LM106607–LE004

Package leaflet: Information for the user

# Remsima®

## Infliximab

**Remsima 100 mg powder for concentrate for solution for infusion**

**▼ 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 Alert Card, which contains important safety information you need to be aware of before and during your treatment with Remsima.
- If you have any further questions, ask your doctor .
- 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. This includes any possible side effects not listed in this leaflet. See section 4

**What is in this leaflet:**



## 1. What Remsima is and what it is used for

Remsima contains the active substance called infliximab. Infliximab is a type of protein of human and mouse origin.

Remsima belongs to a group of medicines called 'TNF blockers'. It is used in adults for the following inflammatory diseases:

- Rheumatoid arthritis
- Psoriatic arthritis
- Ankylosing spondylitis (Bechterew's disease)
- Psoriasis.

Remsima is also used in adults and children 6 years of age or older for:

- Crohn's disease
- Ulcerative colitis.

Remsima works by blocking the action of a protein called 'tumour necrosis factor alpha' (TNFα). This protein is involved in inflammatory processes of the body and blocking it can reduce the inflammation in your body.

### Rheumatoid arthritis

Rheumatoid arthritis is an inflammatory disease of the joints. If you have active rheumatoid arthritis you will first be given other medicines. If you do not respond well enough to these medicines, you will be given Remsima which you will take in combination with another medicine called methotrexate to:

- reduce the signs and symptoms of your disease,
- slow down the damage in your joints,
- improve your physical function.

### Psoriatic arthritis

Psoriatic arthritis is an inflammatory disease of the joints, usually accompanied by psoriasis. If you have active psoriatic arthritis you will first be given other medicines. If you do not respond well enough to these medicines, you will be given Remsima to:

- reduce the signs and symptoms of your disease,
- slow down the damage in your joints,
- improve your physical function.

### Ankylosing spondylitis (Bechterew's disease)

Ankylosing spondylitis is an inflammatory disease of the spine. If you have ankylosing spondylitis you will first be given other medicines. If you do not respond well enough to these medicines, you will be given Remsima to:

- reduce the signs and symptoms of your disease,
- improve your physical function.

### Psoriasis

Psoriasis is an inflammatory disease of the skin. If you have moderate to severe plaque psoriasis, you will first be given other medicines or treatments, such as phototherapy. If you do not respond well enough to these medicines or treatments, you will be given Remsima to reduce the signs and symptoms of your disease.

### Ulcerative colitis

Ulcerative colitis is an inflammatory disease of the bowel. If you have ulcerative colitis you will first be given other medicines. If you do not respond well enough to these medicines, you will be given Remsima to treat your disease.

### Crohn's disease

Crohn's disease is an inflammatory disease of the bowel. If you have Crohn's disease you will first be given other medicines. If you do not respond well enough to these, you will be given Remsima to:

- treat active Crohn's disease,
- reduce the number of abnormal openings (fistulae) between your bowel and your skin that have not been controlled by other medicines or surgery.

## 2. What you need to know before you use Remsima

### You must not be given Remsima if

- you are allergic to infliximab (the active ingredient in Remsima) or any of the other ingredients of this medicine (listed in section 6),
- you are allergic to proteins that come from mice,
- you have tuberculosis (TB) or another serious infection such as pneumonia or sepsis (serious bacterial infection of the blood),
- you have heart failure that is moderate or severe.

Do not have Remsima if any of the above applies to you. If you are not sure, talk to your doctor before you are given Remsima.

### Warnings and precautions

Talk to your doctor before you are given Remsima if you have:

Had treatment with any medicine containing infliximab before

- Tell your doctor if you have had treatment with medicines containing infliximab in the past and are now starting Remsima treatment again.
- If you have had a break in your treatment with infliximab of more than 16 weeks, there is a higher risk for allergic reactions when you start the treatment again.

Infections

- Tell your doctor if you have an infection even if it is a very minor one before you are given Remsima.
- Tell your doctor if you have lived in or travelled to an area where infections called histoplasmosis, coccidioidomycosis, or blastomycosis are common before you are given Remsima. These infections are caused by specific types of fungi that can affect the lungs or other parts of your body.
- You may get infections more easily when you are being treated with Remsima. If you are 65 years of age or older, you have a greater risk.
- These infections may be serious and include tuberculosis, infections caused by viruses, fungi or bacteria, or other opportunistic infections and sepsis that may be life-threatening.

Tell your doctor straight away if you get signs of infection during treatment with Remsima. Signs include fever, cough, flu-like signs, feeling unwell, red or hot skin, wounds or dental problems. Your doctor may recommend temporary discontinuation of Remsima.

