Package leaflet: Information for the patient

Imraldi 40 mg solution for injection in pre-filled pen
adalimumab

▼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. See the end of section 4 for how to report side effects.
Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- Your doctor will also give you a Patient Reminder Card,which contains important safety information that you need to be aware of before you are given Imraldi and during treatment with Imraldi. Keep this Patient Reminder Card with you during your treatment and for 4 months after your (or your child's) last injection of Imraldi.
- If you have any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet (See section 4).

What is in this leaflet

1. What Imraldi is and what it is used for

Imraldi contains the active substance adalimumab, a medicine that acts on your body's immune (defence) system.

Imraldi is intended for treatment of:
- rheumatoid arthritis,
- polyarticular juvenile idiopathic arthritis,
- enthesitis-related arthritis
- ankylosing spondylitis,
- axial spondyloarthritis without radiographic evidence of ankylosing spondylitis,
- psoriatic arthritis,
- psoriasis,
- hidradenitis suppurativa,
- Crohn's disease,
- ulcerative colitis and
- non-infectious uveitis.

The active ingredient in Imraldi, adalimumab, is a monoclonal antibody. Monoclonal antibodies are proteins that attach to a specific target.

The target of adalimumab is a protein called tumour necrosis factor (TNFα), which is present at increased levels in the inflammatory diseases listed above. By attaching to TNFα, Imraldi decreases the process of inflammation in these diseases.

Rheumatoid arthritis

Rheumatoid arthritis is an inflammatory disease of the joints.

Imraldi is used to treat rheumatoid arthritis in adults. If you have moderate to severe active rheumatoid arthritis, you may first be given other disease-modifying medicines, such as methotrexate. If these medicines do not work well enough, you will be given Imraldi to treat your rheumatoid arthritis.

Imraldi can also be used to treat severe, active and progressive rheumatoid arthritis without previous methotrexate treatment.

Imraldi can slow down the damage to the cartilage and bone of the joints caused by the disease and improve physical function.

Usually, Imraldi is used with methotrexate. If your doctor considers that methotrexate is inappropriate, Imraldi can be given alone.

Polyarticular juvenile idiopathic arthritis and enthesitis-related arthritis

Polyarticular juvenile idiopathic arthritis and enthesitis-related arthritis are inflammatory diseases of the joints that usually first appear in childhood.

Imraldi is used to treat polyarticular juvenile idiopathic arthritis in children and adolescents aged 2 to 17 years and enthesitis-related arthritis in children and adolescents aged 6 to 17 years. Patients may first be given other disease-modifying medicines, such as methotrexate. If these medicines do not work well enough, patients will be given Imraldi to treat their polyarticular juvenile idiopathic arthritis or enthesitis-related arthritis.

Ankylosing spondylitis and axial spondyloarthritis without radiographic evidence of ankylosing spondylitis

Ankylosing spondylitis and axial spondyloarthritis without radiographic evidence of ankylosing spondylitis, are inflammatory diseases of the spine.

Imraldi is used to treat ankylosing spondylitis and axial spondyloarthritis without radiographic evidence of ankylosing spondylitis in adults. If you have ankylosing spondylitis or axial spondyloarthritis without radiographic evidence of ankylosing spondylitis, you will first be given other medicines. If these medicines do not work well enough, you will be given Imraldi to reduce the signs and symptoms of your disease.

Psoriatic arthritis

Psoriatic arthritis is an inflammatory disease of the joints associated with psoriasis.

Imraldi is used to treat psoriatic arthritis in adults. Imraldi can slow down the damage to the cartilage and bone of the joints caused by the disease and to improve physical function.

Plaque psoriasis in adults and children

Plaque psoriasis is an inflammatory skin condition that causes red, flaky, crusty patches of skin covered with silvery scales. Plaque psoriasis can also affect the nails, causing them to crumble, become thickened and lift away from the nail bed which can be painful. Psoriasis is believed to be

caused by a problem with the body's immune system that leads to an increased production of skin cells.

Imraldi is used to treat moderate to severe plaque psoriasis in adults. Imraldi is also used to treat severe plaque psoriasis in children and adolescents weighing 30 kg or greater for whom topical therapy and phototherapies have either not worked very well or are not suitable.

Hidradenitis suppurativa in adults and adolescents

Hidradenitis suppurativa (sometimes called acne inversa) is a chronic and often painful inflammatory skin disease. Symptoms may include tender nodules (lumps) and abscesses (boils) that may leak pus. It most commonly affects specific areas of the skin, such as under the breasts, the armpits, inner thighs, groin and buttocks. Scarring may also occur in affected areas.

Imraldi is used to treat hidradenitis suppurativa in adults and adolescents from 12 years of age. Imraldi can reduce the number of nodules and abscesses you have, and the pain that is often associated with the disease. You may first be given other medicines. If these medicines do not work well enough, you will be given Imraldi.

