Important Safety Information for REMICADE® (infliximab)

Contraindications

REMICADE is contraindicated in patients with:

- History of hypersensitivity to infliximab, to other murine proteins, or to any of the excipients (sucrose, polysorbate 80, monobasic sodium phosphate, dibasic sodium phosphate)
- Tuberculosis (TB) or other severe infections such as sepsis, abscesses, and opportunistic infections
- Moderate or severe heart failure (NYHA class III/IV)

Before initiating therapy with REMICADE

The Patient Alert Card for REMICADE provides safety information to patient. It should be given and explained to all patients.

Patients must show the Alert Card to any doctor involved in their treatment, during and up to 6 months after treatment with REMICADE.

Before initiating therapy with REMICADE, patients should be screened for:

- TB: active TB, TB risk factors, and latent TB. If latent TB is detected, appropriate treatment should be started prior to therapy with REMICADE
- (Prior) hepatitis B infection: The value of antiviral therapy to prevent hepatitis B virus (HBV) reactivation in patients treated with TNF antagonists is unknown. HBV carrier patients should be closely monitored for HBV reactivation, and consultation with a physician with expertise in the treatment of HBV is recommended
- Malignancy: Test for history (patient and/or family) of malignancy. Periodic skin examination is recommended, particularly for patients with risk factors for skin cancer. Periodic cervical cancer screening is recommended in women, including those above 60 years of age
- Colon carcinoma or dysplasia, in patents with ulcerative colitis, at regular time intervals and specifically in those who are at increased risk for these events

Benefit and risks of treatment with REMICADE should be carefully considered inpatients with pre-existing or recent onset of demyelinating disorders.

Before initiating therapy with REMICADE, paediatric patients with Crohn's disease or ulcerative colitis should be brought up to date with vaccinations.

Importantly, live vaccines and other therapeutic infectious agents (such as live attenuated bacteria) should not be given concurrently with REMICADE.

During treatment with REMICADE

Monitoring should be performed for the following patients treated with REMICADE:

- All patients for developing infections, including sepsis, opportunistic infections, and TB
- Carriers of HBV for signs and symptoms of active HBV
- Patients who develop new or worsening symptoms of heart failure
- All patients for developing lymphomas including HSTCL and other malignancies, including melanoma and Merkel cell carcinoma
- All patients, particularly those with risk factors for skin cancer, are recommended to undergo periodic skin examinations
- All women, including those above 60 years of age, should continue periodic cervical cancer screening
- All patients for developing acute infusion-related reactions (including anaphylactic shock) and serum-sickness (delayed hypersensitivity reactions)
- All patients for developing symptoms or signs of liver dysfunction and/or liver injury

In case of an event, REMICADE should be stopped and appropriate alternative treatment should be started.

Associated with the use of REMICADE during pregnancy, very few cases of agranulocytosis and Bacillus CalmetteGuérin (BCG) breakthrough infection in the newborn have been reported. A mother should inform her infant's doctors and other health care professionals of her use of REMICADE during pregnancy as the infant should not receive a 'live vaccine' such as BCG within 6 months after birth.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions for REMICADE to: ADR Reporting, The Medicines Authority, Post-Licensing Directorate, 203 Level 3, Rue D'Argens, GŻR-1368 Gżira, Website: www.medicinesauthority.gov.mt, e-mail: postlicensing.medicinesauthority@gov.mt

Adverse events should also be reported to Merck Cyprus Ltd by calling 800 7 4433 or at malta_info@merck.com

Marketing authorisation holder

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