Tuberculosis (TB)

- It is very important that you tell your doctor if you have ever had TB or if you have been in close contact with someone who has had or has TB.
- Your doctor will test you to see if you have TB. Cases of TB have been reported in patients treated with Remsima, even in patients who have been treated with medications for TB. Your doctor will record these tests on your Patient Alert Card.
- If your doctor feels that you are at risk for TB, you may be treated with medicines for TB before you are given Remsima.

Tell your doctor straight away if you get signs of TB during treatment with Remsima. Signs include persistent cough, weight loss, feeling tired, fever, night sweats.

Hepatitis B virus (HBV)

- Tell your doctor if you are a carrier or if you have or have had hepatitis B before you are given Remsima.
- Tell your doctor if you think you might be at risk of contracting HBV.
- Your doctor should test you for HBV.
- Treatment with TNF blockers such as Remsima may result in reactivation of hepatitis B virus in patients who carry this virus, which can be life-threatening in some cases.

Heart problems

- Tell your doctor if you have any heart problems, such as mild heart failure.
- Your doctor will want to closely monitor your heart function.

Tell your doctor straight away if you get new or worsening signs of heart failure during treatment with Remsima. Signs include shortness of breath or swelling of your feet.

Cancer and lymphoma

- Tell your doctor if you have or have ever had lymphoma (a type of blood cancer) or any other cancer before you are given Remsima.
- Patients with severe rheumatoid arthritis, who have had the disease for a long time, may be at higher than average risk of developing lymphoma.
- Children and adults taking Remsima may have an increased risk of developing lymphoma or another cancer.
- Some patients who have received TNF-blockers, including Remsima have developed a rare type of cancer called Hepatosplenic T-cell Lymphoma. Of these patients, most were adolescent or young adult males and most had either Crohn's disease or ulcerative colitis. This type of cancer has usually resulted in death. Almost all patients had also received drugs known as azathioprine or 6-mercaptopurine in addition to TNF-blockers.
- Some patients treated with infliximab have developed certain kinds of skin cancer. If any changes in the appearance of the skin or growths on the skin occur during or after therapy, tell your doctor.
- Some women being treated for rheumatoid arthritis with Remsima have developed cervical cancer. For women taking Remsima including those over 60 years of age, your doctor may recommend that you continue to be regularly screened for cervical cancer.

Lung disease or heavy smoking

- Tell your doctor if you have a lung disease called Chronic Obstructive Pulmonary Disease (COPD) or if you are a heavy smoker, before you are given Remsima.
- Patients with COPD and patients who are heavy smokers may have a higher risk of developing cancer with Remsima treatment.

Nervous system disease

- Tell your doctor if you have or have ever had a problem that affects your nervous system before you are given Remsima. This includes multiple sclerosis, Guillain-Barre syndrome, if you have fits or have been diagnosed with 'optic neuritis'.

Tell your doctor straight away if you get symptoms of a nerve disease during treatment with Remsima. Signs include changes in your vision, weakness in your arms or legs, numbness or tingling in any part of your body.

Vaccinations

- Talk to your doctor if you recently have had or are due to have a vaccine.
- You should not receive certain vaccines while using Remsima.
- Certain vaccinations may cause infections. If you received Remsima while you were pregnant, your baby may be at higher risk for getting such an infection up to six months after birth. It is important that you tell your baby's doctors and other health care professionals about your Remsima use so they can decide when your baby should receive any vaccine, including live vaccines such as BCG (used to prevent tuberculosis). For more information see section on Pregnancy and breast-feeding.

Therapeutic infectious agents

- Talk to your doctor if you have recently received or are scheduled to receive treatment with a therapeutic infectious agent (such as BCG instillation used for the treatment of cancer).

Operations or dental procedures

- Tell your doctor if you are going to have any operations or dental procedures.
- Tell your surgeon or dentist performing the procedure that you are having treatment with Remsima by showing them your Patient Alert Card.

### Children and adolescents

The information above also applies to children and adolescents. In addition:

- Some children and teenage patients who have received TNF-blockers such as Remsima have developed cancers, including unusual types, which sometimes resulted in death.
- More children taking Remsima developed infections as compared to adults.
- Children should receive recommended vaccinations before starting Remsima treatment.

Remsima should only be used in children if they are being treated for Crohn's disease or ulcerative colitis. These children must be 6 years of age or older.

If you are not sure if any of the above applies to you, talk to your doctor before you are given Remsima.

### Other medicines and Remsima

Patients who have inflammatory diseases already take medicines to treat their problem. These medicines may cause side effects. Your doctor will advise you what other medicines you must keep using while you are having Remsima.