Crohn's disease in adults and children

Crohn's disease is an inflammatory disease of the digestive tract.

Imraldi is used to treat Crohn's disease in adults and children aged 6 to 17 years. If you have Crohn's disease you will first be given other medicines. If these medicines do not work well enough, you will be given Imraldi to reduce the signs and symptoms of your Crohn's disease.

Ulcerative colitis in adults and children

Ulcerative colitis is an inflammatory disease of the large intestine.

Imraldi is used to treat moderate to severe ulcerative colitis in adults and children aged 6 to 17 years. If you have ulcerative colitis you may first be given other medicines. If these medicines do not work well enough, you will be given Imraldi to reduce the signs and symptoms of your disease.

Non-infectious uveitis in adults and children

Non-infectious uveitis is an inflammatory disease affecting certain parts of the eye.

Imraldi is used to treat
- Adults with non-infectious uveitis with inflammation affecting the back of the eye
- Children from 2 years of age with chronic non-infectious uveitis with inflammation affecting the front of the eye

This inflammation may lead to a decrease of vision and/or the presence of floaters in the eye (black dots or wispy lines that move across the field of vision). Imraldi works by reducing this inflammation.

2. What you need to know before you use Imraldi

Do not use Imraldi
- If you are allergic to adalimumab or any of the other ingredients of this medicine (listed in section 6).
- If you have a severe infection, including tuberculosis (see "Warnings and precautions"). It is important that you tell your doctor if you have symptoms of infections, e.g. fever, wounds, feeling tired, dental problems.

- If you have moderate or severe heart failure. It is important to tell your doctor if you have had or have a serious heart condition (see "Warnings and precautions").

Warnings and precautions

Talk to your doctor or pharmacist before using Imraldi.

Allergic reaction

- If you have **allergic reactions** with symptoms such as chest tightness, wheezing, dizziness, swelling or rash do not inject more Imraldi and contact your doctor immediately since, in rare cases, these reactions can be life-threatening.

Infection

- If you have an **infection**, including long-term or localised infection (for example, leg ulcer) consult your doctor before starting Imraldi. If you are unsure, contact your doctor.
- You might get infections more easily while you are receiving Imraldi treatment. This risk may increase if your lung function is impaired. These infections may be serious and include tuberculosis, infections caused by viruses, fungi, parasites or bacteria, other opportunistic infections (unusual infections associated with a weakened immune system) and sepsis (blood poisoning). In rare cases, these infections may be life-threatening. It is important to tell your doctor if you get symptoms such as fever, wounds, feeling tired or dental problems. Your doctor may recommend temporary discontinuation of Imraldi.

Tuberculosis

- As cases of **tuberculosis** have been reported in patients treated with Imraldi, your doctor will check you for signs and symptoms of tuberculosis before starting Imraldi. This will include a thorough medical evaluation including your medical history and screening tests (for example chest X-ray and a tuberculin test). The conduct and results of these tests should be recorded on your Patient Reminder Card. It is very important that you tell your doctor if you have ever had tuberculosis, or if you have been in close contact with someone who has had tuberculosis. Tuberculosis can develop during therapy even if you have received preventative treatment for tuberculosis. If symptoms of tuberculosis (persistent cough, weight loss, listlessness, mild fever), or any other infection appear during or after therapy tell your doctor immediately.

Travel/recurrent infection

- Tell your doctor if you reside or travel in regions where fungal infections such as histoplasmosis, coccidioidomycosis or blastomycosis are endemic.
- Tell your doctor if you have a history of recurrent infections or other conditions that increase the risk of infections.

Hepatitis B virus

- Tell your doctor if you are a carrier of the **hepatitis B virus (HBV)**, if you have active HBV infection or if you think you might be at risk of contracting HBV. Your doctor should test you for HBV. Imraldi can reactivate HBV infection in people who carry this virus. In some rare cases, especially if you are taking other medicines that suppress the immune system, reactivation of HBV infection can be life-threatening.

Age over 65 years

- If you are over 65 years you may be more susceptible to infections while taking Imraldi. You and your doctor should pay special attention to signs of infection while you are being treated

with Imraldi. It is important to tell your doctor if you get symptoms of infections, such as fever, wounds, feeling tired or dental problems.

Surgery or dental procedure

- If you are about to have **surgery or dental procedures,** tell your doctor that you are taking Imraldi. Your doctor may recommend temporary discontinuation of Imraldi.

Demyelinating disease

- If you have or develop **demyelinating disease** (a disease that affects the insulating layer around the nerves, such as multiple sclerosis), your doctor will decide if you should receive or continue to receive Imraldi. Tell your doctor immediately if you get symptoms like changes in your vision, weakness in your arms or legs or numbness or tingling in any part of your body.

