Package leaflet: Information for the user

Remsima 100 mg powder for concentrate for solution for infusion
infliximab

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 you need to be aware of before and during your treatment with Remsima.
- When starting a new card, keep this card as a reference for 4 months after your last dose of 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
2. What you need to know before you use Remsima
3. How Remsima will be given
4. Possible side effects
5. How to store Remsima
6. Contents of the pack and other information

1. What Remsima is and what it is used for

Remsima contains the active substance infliximab. Infliximab is a monoclonal antibody - a type of protein that attaches to a specific target in the body called TNF (tumour necrosis factor) alpha.

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 selectively attaching to TNF alpha and blocking its action. TNF alpha is involved in inflammatory processes of the body so 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 these medicines do not work well enough, you will be given Remsima which you will take 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 these medicines do not work well enough, 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 these medicines do not work well enough, 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 these medicines or treatments do not work well enough, 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 these medicines do not work well enough, 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 these medicines do not work well enough, 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 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 use 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 or during treatment with Remsima if you have:

<u>Had treatment with any medicine containing infliximab before</u>

- 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 before you are given Remsima if you have an infection even if it is a very minor one.
- Tell your doctor before you are given Remsima if you have ever lived in or travelled to an area where infections called histoplasmosis, coccidioidomycosis, or blastomycosis are common. 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, bacteria or other organisms in the environment 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 temporarily stopping 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 infliximab, even in patients who have already been treated with medicines for TB. Your doctor will record these tests on your patient reminder 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

- Tell your doctor before you are given Remsima if you are a carrier of hepatitis B or have ever had it.
- Tell your doctor if you think you might be at risk of contracting hepatitis B.
- Your doctor should test you for hepatitis B virus.
- 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.
- If you experience reactivation of hepatitis B, your doctor may need to stop your treatment and may give you medicines such as effective antiviral therapy with supportive treatment.

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.

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 before you are given Remsima if you have or have ever had lymphoma (a type of blood cancer) or any other cancer.
- Patients with severe rheumatoid arthritis, who have had the disease for a long time, may be at higher 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 infliximab have developed a rare type of cancer called hepatosplenic T-cell lymphoma. Of these patients, most were teenage boys

or young men 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 medicines containing azathioprine or mercaptopurine in addition to TNF-blockers.
- Some patients treated with infliximab have developed certain kinds of skin cancer. If there are any changes in your skin or growths on the skin during or after therapy, tell your doctor.
- Some women being treated for rheumatoid arthritis with infliximab have developed cervical cancer. For women taking Remsima including those over 60 years of age, your doctor may recommend regular screening for cervical cancer.

Lung disease or heavy smoking

- Tell your doctor before you are given Remsima if you have a lung disease called chronic obstructive pulmonary disease (COPD) or if you are a heavy smoker.
- 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 before you are given Remsima if you have or have ever had a problem that affects your nervous system. This includes multiple sclerosis, Guillain-Barré 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.

Abnormal skin openings

- Tell your doctor if you have any abnormal skin openings (fistulae) before you are given Remsima.

Vaccinations

- Talk to your doctor if you recently have had or are due to have a vaccine.
- You should receive recommended vaccinations before starting Remsima treatment. You may receive some vaccines during treatment with Remsima but you should not receive live vaccines (vaccines that contain a living but weakened infectious agent) while using Remsima because they may cause infections.
- If you received Remsima while you were pregnant, your baby may also be at higher risk for getting an infection as a result of receiving a live vaccine during the first year of life. 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 the BCG vaccine (used to prevent tuberculosis).
- If you are breast-feeding, it is important that you tell your baby's doctors and other healthcare professionals about your Remsima use before your baby is given any vaccine. 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 that you are having treatment with Remsima by showing them your patient reminder card.

Liver problems

- Some patients receiving infliximab have developed serious liver problems.
- Tell your doctor straight away if you get symptoms of liver problems during treatment with Remsima. Signs include yellowing of the skin and eyes, dark-brown coloured urine, pain or swelling in the upper right side of the stomach area, joint pain, skin rashes, or fever.