Tell your doctor if you are using, have recently used or might use any other medicines, including any other medicines to treat Crohn's disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis or psoriasis or medicines obtained without a prescription, such as vitamins and herbal medicines.

In particular, tell your doctor if you are using any of the following medicines:

- Medicines that affect your immune system.
- Kineret (which contains anakinra). Remsima and Kineret should not be used together.
- Orencia (which contains abatacept). Remsima and Orencia should not be used together.

While using Remsima you should not receive live vaccines. If you were using Remsima during pregnancy, tell your baby's doctor and other health care professionals caring for your baby about your Remsima use before the baby receives any vaccines.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using Remsima.

### Pregnancy and breast-feeding

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine. Remsima is not recommended for use during pregnancy.
- You must avoid getting pregnant when you are being treated with Remsima and for 6 months after you stop being treated with it. Make sure you use contraception during this time.
- Do not breast-feed when you are being treated with Remsima or for 6 months after your last treatment with Remsima.
- If you received Remsima 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 healthcare professionals about your Remsima use before your baby receives any vaccine. If you received Remsima while pregnant, administration of BCG vaccine (used to prevent tuberculosis) to your baby within 6 months after birth may result in infection with serious complications, including death. Live vaccines such as BCG should not be given to your baby within 6 months after birth. For more information see section on vaccination.
- Severely decreased numbers of white blood cells have been reported in infants born to women treated with Remsima during pregnancy. If your baby has continual fevers or infections, contact your baby's doctor immediately.

### Driving and using machines

Remsima is not likely to affect your ability to drive or use tools or machines. If you feel dizzy after having Remsima, do not drive or use any tools or machines.

### Remsima contains Sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium- free'.

## 3. How Remsima will be given

### How Remsima is given

- Remsima will be given to you by your doctor or nurse.
- Your doctor or nurse will prepare the Remsima solution for injection.
- The Remsima solution will be slowly injected (over a 2 hour period) into one of your veins. This will usually be in your arm. This is called an 'intravenous infusion' or drip. After the third treatment, your doctor may decide to give you Remsima over a 1 hour period.
- You will be monitored while you are given Remsima and also for 1 to 2 hours after.

### How much Remsima is given

- The doctor will decide your dose (in mg) and how often you will be given Remsima. This will depend on your disease, weight and how well you respond to Remsima.

**THE FOLLOWING INFORMATION IS INTENDED FOR HEALTHCARE PROFESSIONALS ONLY:**

***Instructions for use and handling – storage conditions***

Store at 2°C-8°C.

Remsima may be stored at temperatures up to a maximum of 25°C for a single period of up to 6 months, but not exceeding the original expiry date. The new expiry date must be written on the carton. Upon removal from refrigerated storage, Remsima must not be returned to refrigerated storage.

***Instructions for use and handling – reconstitution, dilution and administration***

1. The dose and the number of Remsima vials have to be calculated. Each Remsima vial contains 100 mg infliximab. The required total volume of reconstituted Remsima solution has to be calculated.
2. Under aseptic conditions, each Remsima vial should be reconstituted with 10 mL of water for injections, using a syringe equipped with a 21-gauge (0.8 mm) or smaller needle. The flip-top from the vial has to be removed and the top has to be wiped with a 70% alcohol swab. The syringe needle should be inserted into the vial through the centre of the rubber stopper and the stream of water for injections directed to the glass wall of the vial. The solution has to be gently swirled by rotating the vial to dissolve the powder. Prolonged or vigorous agitation must be avoided. THE VIAL MUST NOT BE SHAKEN. Foaming of the solution on reconstitution may occur. The reconstituted solution should stand for 5 minutes. The solution should be colourless to light yellow and opalescent. The solution may develop a few fine translucent particles, as infliximab is a protein. The solution must not be used if opaque particles, discolouration, or other foreign particles are present.
3. The required volume of the reconstituted Remsima solution should be diluted to 250 mL with sodium chloride 9 mg/mL (0.9%) solution for infusion. Do not dilute the reconstituted Remsima solution with any other diluent. This can be accomplished by withdrawing a volume of the sodium chloride 9 mg/mL (0.9%) solution for infusion from the 250-mL glass bottle or infusion bag equal to the volume of reconstituted Remsima. The required volume of reconstituted Remsima solution should slowly be added to the 250-mL infusion bottle or bag and gently be mixed.
4. The infusion solution has to be administered over a period of not less than the infusion time recommended (see section 3). Only an infusion set with an in-line, sterile, non-pyrogenic, low protein-binding filter (pore size 1.2 micrometer or less) should be used. Since no preservative is present, it is recommended that the administration of the solution for infusion is to be started as soon as possible and within 3 hours of reconstitution and dilution. When reconstitution and dilution are performed under aseptic conditions, Remsima infusion solution can be used within 24 hours if stored at 2°C to 8°C. Any unused portion of the infusion solution should not be stored for reuse.
5. Remsima should be visually inspected for particulate matter or discolouration prior to administration. If visibly opaque particles, discolouration or foreign particles are observed it should not be used.
6. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

