

ZESSLY (INFLIXIMAB)

PATIENT REMINDER CARD

Patient name: _____

Doctor name: _____

Doctor telephone number: _____

This Patient Reminder Card contains important safety information that you need to be aware of before, during, and after your treatment with Zessly. Please show this card to any doctor involved in your treatment (of any disease).

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

Date of Zessly therapy initiation: __ / __ / __

Current administrations: _____

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

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

Test: _____
Date: __ / __ / __
Results: _____

Test: _____
Date: __ / __ / __
Results: _____

Test: _____
Date: __ / __ / __
Results: _____

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 Zessly:

- 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 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 Zessly:

- Tell your doctor straight away if you have signs of an infection. Signs include 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 Zessly 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 [TB]) within 12 months after birth or while you are breast-feeding, unless your baby's doctor recommends otherwise.

Keep this card with you for 4 months after your last dose of Zessly, 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.

Suspected adverse reactions and medication errors associated with the use of **Zessly** should be reported using the Medicines Authority ADR reporting form, which is available online at

<http://www.medicinesauthority.gov.mt/adrportal> and sent free by post (no stamp required) or email to

Post:

Pharmacovigilance Section at Post-Licensing Directorate,
Medicines Authority,
Sir Temi Zammit Buildings,
Malta Life Sciences Park,
San Gwann SGN 3000

E-mail:

postlicensing.medicinesauthority@gov.mt

Alternatively at:

Sandoz GmbH
Biochemiestr. 10
6250 Kundl
Austria

Marketing Authorization Holder:

Sandoz GmbH
Biochemiestr. 10
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