

## Some people taking Imraldi may get serious side effects, including:

### Infections

Imraldi helps people with certain inflammatory diseases. It does this by blocking a part of the immune system. However, this part of the immune system also helps fight infection. This means Imraldi can make you (or child) more likely to get infections or make any infection that you (or your child) may have worse. This includes infections such as colds or more serious infections like tuberculosis.

### Cancer

If you (or your child) take Imraldi, the risk of getting certain types of cancer may increase.

### Nervous system problems

Some people have developed new or worsening nervous system problems with Imraldi. This includes multiple sclerosis.

Please read the Imraldi package leaflet for more information. These are not all of the

possible side effects that may occur during treatment with Imraldi.

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

## Call your (or your child's) doctor or get medical care right away if there are any of the following symptoms of these possible serious side effects:

### Infections

fever, chills, unusual sweating, feeling unwell or more tired than normal, feeling or being sick (such as nausea or vomiting), diarrhoea, 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

### 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 existing skin lesions (such as moles or freckles); severe itchiness that cannot be explained

### Nervous system problems

numbness or tingling, vision changes, muscle weakness, unexplained dizziness

Tell your (or your child's) doctor about any unusual symptoms that you (or your child) may have during treatment with Imraldi. These are not all of the possible symptoms of these 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 get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. See [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) for how to report side effects. By reporting side effects you can help provide more information on the safety of this medicine.

## Information for you and health care professionals involved in your (or your child's) 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 (or your child) have ever been tested for TB:

YES [Ask your (or your child's) doctor if you do not know]

Mark this box if you (or your child) have ever had any test that was positive for TB:

YES [Ask your (or your child's) doctor if you do not know]

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

YES [Ask your (or your child's) doctor if you do not know]

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

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## PATIENT REMINDER CARD

This card contains select important safety information that you need to know before and during your (or your child's) treatment with Imraldi.

- Keep this card with you at all times and for 70 days after your last injection of Imraldi.
- Show this card to any doctor or health care professional that you (or your child) see.
- Record information about any tuberculosis tests or treatment you (or your child) have had on the back of this card.

## 1 Introduction

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

While Imraldi can be effective in treating these diseases, some people can have one or more side effects. It is important to talk to your (or your child's) doctor about the possible benefits and possible side effects of taking Imraldi. These can be different for each person.

- The purpose of this card is to tell you about some of the possible side effects of Imraldi.
- Some of the serious side effects that could occur include infections, cancer, and nervous system problems.
- These are not all of the possible side effects of Imraldi.

## 2 Before Imraldi Treatment

- **Tell your (or your child's) doctor about any health problems you (or your child) have and any medicines you (or your child) take.** This will help you and your (or your child's) doctor decide if Imraldi is right for you (or your child).
- Tell your (or your child's) doctor if you (or your child):
  - 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 cancer.
  - have any numbness or tingling or have a problem that affects your (or your child's) nervous system, such as multiple sclerosis.
- Your (or your child's) doctor should check for signs and symptoms of tuberculosis before starting Imraldi. You (or your child) may need to be treated for tuberculosis

before starting Imraldi. Please record your TB test results in the notes section of this card.

## 3 Vaccinations

### For Adults

- You may receive vaccinations except for live vaccines.
- If you receive Imraldi while you are pregnant, it is important that you inform your baby's doctor before your baby receives any vaccine. Your baby should not receive a 'live vaccine,' such as BCG (used to prevent tuberculosis) within 5 months following your last Imraldi injection during pregnancy.

### For Children

- Your child's doctor may suggest certain vaccinations for your child before they start Imraldi.
- Live vaccines should not be administered to your child while taking Imraldi.
- If your child receives Imraldi while pregnant, it is important that you inform the baby's

doctor before the baby receives any vaccine. The baby should not receive a 'live vaccine,' such as BCG (used to prevent tuberculosis) within 5 months following your child's last Imraldi injection during pregnancy.

## 4 During Imraldi Treatment

- To make sure that Imraldi is working properly and safely for you (or your child), you should check in with your (or your child's) doctor regularly to discuss how you (or your child) are doing. Tell the doctor right away about any changes in your (or your child's) condition.
- Keep your (or your child's) doctor informed about how Imraldi is working for you (or your child).
- **It is important to call your (or your child's) doctor right away about any unusual symptoms you (or your child) may have.** This will help make sure you (or your child)

- get the right care. It will also lower the chance of a side effect becoming worse.
- Many side effects, including infections, can be managed if you tell your (or your child's) doctor right away.
  - If you or your child get a side effect, your (or your child's) doctor will decide if you (or your child) should continue or stop Imraldi treatment. It is important to talk with your (or your child's) doctor to find out what is right for you (or your child).
  - Since side effects can happen after your (or your child's) last dose of Imraldi, tell your (or your child's) doctor about any problems that you may have up to **70 days** after your (or your child's) last injection of Imraldi.
  - Tell your (or your child's) doctor about your (or your child's):
    - new medical conditions.
    - new medicine.
    - surgery or operation planned.

## Notes

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