- The table below shows how often you will usually have this medicine.

| | |
|---|---|
| 1st treatment | 0 weeks |
| 2nd treatment | 2 weeks after your 1st treatment |
| 3rd treatment | 6 weeks after your 1st treatment |
| Further treatments | Every 6 to 8 weeks depending on your disease |

**Rheumatoid arthritis**
The recommended dose is 3 mg for every kg of body weight.

**Psoriatic arthritis, ankylosing spondylitis (Bechterew's disease), psoriasis, ulcerative colitis and Crohn's disease**
The recommended dose is 5 mg for every kg of body weight.

### Use in children and adolescents
In children (6 years of age or older) treated for Crohn's disease or ulcerative colitis, the recommended dose is the same as for adults.

### If you are given too much Remsima
As this medicine is being given by your doctor or nurse, it is unlikely that you will be given too much. There are no known side effects of having too much of Remsima.

### If you forget or miss your Remsima infusion
If you forget or miss an appointment to receive Remsima, make another appointment as soon as possible.

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

## 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 patients may experience serious side effects and may require treatment. Side effects may also occur after your treatment with Remsima has stopped.

**Tell your doctor straight away if you notice any of the following:**
- **Signs of an allergic reaction** such as swelling of your face, lips, mouth or throat which may cause difficulty in swallowing or breathing, skin rash, hives, swelling of the hands, feet or ankles. An allergic reaction could happen within 2 hours of your injection or later. More signs of an allergic reaction that may happen up to 12 days after your injection include pain in the muscles, fever, joint or jaw pain, sore throat or headache
- **Signs of a heart problem** such as chest discomfort or pain, arm pain, stomach pain, shortness of breath, anxiety, lightheadedness, dizziness, fainting, sweating, nausea, vomiting, fluttering or pounding in your chest, a fast or a slow heartbeat, and/or swelling of your feet
- **Signs of infection (including TB)** such as fever, feeling tired, (persistent) cough, shortness of breath, flu-like symptoms, weight loss, night sweats, diarrhoea, wounds, dental problems or burning when urinating
- **Signs of a lung problem** such as coughing, breathing difficulties or tightness in the chest
- **Signs of a nervous system problem (including eye problems)** such as fits, tingling or numbness in any part of your body, weakness in arms or legs, changes in eyesight such as double vision or other eye problems
- **Signs of a liver problem** such as yellowing of the skin or eyes, dark-brown coloured urine or pain in the upper right side of the stomach area, fever
- **Signs of an immune system disorder called lupus** such as joint pain or a rash on cheeks or arms that is sensitive to the sun
- **Signs of a low blood count** such as persistent fever, bleeding or bruising more easily or looking pale.

Tell your doctor straight away if you notice any of the above.

### Very common side effects (may affect more than 1 in 10 people)
- Stomach pain, feeling sick
- Viral infections such as herpes or flu
- Upper respiratory infections such as sinusitis
- Headache
- Side effect due to an infusion
- Pain.

### Common side effects (may affect up to 1 in 10 people)
- Changes in how your liver works, increase in liver enzymes (shown in blood tests)
- Lung or chest infections such as bronchitis or pneumonia
- Difficult or painful breathing, chest pain
- Bleeding in the stomach or intestines, diarrhoea, indigestion, heartburn, constipation
- Nettle-type rash (hives), itchy rash or dry skin
- Balance problems or feeling dizzy
- Fever, increased sweating
- Circulation problems such as low or high blood pressure
- Bruising, hot flush or nosebleed, warm, red skin (flushing)
- Feeling tired or weak
- Bacterial infections such as blood poisoning, abscess or infection of the skin (cellulitis)
- Blood problems such as anaemia or low white blood cell count
- Swollen lymph nodes
- Depression, problems sleeping
- Eye problems, including red eyes and infections
- Fast heart beat (tachycardia) or palpitations
- Pain in the joints, muscles or back
- Urinary tract infection
- Psoriasis, skin problems such as eczema and hair loss
- Reactions at the injection site such as pain, swelling, redness or itching
- Chills, a build up of fluid under the skin causing swelling
- Feeling numb or having a tingling feeling.