Vaccine

- Certain **vaccines** contain weakened but live forms of disease-causing bacteria or viruses, and these vaccines should not be given while receiving Imraldi. Check with your doctor before you receive any vaccines. It is recommended that children, if possible, be given all the scheduled vaccinations for their age before they start treatment with Imraldi. If you receive Imraldi while you are pregnant, your baby may be at higher risk for getting an infection for up to about five months after the last dose you received during pregnancy. It is important that you tell your baby's doctors and other health care professionals about your Imraldi use during your pregnancy so they can decide when your baby should receive any vaccine.

Heart Failure

- If you have **mild heart failure** and you are being treated with Imraldi, your heart failure status must be closely monitored by your doctor. It is important to tell your doctor if you have had or have a serious heart condition. If you develop new or worsening symptoms of heart failure (e.g. shortness of breath, or swelling of your feet), you must contact your doctor immediately. Your doctor will decide if you should receive Imraldi.

Fever, bruising, bleeding or looking pale

- In some patients the body may fail to produce enough of the blood cells to fight off infections or help you to stop bleeding. If you develop a **fever** that does not go away, or you **bruise** or **bleed** very easily or look very **pale**, call your doctor right away. Your doctor may decide to stop treatment.

Cancer

- There have been very rare cases of certain kinds of **cancer** in children and adults taking Imraldi or other TNFα blockers. People with more serious rheumatoid arthritis who have had the disease for a long time may have a higher than average risk of getting **lymphoma** (a cancer that affects the lymph system), and leukaemia (a cancer that affects the blood and bone marrow). If you take Imraldi the risk of getting lymphoma, leukaemia, or other cancers may increase. On rare occasions, a specific and severe type of lymphoma has been observed in patients taking Imraldi. Some of those patients were also treated with the medicines azathioprine or mercaptopurine. Tell your doctor if you are taking azathioprine or mercaptopurine with Imraldi.
- In addition, cases of **non-melanoma skin cancer** have been observed in patients taking Imraldi. If new areas of damaged skin appear during or after therapy or if existing marks or areas of damage change appearance, tell your doctor.
- There have been cases of **cancers, other than lymphoma** in patients with a specific type of lung disease called chronic obstructive pulmonary disease (COPD) treated with another TNFα

blocker. If you have COPD, or you are a heavy smoker, you should discuss with your doctor whether treatment with a TNFα blocker is appropriate for you.

Lupus-like syndrome

- On rare occasions, treatment with Imraldi could result in lupus-like syndrome. Contact your doctor if symptoms such as persistent unexplained rash, fever, joint pain or tiredness occur.

Children and adolescents

- Do not give Imraldi to children with polyarticular juvenile idiopathic arthritis below the age of 2 years.
- Do not use the 40 mg pre-filled pen if doses other than 40 mg are recommended.

Other medicines and Imraldi

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Imraldi can be taken together with methotrexate or certain disease-modifying anti-rheumatic agents (sulfasalazine, hydroxychloroquine, leflunomide and injectable gold preparations), corticosteroids or pain medications including non-steroidal anti-inflammatory drugs (NSAIDs).

You should not take Imraldi with medicines containing the active substances anakinra or abatacept due to increased risk of serious infection.. If you have questions, please ask your doctor.

Pregnancy and breast-feeding

- You should consider the use of adequate contraception to prevent pregnancy and continue its use for at least 5 months after the last Imraldi injection.
- If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice about taking this medicine.
- Imraldi should only be used during a pregnancy if needed.
- According to a pregnancy study, there was no higher risk of birth defects when the mother had received adalimumab during pregnancy compared with mothers with the same disease who did not receive adalimumab.
- Imraldi can be used during breast-feeding.
- If you received Imraldi during your pregnancy, your baby may have a higher risk for getting an infection.
- It is important that you tell your baby's doctors and other health care professionals about your Imraldi use during your pregnancy before the baby receives any vaccine (for more information on vaccines see the "Warnings and precautions" section).

Driving and using machines

Imraldi may have a minor influence on your ability to drive, cycle or use machines. Room spinning sensation (vertigo) and vision disturbances may occur after taking Imraldi.

Imraldi contains sodium and sorbitol

This medicinal product contains 20 mg sorbitol in each pre-filled pen. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Also this medicinal product contains less than 1 mmol of sodium (23 mg) per 0.8 ml dose, i.e. essentially 'sodium-free'.

3. How to use Imraldi

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis or axial spondyloarthritis without radiographic evidence of ankylosing spondylitis

Imraldi pre-filled syringe and pre-filled pen are only available as a 40 mg dose. Thus, it is not possible to administer Imraldi pre-filled syringe and pre-filled pen to paediatric patients that require less than a full 40 mg dose. If an alternative dose is required, other presentations offering such an option should be used.

