



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## EPAR summary for the public

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# Imraldi

## adalimumab

This is a summary of the European public assessment report (EPAR) for Imraldi. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Imraldi.

For practical information about using Imraldi, patients should read the package leaflet or contact their doctor or pharmacist.

### What is Imraldi and what is it used for?

Imraldi is a medicine that acts on the immune system and is used to treat the following conditions:

- plaque psoriasis (a disease causing red, scaly patches on the skin)
- psoriatic arthritis (a disease causing red, scaly patches on the skin with inflammation of the joints)
- rheumatoid arthritis (a disease causing inflammation of the joints)
- axial spondyloarthritis (inflammation of the spine causing back pain), including ankylosing spondylitis and when there is no damage on X-ray but clear signs of inflammation
- Crohn's disease (a disease causing inflammation of the gut)
- ulcerative colitis (a disease causing inflammation and ulcers in the lining of the gut)
- polyarticular juvenile idiopathic arthritis and active enthesitis-related arthritis (both rare diseases causing inflammation in the joints)
- hidradenitis suppurativa (acne inversa), a chronic skin disease that causes lumps, abscesses (collections of pus) and scarring on the skin
- non-infectious uveitis (inflammation of the layer beneath the white of the eyeball).



Imraldi is mostly used in adults when their conditions are severe, moderately severe or getting worse, or when patients cannot use other treatments. For detailed information on the use of Imraldi in all conditions, including when it can be used in children, see the summary of product characteristics (also part of the EPAR).

Imraldi contains the active substance adalimumab and is a 'biosimilar medicine'. This means that Imraldi is highly similar to a biological medicine (also known as the 'reference medicine') that is already authorised in the European Union (EU). The reference medicine for Imraldi is Humira. For more information on biosimilar medicines, see the question-and-answer document [here](#).

## **How is Imraldi used?**

Imraldi can only be obtained with a prescription and treatment should be started and supervised by specialist doctors experienced in the diagnosis and treatment of the conditions for which it is authorised. Eye specialists treating uveitis with Imraldi should also take advice from doctors who have experience of using the medicine.

The medicine is available as a solution for injection under the skin in a pre-filled syringe. The dose depends on the condition to be treated and in children is usually calculated according to the child's weight and height. After the starting dose, Imraldi is most often given every two weeks, but it may be given every week in certain situations. After training, patients or their carers may inject Imraldi if their doctor considers it appropriate. Patients may be given other medicines during treatment with Imraldi, such as methotrexate or corticosteroids (other anti-inflammatory medicines).

For information on the doses to be used for each condition and other information on the use of Imraldi, see the package leaflet.

## **How does Imraldi work?**

The active substance in Imraldi, adalimumab, is a monoclonal antibody (a type of protein) that has been designed to recognise and attach to a chemical messenger in the body called tumour necrosis factor (TNF). This messenger is involved in causing inflammation and is found at high levels in patients with the diseases that Imraldi is used to treat. By attaching to TNF, adalimumab blocks its activity, thereby reducing inflammation and other symptoms of the diseases.

## **What benefits of Imraldi have been shown in studies?**

Laboratory studies comparing Imraldi with Humira have shown that the active substance in Imraldi is highly similar to that in Humira in terms of structure, purity and biological activity. Studies have also shown that giving Imraldi produces similar levels of the active substance in the body to giving Humira.

In addition, a main study involving 544 patients with moderate or severe rheumatoid arthritis despite treatment with methotrexate showed that Imraldi and Humira had similar effectiveness. Response was measured as a 20% or more improvement in symptom score after 24 weeks of treatment: 68% of those given Imraldi responded (183 of 269 patients), compared with 67% of those given Humira (184 of 273 patients). Benefit continued to be seen with longer term treatment for 1 year.

Because Imraldi is a biosimilar medicine, the studies on effectiveness and safety of adalimumab carried out with Humira do not all need to be repeated for Imraldi.

## **What are the risks associated with Imraldi?**

The most common side effects with adalimumab (seen in more than 1 patient in 10) are infections in the nose and throat and sinuses, injection site reactions (redness, itching, bleeding, pain or swelling), headache and muscle and bone pain.

Imraldi and other medicines of its class may affect the ability of the immune system to fight off infections and cancer, and there have been some cases of serious infections and blood cancers in patients using adalimumab.

Other rare serious side effects (which may affect up to 1 in 1,000 people) include failure of bone marrow to produce blood cells, disorder of the nerves, lupus and lupus-like conditions (where the immune system attacks the patient's own tissues, causing inflammation and organ damage), and Stevens-Johnson syndrome (a serious skin condition).

Imraldi must not be used in patients with active tuberculosis or other severe infections, or in patients with moderate to severe heart failure (an inability of the heart to pump enough blood around the body). For the full list of side effects and restrictions with Imraldi, see the package leaflet.

## **Why is Imraldi approved?**

The European Medicines Agency decided that, in accordance with EU requirements for biosimilar medicines, Imraldi has a highly similar structure, purity and biological activity to Humira and is distributed in the body in the same way.

In addition, a study in rheumatoid arthritis has shown that the effects of the medicine are equivalent to those of Humira in this condition. All these data were considered sufficient to conclude that Imraldi will behave in the same way as Humira in terms of effectiveness and safety in its approved uses. Therefore, the Agency's view was that, as for Humira, the benefit outweighs the identified risk, and it recommended that Imraldi be given marketing authorisation.

## **What measures are being taken to ensure the safe and effective use of Imraldi?**

The company that markets Imraldi must provide educational packs for doctors who prescribe the medicine. These packs will include information on the safety of the medicine. An alert card will also be given to patients.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Imraldi have also been included in the summary of product characteristics and the package leaflet.

## **Other information about Imraldi**

The European Commission granted a marketing authorisation valid throughout the European Union for Imraldi on 24 August 2017.

The full EPAR for Imraldi can be found on the Agency's website: [ema.europa.eu/Find\\_medicine/Human\\_medicines/European\\_public\\_assessment\\_reports](http://ema.europa.eu/Find_medicine/Human_medicines/European_public_assessment_reports). For more information about treatment with Imraldi, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 08-2017.