Patient Safety Information Card

Remsima® 100 mg I.V.

Infliximab

Show this card to any physician involved in your treatment.

Pharma code area

This Patient Safety Information Card contains important safety information that you need to be aware of before and during treatment with Remsima 100 mg I.V.

Patient: _____

Physician: _____

Telephone no.: _____

It is important that you and your physician record the brand name and batch number of your medication.

Name of the preparation:

_____

Batch number:

_____

HEALTHCARE CELLTRION™

Date of Remsima 100 mg I.V. therapy initiation:

_____

Dates of administration in the current cycle:

_____

When starting a new card, please keep this card for an extra four months should you need to reference it.

Read the Remsima 100 mg I.V. 'Patient Leaflet' carefully before you start using this medicine.

Remsima 100 mg I.V. is a biosimilar preparation. For further information on biosimilar preparations, refer to the Ministry of Health website: https://www.health.gov.il/UnitsOffice/HD/MTI/Drugs/Registration/Pages/Biosimilars.aspx

For your attention, the Ministry of Health approved a one-time swap between an original medicine and a biosimilar, and vice versa. The doctor will provide you an explanation about the medicine and the meaning of the swap. Any swap of a biological medicine must be performed by the treating doctor. The trade name of the medicine that appears in the prescription must be identical to the trade name that appears on the package of the medicine supplied to you by the pharmacy. In any case of doubt, refer to the pharmacist or attending doctor.

Ask your physician to record the type and date of the last tuberculosis (TB) screening test below:

Test: __________

Date: __________

Result: __________

List of known sensitivities (allergies):

_____

List of other medicines you are taking:

_____

REM 100 POWD SH280623

Infections

Before using Remsima

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

During treatment with Remsima

- Tell your physician 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.

Heart Problems

Before using Remsima

- Tell your physician if you have any heart problems such as heart failure.

During treatment with Remsima

- Tell your physician straight away if you notice signs of a heart problem. Signs include shortness of breath, swelling of the feet or changes in your heartbeat.

Pregnancy and Vaccinations

In case you have received this medicine while you were pregnant, it is important that you inform the medical staff about it before your baby receives any vaccine. Your baby must not receive a "live vaccine" within the first 6 months after birth. Your baby must not receive BCG vaccine (intended to prevent tuberculosis) within the first 12 months after birth.

At any visit to a healthcare professional, please make sure to bring a list of all other medicines that you are using.

Keep this card with you for 4 months after receiving your last dose of Remsima.

In case of pregnancy, keep this card for at least 12 months after birth.

Side effects may occur a long time after receiving your last dose.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il), that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

In addition, you can report to Padagis via the following address: padagis.co.il

Approved in April 2023 according to the Ministry of Health