Imraldi is injected under the skin (subcutaneous use). The usual dose for adults with rheumatoid arthritis, ankylosing spondylitis, axial spondyloarthritis without radiographic evidence of ankylosing spondylitis, and for patients with psoriatic arthritis is 40 mg adalimumab given every two weeks as a single dose.

In rheumatoid arthritis, methotrexate is continued while using Imraldi. If your doctor determines that methotrexate is inappropriate, Imraldi can be given alone.

If you have rheumatoid arthritis and you do not receive methotrexate with your Imraldi therapy, your doctor may decide to give 40 mg adalimumab every week or 80 mg every other week.

Children, adolescents and adults with polyarticular juvenile idiopathic arthritis

Children and adolescents from 2 years of age weighing 10 kg to less than 30 kg

The recommended dose of Imraldi is 20 mg every other week.

Children, adolescents and adults from 2 years of age weighing 30 kg or more

The recommended dose of Imraldi is 40 mg every other week.

Children, adolescents and adults with enthesitis-related arthritis

Children and adolescents from 6 years of age weighing 15 kg to less than 30 kg

The recommended dose of Imraldi is 20 mg every other week.

Children, adolescents and adults from 6 years of age weighing 30 kg or more

The recommended dose of Imraldi is 40 mg every other week.

Adults with psoriasis

The usual dose for adults with psoriasis is an initial dose of 80 mg (as two 40 mg injections in one day), followed by 40 mg given every other week starting one week after the initial dose. You should continue to inject Imraldi for as long as your doctor has told you. Depending on your response, your doctor may increase the dosage to 40 mg every week or 80 mg every other week.

Children and adolescents with plaque psoriasis

Children and adolescents from 4 to 17 years of age weighing 15 kg to less than 30 kg

The recommended dose of Imraldi is an initial dose of 20 mg, followed by 20 mg one week later. Thereafter, the usual dose is 20 mg every other week.

Children and adolescents from 4 to 17 years of age weighing 30 kg or more

The recommended dose of Imraldi is an initial dose of 40 mg, followed by 40 mg one week later. Thereafter, the usual dose is 40 mg every other week.

Adults with hidradenitis suppurativa

The usual dose regimen for hidradenitis suppurativa is an initial dose of 160 mg (as four 40 mg injections in one day or two 40 mg injections per day for two consecutive days), followed by an 80 mg dose (as two 40 mg injections in one day) two weeks later. After two further weeks, continue with a dosage of 40 mg every week. or 80 mg every other week, as prescribed by your doctor It is recommended that you use an antiseptic wash daily on the affected areas.

Adolescents with hidradenitis suppurativa from 12 to 17 years of age weighing 30 kg or more

The recommended dose of Imraldi is an initial dose of 80 mg (as two 40 mg injections in one day), followed by 40 mg every other week starting one week later. If this dose does not work well enough to Imraldi 40 mg every other week, your doctor may increase the dosage to 40 mg every week or 80 mg every other week.

It is recommended that you use an antiseptic wash daily on the affected areas.

Adults with Crohn’s disease

The usual dose regimen for Crohn’s disease is 80 mg (as two 40 mg injections in one day) initially followed by 40 mg every other week starting two weeks later. If a faster effect is required your doctor may prescribe an initial dose of 160 mg (as four 40 mg injections in one day or two 40 mg injections per day for two consecutive days), followed by 80 mg (as two 40 mg injections in one day) two weeks later, and thereafter as 40 mg every other week. If this dose does not work well enough, your doctor may increase the dosage to 40 mg every week or 80 mg every other week.

Children and adolescents with Crohn's disease

Children and adolescents from 6 to 17 years of age weighing less than 40 kg

The usual dose regimen is 40 mg initially followed by 20 mg two weeks later. If a faster response is required, your doctor may prescribe an initial dose of 80 mg (as two 40 mg injections in one day) followed by 40 mg two weeks later.

Thereafter, the usual dose is 20 mg every other week. Depending on your response, your doctor may increase the dose frequency to 20 mg every week.

Children and adolescents from 6 to 17 years of age weighing 40 kg or more:

The usual dose regimen is 80 mg (as two 40 mg injections in one day) initially followed by 40 mg two weeks later. If a faster response is required, your doctor may prescribe an initial dose of 160 mg (as four 40 mg injections in one day or as two 40 mg injections per day for two consecutive days) followed by 80 mg (as two 40 mg injections in one day) two weeks later.

Thereafter, the usual dose is 40 mg every other week. If this dose does not work well enough, your doctor may increase the dosage to 40 mg every week or 80 mg every other week.

Adults with ulcerative colitis

The usual Imraldi dose for adults with ulcerative colitis is 160 mg initially (as four 40 mg injections in one day or as two 40 mg injections per day for two consecutive days) followed by 80 mg (as two 40 mg injections in one day) two weeks later and thereafter 40 mg every other week. If this dose does not work well enough, your doctor may increase the dosage to 40 mg every week or 80 mg every other week.

