years, who:

- have had an inadequate response to conventional therapy including corticosteroids and 6-MP or AZA; or
- are intolerant to or have medical contraindications for such therapies

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

**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 in the management of children with Crohn's disease and ulcerative colitis.**

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

## INFECTIONS

Patients taking Tumour Necrosis Factor (TNF) blockers are more susceptible to serious infections. In clinical studies, infections have been reported in a higher proportion of paediatric patients compared to adult patients.

- Patients should be advised of and avoid exposure to potential risk factors for infection as appropriate

Tuberculosis (TB), bacterial infections, including sepsis and pneumonia, invasive fungal, viral, and other opportunistic infections have been observed in patients treated with infliximab.

- Patients must be monitored closely for infections including TB before, during and after treatment with INFLECTRA™
- As the elimination of infliximab may take up to six months, monitoring should be continued throughout this period

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

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

### 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 tuberculosis must be started with antituberculosis therapy before initiation of INFLECTRA™

## VACCINATIONS

Children may be at risk of developing infections and should be kept up to date with childhood immunisation schedules.

- If possible, paediatric patients should be brought up to date with all vaccinations in agreement with current vaccination guidelines prior to initiating INFLECTRA™
- It is recommended that live vaccines should not be given concurrently with INFLECTRA™

# INFUSION REACTIONS AND HYPERSENSITIVITY

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

### Acute infusion-related reactions

Acute infusion reactions may develop during (within seconds) or within a few hours following infusion.

- If acute infusion reactions occur, infusion of INFLECTRA™ must be interrupted immediately
- Observe all patients administered INFLECTRA™ for at least 1-2 hours post-infusion for acute infusion-related reactions
- Emergency equipment, such as adrenaline, antihistamines, corticosteroids and an artificial airway must be available
- Patients may be pre-treated, e.g. with an antihistamine, hydrocortisone and/or paracetamol, and infusion rate slowed to decrease risk of infusion-related reactions, especially if infusion-related reactions have occurred previously

### Serum sickness (delayed hypersensitivity reaction)

Following re-administration of infliximab, available data suggest an increased risk for delayed hypersensitivity with increasing infliximab-free interval. In clinical studies, delayed hypersensitivity reactions have been uncommon and occurred after infliximab-free intervals of <1 year.

- 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
- When treatment with INFLECTRA™ is interrupted and there is a need to restart therapy, use of a re-induction regimen is not recommended. INFLECTRA™ should be re-initiated as a single dose followed by the maintenance dose recommendations described in the SmPC

# MALIGNANCIES AND LYMPHOPROLIFERATIVE DISORDERS

Malignancies, some fatal, have been reported in the post-marketing setting among children, adolescents and young adults (up to 22 years of age) treated with TNF-blocking agents (initiation of therapy ≤18 years of age), including infliximab. Approximately half of cases were lymphomas.

- 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

### Hepatosplenic T-cell lymphoma (HSTCL)

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 treatment with AZA (azathioprine) or 6-MP (6-mercaptopurine) concomitantly with or immediately prior to infliximab.

- The potential risk with the combination of AZA or 6-MP and INFLECTRA™ should be carefully considered

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

On initiation of treatment with INFLECTRA™, patients or carers 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

Contact Hospira UK Ltd:
Medical Information: +44 (0)1926 834400
medinfoUK@hospira.com

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

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