

**Patient Safety
Information
Card**

**Remsima[®]
120
mg/ml
S.C.
Infliximab**

**Show this card to any
physician involved
in your treatment.**

**This Patient Safety
Information Card
contains important
safety information that
you need to be aware
of before and during
treatment with
Remsima 120 mg/ml
S.C.**

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:



Date of Remsima
120 mg/ml S.C. 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
120 mg/ml S.C. 'Patient
Leaflet' carefully before
you start using this
medicine.

Remsima 120 mg/ml S.C.
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/
s/Registration/Pages/Bio
similars.aspx](https://www.health.gov.il/UnitsOffice/HD/MTI/Drugs/Registration/Pages/Bio-similars.aspx)

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:

| 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