Children and adolescents with ulcerative colitis

Children and adolescents from 6 years of age weighing less than 40 kg

The usual Imraldi dose is 80 mg (as two 40 mg injections in one day) initially followed by 40 mg (as one 40 mg injection) two weeks later. Thereafter, the usual dose is 40 mg every other week.

Patients who turn 18 years of age while on 40 mg every other week, should continue their prescribed dose.

Children and adolescents from 6 years of age weighing 40 kg or more

The usual Imraldi dose is 160 mg (as four 40 mg injections in one day or two 40 mg injections per day for two consecutive days) initially, followed by 80 mg (as two 40 mg injections in one day) two weeks later. Thereafter the usual dose is 80 mg every other week.

Patients who turn 18 years of age while on 80 mg every other week, should continue their prescribed dose.

Adults with non-infectious uveitis

The usual dose for adults with non-infectious uveitis is an initial dose of 80 mg (as two 40 mg injections in one day), followed by 40 mg given every other week starting one week after the initial dose. You should continue to inject Imraldi for as long as your doctor has told you.

In non-infectious uveitis, corticosteroids or other medicines that influence the immune system may be continued while using Imraldi. Imraldi can also be given alone.

Children and adolescents with chronic non-infectious uveitis from 2 years of age

Children and adolescents from 2 years of age weighing less than 30 kg

The usual dose of Imraldi is 20 mg every other week with methotrexate.

Your child’s doctor may also prescribe an initial dose of 40 mg which may be administered one week prior to the start of the usual dose.

Children and adolescents from 2 years of age weighing 30 kg or more

The usual dose of Imraldi is 40 mg every other week with methotrexate.

Your doctor may also prescribe an initial dose of 80 mg which may be administered one week prior to the start of the usual dose.

Method and route of administration

Imraldi is given by injection under the skin (by subcutaneous injection). For instructions for use, refer to section 7.

If you use more Imraldi than you should

If you accidentally inject Imraldi more frequently than you should, call your doctor or pharmacist and

explain that you have taken more. Always take the outer carton of the medicine with you, even if it is empty.

If you forget to use Imraldi

If you forget to give yourself an injection, you should inject the next dose of Imraldi as soon as you remember. Then take your next dose as you would have on your originally scheduled day, had you not forgotten a dose.

If you stop using Imraldi

The decision to stop using Imraldi should be discussed with your doctor. Your symptoms may return upon stopping treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Most side effects are mild to moderate. However, some may be serious and require treatment. Side effects may occur up to 4 months or more after the last Imraldi injection.

Seek medical attention urgently if you notice any of the following:
- severe rash, hives or other signs of allergic reaction;
- swollen face, hands, feet;
- trouble breathing, swallowing;
- shortness of breath with exertion or upon lying down or swelling of the feet.

Tell your doctor as soon as possible if you notice any of the following:
- signs of infection such as fever, feeling sick, wounds, dental problems, burning on urination;
- feeling weak or tired;
- coughing;
- tingling;
- numbness;
- double vision;
- arm or leg weakness;
- a bump or open sore that doesn't heal;
- signs and symptoms suggestive of blood disorders such as persistent fever, bruising, bleeding, paleness.

The symptoms described above can be signs of the below listed side effects, which have been observed with adalimumab:

Very common (may affect more than 1 in 10 people):

- injection site reactions (including pain, swelling, redness or itching);
- respiratory tract infections (including cold, runny nose, sinus infection, pneumonia);
- headache;
- abdominal (belly) pain;
- nausea and vomiting;
- rash;
- pain in the muscles.

Common (may affect up to 1 in 10 people):

- serious infections (including blood poisoning and influenza);
- intestinal infections (including gastroenteritis);
- skin infections (including cellulitis and shingles);
- ear infections;
- mouth infections (including tooth infections and cold sores);
- reproductive tract infections;
- urinary tract infection;
- fungal infections;
- joint infections;
- benign tumours;
- skin cancer;
- allergic reactions (including seasonal allergy);
- dehydration;
- mood swings (including depression);
- anxiety;
- difficulty sleeping;
- sensation disorders such as tingling, prickling or numbness;

- migraine;
- symptoms of nerve root compression(including low back pain and leg pain);
- vision disturbances;
- eye inflammation;
- inflammation of the eyelid and eye swelling;
- vertigo (sensation of the room spinning);
- sensation of heart beating rapidly;
- high blood pressure;
- flushing;
- haematoma (a solid swelling with clotted blood);
- cough;
- asthma;
- shortness of breath;
- gastrointestinal bleeding;
- dyspepsia (indigestion, bloating, heart burn);
- acid reflux disease;
- sicca syndrome (including dry eyes and dry mouth);
- itching;
- itchy rash;
- bruising;
- inflammation of the skin (such as eczema);
- breaking of finger nails and toe nails;
- increased sweating;
- hair loss;
- new onset or worsening of psoriasis;
- muscle spasms;
- blood in urine;
- kidney problems;
- chest pain;
- oedema (a build up of fluid in the body which causes the affected tissue to swell);
- fever;
- reduction in blood platelets which increases risk of bleeding or bruising;
- impaired healing.

