

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.

By reporting side effects you can help provide more information on the safety of this medicine.

Call your doctor or get medical care right away if you have any of the following symptoms as they may indicate a serious side effect of Imraldi treatment:

Infections
fever, chills, unusual sweating, feeling unwell or more tired than normal, feeling or being sick (such as nausea or vomiting), diarrhea, stomach pain, loss of appetite or

weight loss, cough or coughing up blood or mucus, shortness of breath, problems urinating, skin sores, wounds, muscle aches, dental problems

Heart failure
shortness of breath, swelling of your ankles or feet, sudden weight gain

Cancer
night sweats, swelling of the lymph nodes (swollen glands) in the neck, armpits, groin or other areas, weight loss, new skin lesions or change in skin lesions (such as moles or freckles) you already have, severe itchiness that cannot be explained

Nervous system problems
numbness or tingling, vision changes, muscle weakness, unexplained dizziness

Information for you and health care professionals involved in your medical care or treatment

Your (or your child's) Name

Doctor's name (who prescribed Imraldi)

Doctor's phone number

Condition prescribed for

Date of first Imraldi injection

Dose of Imraldi injection

Date of last Imraldi injection (if no longer taking Imraldi)

Tuberculosis (TB) Tests and Treatment

Mark this box if you have ever been tested for TB:

YES (Ask your doctor if you do not know)

Mark this box if you have ever had any test that was positive for TB:

YES (Ask your doctor if you do not know)

Mark this box if you have ever taken any pills to treat or prevent TB:

YES (Ask your doctor if you do not know)

Please read the Imraldi package leaflet for more information. If you have any other questions, talk to your doctor or another health care professional.

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PATIENT ALERT CARD

This card contains select important safety information that you need to know before and during treatment with Imraldi.

- Keep this card with you at all times and for 4 months after your (or your child's) last injection of Imraldi.
- Show this card to any doctor or health care professional that you see.
- Record information about any tuberculosis tests or treatment you have had on the back of this card.

Not all possible side effects are listed on this card.

- Please read the Imraldi package leaflet or talk with your doctor for more information about side effects.

1 Introduction

Imraldi is a medicine that is intended to treat certain diseases that affect a part of the immune system.

To make sure that Imraldi is working properly and safely for you, you should check in with your doctor regularly to discuss how you are doing. Tell your doctor right away about any changes in your condition.

2 Before Imraldi Treatment

• **Tell your doctor about any health problems you have and any medicines you take.** This will help you and your doctor decide if Imraldi is right for you.

- Tell your doctor if you:
 - have an infection or have symptoms of an infection (such as fever, wounds, feeling tired, dental problems)
 - have tuberculosis or have been in close contact with someone with tuberculosis
 - have or have had a serious heart condition or heart failure
 - have or have had cancer
 - have any numbness or tingling or have a problem that affects your nervous system, such as multiple sclerosis.
- Your doctor should check you for signs and symptoms of tuberculosis before starting Imraldi. You may need to be treated for tuberculosis before you start Imraldi. Please record your TB test results in the notes section of this card.

3 During Imraldi Treatment

- Keep your doctor informed about how Imraldi is working for you.
- **It is important to call your doctor right away about any unusual symptoms you may have.** This will help make sure you get the right care. It will also lower the chance of a side effect becoming worse.
 - If you get a side effect, your doctor will decide if you should continue or stop your Imraldi treatment.
 - Since side effects can happen after your last dose of Imraldi, tell your doctor about any problems that you may have up to **4 months** after your last injection of Imraldi.
- Tell your doctor about:
 - any new medical conditions that you have.
 - new medicines you are taking.
 - any surgery or operation that you have planned.

Notes

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