

## Reporting of side effects

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. If you experience 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).

### Please report it to:

**Post:** The Drug Surveillance Centre,

Roche Products (Ireland) Limited, 3004 Lake Drive, Citywest, Naas Road, Dublin 24, Ireland.

Telephone: 00 353 (0)1 4690700

Email: ireland.drug\_surveillance\_centre@roche.com

**Alternatively, side effects may be reported using the Medicines Authority ADR reporting form,** which is available online at:

<http://www.medicinesauthority.gov.mt/adrportal>,

and sent by post or email to:

**Post:** Pharmacovigilance Section at

Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000, Malta.

**Email:** [postlicensing.medicinesauthority@gov.mt](mailto:postlicensing.medicinesauthority@gov.mt)

## Further information

Talk to your doctor, nurse or pharmacist if you have any questions or concerns.

Please read this material along with the Package Leaflet supplied with this medicine or also available on [www.medicines.ie](http://www.medicines.ie) and [www.ema.europa.eu](http://www.ema.europa.eu) before taking this medicine.



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**FOR USE IN MALTA**

**Important Safety Information  
for Patients using  
ENSPRYNG<sup>®</sup>▼ (Satralizumab)  
Patient Alert Card**

## **Enspryng® (satralizumab) may make you less able to fight infections**

Call your doctor right away if you feel unwell or have signs of infection (**with or without a fever**) such as:

- chills, feeling tired, muscle aches, cough that will not go away or a sore throat.
- skin redness, swelling, tenderness, pain or sores on your body.
- diarrhoea, tummy pain, or feeling sick.
- burning when you urinate or urinating more often than usual.

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This is because you may need to **delay your next dose of Enspryng® (satralizumab)** if you have an infection (even a cold) at that time.

### **Information for your Treating Doctor**

This patient has been prescribed Enspryng® (satralizumab) – **which may make them more susceptible to infection.**

- Evaluate immediately if infection is suspected.
- Enspryng® (satralizumab) can reduce the level of some tests used to evaluate a potential infection e.g. blood neutrophil counts, C-reactive protein.

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- **Contact the prescribing doctor** as soon as possible – they may need to delay giving Enspryng® (satralizumab) until the infection is controlled.

For more information about Enspryng® (satralizumab), read the Summary of Product Characteristics available at [www.medicines.ie](http://www.medicines.ie) and [www.ema.europa.eu](http://www.ema.europa.eu)

### **Contact Information**

Patient's name:

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Doctor's name:

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Doctor's phone number:

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Date of Enspryng® initiation:

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