Uncommon (may affect up to 1 in 100 people):

- opportunistic infections (which include tuberculosis and other infections that occur when resistance to disease is lowered);
- neurological infections (including viral meningitis);
- eye infections;
- bacterial infections;
- diverticulitis (inflammation and infection of the large intestine);
- cancer, including cancer of the lymph system (lymphoma) and melanoma (a type of skin cancer);
- immune disorders that could affect the lungs, skin and lymph nodes (most commonly as a condition called sarcoidosis);
- vasculitis (inflammation of blood vessels);
- tremor;
- neuropathy (nerve damage);
- stroke;
- hearing loss, buzzing;
- sensation of heart beating irregularly such as skipped beats;
- heart problems that can cause shortness of breath or ankle swelling;
- myocardial infarction;

- a sac in the wall of a major artery, inflammation and clot of a vein; blockage of a blood vessel;
- lung diseases causing shortness of breath (including inflammation);
- pulmonary embolism (blockage in an artery of the lung);
- pleural effusion (abnormal collection of fluid in the pleural space);
- inflammation of the pancreas which causes severe pain in the abdomen and back;
- difficulty in swallowing;
- facial oedema;
- gallbladder inflammation, gallbladder stones;
- fatty liver (build up of fat in liver cells);
- night sweats;
- scar;
- abnormal muscle breakdown;
- systemic lupus erythematosus (including inflammation of skin, heart, lung, joints and other organ systems);
- sleep interruptions;
- impotence;
- inflammations.

Rare (may affect up to 1 in 1,000 people):

- leukaemia (cancer affecting the blood and bone marrow);
- severe allergic reaction with shock;
- multiple sclerosis;
- nerve disorders (such as inflammation of the optic nerve to the eye, and Guillain-Barré syndrome, a condition that may cause muscle weakness, abnormal sensations, tingling in the arms and upper body);
- heart stops pumping;
- pulmonary fibrosis (scarring of the lung);
- intestinal perforation;
- hepatitis;
- reactivation of hepatitis B;
- autoimmune hepatitis (inflammation of the liver caused by the body's own immune system);
- cutaneous vasculitis (inflammation of blood vessels in the skin);
- Stevens-Johnson syndrome (early symptoms include malaise, fever, headache and rash);
- facial oedema associated with allergic reactions;
- erythema multiforme (inflammatory skin rash);
- lupus-like syndrome;
- angioedema (localized swelling of the skin);
- lichenoid skin reaction (itchy reddish-purple skin rash).

Not known (frequency cannot be estimated from available data):

- hepatosplenic T-cell lymphoma (a rare blood cancer that is often fatal);
- Merkel cell carcinoma (a type of skin cancer);
- Kaposi’s sarcoma, a rare cancer related to infection with human herpes virus 8. Kaposi’s sarcoma most commonly appears as purple lesions on the skin.
- liver failure;
- worsening of a condition called dermatomyositis (seen as a skin rash accompanying muscle weakness);
- weight gain (for most patients, the weight gain was small).

Some side effects observed with adalimumab may not have symptoms and may only be discovered through blood tests. These include:

Very common (may affect more than 1 in 10 people):

- low blood measurements for white blood cells;
- low blood measurements for red blood cells;
- increased lipids in the blood;
- raised liver enzymes.

Common (may affect up to 1 in 10 people):

- high blood measurements for white blood cells;
- low blood measurements for platelets;
- increased uric acid in the blood;
- abnormal blood measurements for sodium;
- low blood measurements for calcium;
- low blood measurements for phosphate;
- high blood sugar;
- high blood measurements for lactate dehydrogenase;
- autoantibodies present in the blood;
- low blood potasium.

Uncommon (may affect up to 1 in 100 people)

- elevated bilirubin measurement (liver blood test).

Rare (may affect up to 1 in 1,000 people):

- low blood measurements for white blood cells, red blood cells and platelet count.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Imraldi

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label of the carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C). Do not freeze.

Keep the pre-filled pen in the outer carton in order to protect from light.

Alternative Storage:

When needed (for example when you are travelling), a single Imraldi pre-filled pen may be stored at room temperature (up to 25°C) for a maximum period of 28 days – be sure to protect it from light. Once removed from the refrigerator for room temperature storage, the pen must be used within 28 days or discarded, even if it is returned to the refrigerator.
You should record the date when the pen is first removed from refrigerator, and the date after which it should be discarded.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Imraldi contains

- The active substance is adalimumab.
- The other ingredients are sodium citrate, citric acid monohydrate, histidine, histidine hydrochloride monohydrate, sorbitol, polysorbate 20, and water for injections.