### Uncommon side effects (may affect up to 1 in 100 people)
- Shortage of blood supply, swelling of a vein
- Skin problems such as blistering, warts, abnormal skin colouration or pigmentation, or swollen lips
- Severe allergic reactions (e.g. anaphylaxis), an immune system disorder called lupus, allergic reactions to foreign proteins
- Wounds taking longer to heal
- Swelling of the liver (hepatitis) or gall bladder, liver damage
- Feeling forgetful, irritable, confused, nervous
- Eye problems including blurred or reduced vision, puffy eyes or sties
- New or worsening heart failure, slow heart rate
- Fainting
- Convulsions, nerve problems
- A hole in the bowel or blockage of the intestine, stomach pain or cramps
- Swelling of your pancreas (pancreatitis)
- Fungal infections such as yeast infection
- Lung problems (such as oedema)
- Fluid around the lungs (pleural effusion)
- Kidney infections
- Low platelet count, too many white blood cells
- Infections of the vagina.

### Rare side effects (may affect up to 1 in 1,000 people)
- A type of blood cancer (lymphoma)
- Your blood not supplying enough oxygen to your body, circulation problems such as narrowing of a blood vessel
- Inflammation of the lining of the brain (meningitis)
- Infections due to a weakened immune system
- Hepatitis B infection when you have had hepatitis B in the past
- Abnormal tissue swelling or growth
- Swelling of small blood vessels (vasculitis)
- Immune disorders that could affect the lungs, skin and lymph nodes (such as sarcoidosis)
- Lack of interest or emotion
- Serious skin problems such as toxic epidermal necrolysis, Stevens-Johnson Syndrome or erythema multiforme, skin problems such as boils
- Serious nervous system disorders such as transverse myelitis, multiple sclerosis-like disease, optic neuritis and Guillain-Barré syndrome
- Fluid in the lining of the heart (pericardial effusion)
- Serious lung problems (such as interstitial lung disease)
- Melanoma (a type of skin cancer)
- Cervical cancer
- Low blood counts, including a severely decreased number of white blood cells.

### Other side effects (the frequency is unknown)
- Cancer in children and adults
- A rare blood cancer affecting mostly young people (hepatosplenic T-cell lymphoma)
- Liver failure
- Merkel cell carcinoma (a type of skin cancer)
- Worsening of a condition called dermatomyositis (seen as a skin rash accompanying muscle weakness)
- Temporary loss of sight during or within 2 hours of infusion
- The use of a 'live' vaccine may result in an infection caused by the 'live' viruses or bacteria contained in the vaccine (when you have a weakened immune system).

### Additional side effects in children and adolescents
Children who took infliximab for Crohn's disease showed some differences in side effects compared with adults who took infliximab for Crohn's disease. The side effects that happened more in children were: low red blood cells (anaemia), blood in stool, low white blood cells (leucopenia), redness or blushing (flushing), viral infections, low neutrophils which are white blood cells that fight infection (neutropenia), bone fracture, bacterial infection and allergic reactions of the breathing tract.

### 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 this leaflet. You can also report side effects directly via:

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

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

## 5. How to store Remsima

Remsima will generally be stored by the health professionals.The storage details should you need them are as follows:
- 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 and the carton after "EXP". The expiry date refers to the last day of that month.
- Store in a refrigerator (2°C to 8°C).
- This medicine can also be stored in the original carton outside of refrigerated storage up to a maximum of 25°C for a single period of up to six months. In this situation, do not return to refrigerated storage again. Write the new expiry date on the carton including day/month/year. Discard this medicine if not used by the new expiry date or the expiry date printed on the carton, whichever is earlier.
- It is recommended that when Remsima is prepared for infusion, it is used as soon as possible (within 3 hours). However, if the solution is prepared in germ-free conditions, it can be stored in a refrigerator at 2°C to 8°C for 24 hours.
- Do not use this medicine if it is discoloured or if there are particles present.

## 6. Contents of the pack and other information

### What Remsima contains
- The active substance is infliximab. Each vial contains 100 mg of infliximab. After preparation each ml contains 10 mg of infliximab.
- The other ingredients are sucrose, polysorbate 80, sodium dihydrogen phosphate monohydrate and disodium phosphate dihydrate.

### What Remsima looks like and contents of the pack
Remsima is supplied as a glass vial containing a powder for concentrate for solution for infusion. The powder is white.
Remsima is produced in packs of 1, 2, 3, 4 or 5 vials. Not all pack sizes may be marketed.

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Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.
There are also links to other websites about rare diseases and treatments.
This leaflet is available in all EU/EEA languages on the European Medicines Agency website.