

Hereditary Fructose Intolerance

- Remsima 100 mg and 350 mg concentrate for solution for infusion contains sorbitol. If you have hereditary fructose intolerance (HFI), you must not have that intravenously administered formulation.
- Tell your doctor if you have hereditary fructose intolerance. In that case, there are other suitable intravenous infliximab formulations available.

Keep this card with you for 4 months after your last dose of Remsima, or in case of pregnancy, for 12 months after the birth of your baby. Side effects may occur a long time after your last dose.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the Package Leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine. Please report side effects to:

Mint Health Ltd, 3/4 Cantrija Complex, Triq it-Targa,

Il-Magħtab, Naxxar NXR6613 Malta

Tel: +356 2093 9800

Email: pharmacovigilancemt@mint.com.mt

Or report to: ADR Reporting

Sir Temi Zammit Buildings, Malta Life Sciences Park,

San Gwann SGN 3000, Malta

Email: postlicensing.medicinesauthority@gov.mt

Website: www.medicinesauthority.gov.mt/adrportal

Remsima Infliximab

Patient Reminder Card

Show this card to any doctor involved in your treatment.

This Patient Reminder Card contains important safety information that you need to be aware of before and during treatment with Remsima.

Name patient:

Name doctor:

Tel of doctor:

When starting a new card, please keep this card as a reference for 4 months after your last dose of Remsima.

Please read the Remsima 'Package Leaflet' carefully before you start using this medicine.

Approval date by Malta Medicines Authority:
January 2026

Date of Remsima therapy initiation:

Current administrations:

It is important that you and your doctor record the brand name and batch number of your medicine.

Brand name: _____

Batch number: _____

Ask your doctor to record the type and date of last screening(s) for tuberculosis (TB) below:

Test: _____

Date: _____

Result: _____

Test: _____

Date: _____

Result: _____

Please make sure you also have a list of all other medicines that you are using with you at any visit to a healthcare professional.

List of allergies:

List of other medicines:

Infections

Before treatment with Remsima

- Tell your doctor if you have an infection even if it is a very minor one.
- It is very important that you tell your doctor if you have ever had tuberculosis (TB), or if you have been in close contact with someone who has had TB. Your doctor will test you to see if you have TB. Ask your doctor to record the type and date of your last screening(s) for TB on the card.
- Tell your doctor if you have hepatitis B or if you know or suspect you are a carrier of the hepatitis B virus.

During treatment with Remsima

- Tell your doctor straight away if you have signs of an infection. Signs include a fever, feeling tired, (persistent) cough, shortness of breath, weight loss, night sweats, diarrhoea, wounds, dental problems, burning when urinating or 'flu-like' signs.

Pregnancy, Breast-feeding and Vaccinations

- In case you have received Remsima while you were pregnant or if you are breast-feeding, it is important that you inform your baby's doctor about it before your baby receives any vaccine. Your baby should not receive a 'live vaccine', such as BCG (used to prevent tuberculosis) within 12 months after birth or while you are breast-feeding, unless your baby's doctor recommends otherwise.