What Imraldi looks like and contents of the pack

Imraldi 40 mg solution for injection in pre-filled pen is supplied as a 0.8 ml clear and colourless solution.

Imraldi is available in packs containing 1, 2, 4 or 6 pre-filled pen(s) containing a pre-filled syringe (type I glass) with a stainless steel needle, a rigid needle shield, a rubber plunger for patient use and 2, 2, 4 or 6 alcohol pads are enclosed in packs respectively.

Not all pack sizes may be marketed.

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Manufacturer
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For any information about this medicine, please contact:

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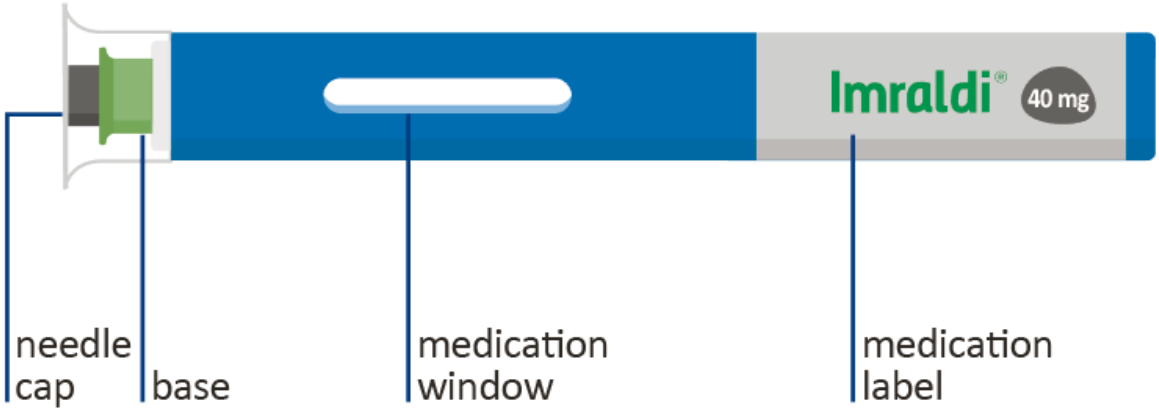
7. Instructions for use

Follow this instruction guide carefully, and soon you will develop a routine for injecting confidently.

- Before you inject, ask your doctor or nurse to show you how to use your pre-filled pen. Your doctor or nurse should make sure you can use your pen correctly.

Your single-dose pre-filled pen



There is no button on your pre-filled pen.
The needle is hidden below the green base. When you push the pre-filled pen firmly onto your skin, the injection will start automatically.

Caring for your pre-filled pen

Pen storage

- Store your pen in the refrigerator, but do not freeze it.
- Keep your pen in its carton, and away from light.
- Keep the pen out of the sight and reach of children.

Pen disposal

- Use each pen only once. Never reuse a pen.
- Throw away your used pen in a special container as instructed by your doctor, nurse or pharmacist.

Cautions

- If you dropped your pen with the cap ON, it is okay to use the pen.
  If you dropped your pen with the cap OFF, do not use it. The needle might be dirty or damaged.
- Do not use a damaged pen.

Injection site care

- Choose a fatty area for injection:
  Fatty areas, like your stomach, are generally the best injection sites. Fatty areas are good for inserting the needle correctly.
- Use a different injection site every time:
  When choosing an injection site, select an area that has not recently been used to avoid soreness and bruises.

How to inject with your pre-filled pen

1. Gather supplies

Place your pre-filled pen and alcohol pads on a clean, dry surface.

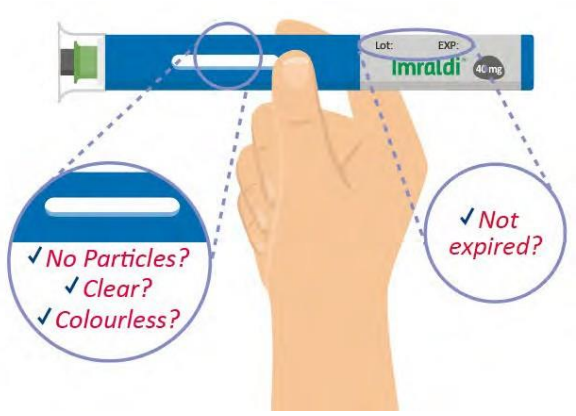
- Remember to wash your hands!
- Do not remove the cap just yet!

2. Wait 15-30 minutes

Wait 15-30 minutes for your pre-filled pen to reach to room temperature, which helps reduce your pain during injection.

- Do not remove the cap just yet!

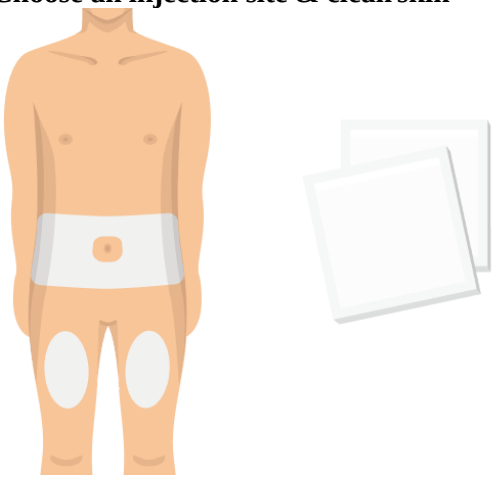
3. Inspect medicine & expiration date



Always make sure your medicine is clear, free of particles, and has not expired. If your medication is not clear, free of particles, or expired, do not use it.
You may see1 or more bubbles, and that is okay. There is no reason to remove it.

- Do not remove the cap just yet!

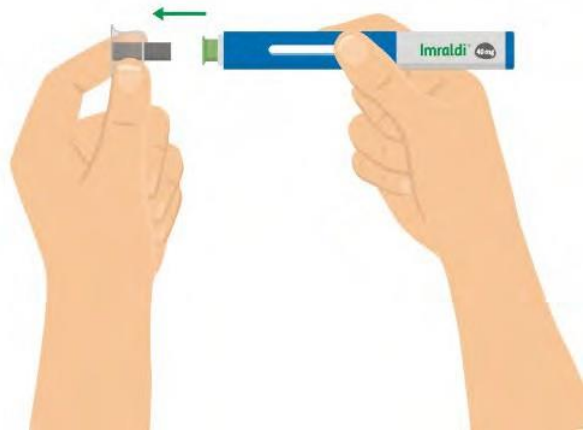
4. Choose an injection site & clean skin



Choose an injection site on your body. Your abdomen (except the area around the navel) or thighs are best.
Clean your injection site with an alcohol pad. Do not touch the area again before the injection.

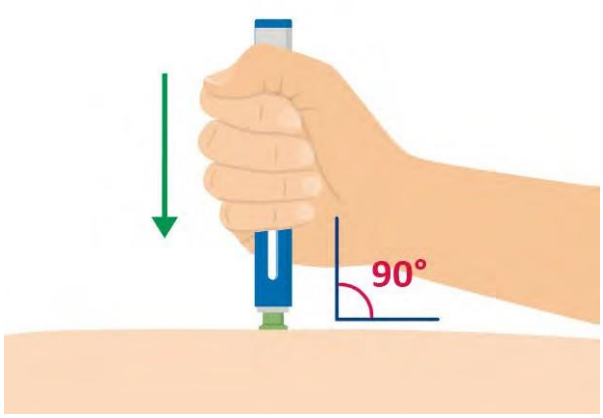
- Avoid skin that is sore, bruised, scarred, scaly, or has red patches.

5. Pull off the clear needle cap



Carefully pull off the clear needle cap with a metal center from the pen.
It is normal to see a few drops of liquid come out of the needle.
If you take off the needle cap before you are ready to inject, **do not put the needle cap back on**. This could bend or damage the needle. You might accidentally stick yourself or waste medication.

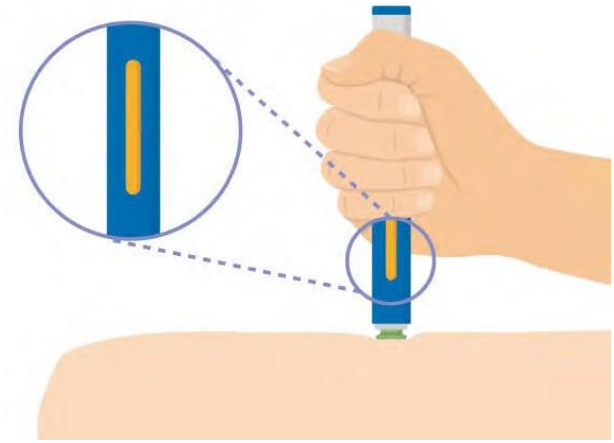
6. Place greenbase, press down, and hold



Place the greenbase straight (90 degrees) on your skin, and push the entire pre-filled pen down firmly to start the injection.

- When you push down, the injection starts. You may hear a 1st click.

7. Continue to hold



Hold the pen against your skin until the yellow indicator fills the medication window and stops moving.

- Several seconds later you may hear a 2nd click.

8. Confirm completion & dispose

After injecting Imraldi, confirm that the entire medication window is yellow.
Throw away the used pen in a special container as instructed by your doctor, nurse or pharmacist.

- Not sure if you received your dose? Contact your doctor, nurse or pharmacist.