Low blood counts

- In some patients receiving infliximab, the body may not make enough of the blood cells that help fight infections or help stop bleeding.
- Tell your doctor straight away if you get symptoms of low blood counts during treatment with Remsima. Signs include persistent fever, bleeding or bruising more easily, small red or purple spots caused by bleeding under the skin, or looking pale.

Immune system disorder

- Some patients receiving infliximab have developed symptoms of an immune system disorder called lupus.
- Tell your doctor straight away if you develop symptoms of lupus during treatment with Remsima. Signs include joint pain or a rash on cheeks or arms that is sensitive to the sun.

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 infliximab have developed cancers, including unusual types, which sometimes resulted in death.
- More children taking infliximab developed infections as compared to adults.
- Children should receive recommended vaccinations before starting Remsima treatment.

Children may receive some vaccines during treatment with Remsima but should not receive live vaccines while using Remsima.

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 or if you are receiving Remsima while breast-feeding, 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, breast-feeding and fertility
- 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 should only be used during pregnancy or while breast-feeding if your doctor feels it is necessary for you.
- You should avoid getting pregnant when you are being treated with Remsima and for 6 months after you stop being treated with it. Discuss the use of contraception during this time with your doctor.
- 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 is given any vaccine. If you received Remsima while pregnant, giving BCG vaccine (used to prevent tuberculosis) to your baby within 12 months after birth may result in infection with serious complications, including death. Live vaccines such as the BCG vaccine should not be given to your baby within 12 months after birth, unless your baby's doctor recommends otherwise. For more information see section on vaccination.
- If you are breast-feeding, it is important that you tell your baby's doctors and other healthcare professionals about your Remsima use before your baby is given any vaccine. Live vaccines should not be given to your baby while you are breast-feeding unless your baby's doctor recommends otherwise.
- Severely decreased numbers of white blood cells have been reported in infants born to women treated with infliximab 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 tired, dizzy, or unwell 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'. However, before Remsima is given to you, it is mixed with a solution that contains sodium. Talk to your doctor if you are on a low salt diet.

3. How to use Remsima

Rheumatoid arthritis
The usual 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 usual dose is 5 mg for every kg of body weight.

How Remsima is given
- Remsima will be given to you by your doctor or nurse.
- Your doctor or nurse will prepare the medicine for infusion.
- The medicine will be given as an infusion (drip) (over 2 hours) into one of your veins, usually in your arm. After the third treatment, your doctor may decide to give your dose of Remsima over 1 hour.
- You will be monitored while you are given Remsima and also for 1 to 2 hours afterwards.

How much Remsima is given

- The doctor will decide your dose and how often you will be given Remsima. This will depend on your disease, weight and how well you respond to Remsima.
- The table below shows how often you will usually have this medicine after your first dose.

2nd dose	2 weeks after your 1st dose
3rd dose	6 weeks after your 1st dose
Further doses	Every 6 to 8 weeks depending on your disease

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. Some of these reactions may be serious or life-threatening. An allergic reaction could happen within 2 hours of your injection or later. More signs of allergic side effects 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 (feeling sick), vomiting, fluttering or pounding in your chest, a fast or a slow heartbeat, and swelling of your feet.
- **Signs of infection (including TB)** such as fever, feeling tired, cough which may be persistent, shortness of breath, flu-like symptoms, weight loss, night sweats, diarrhoea, wounds, collection of pus in the gut or around the anus (abscess), dental problems or burning sensation when urinating.
- **Possible signs of cancer** including but not limited to swelling of lymph nodes, weight loss, fever, unusual skin nodules, changes in moles or skin colouring, or unusual vaginal bleeding.
- **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 signs of a stroke (sudden numbness or weakness of your face, arm or leg, especially on one side of your body; sudden confusion, trouble speaking or understanding; trouble seeing in one or both eyes, trouble walking, dizziness, loss of balance or coordination or a severe headache), fits, tingling/numbness in any part of your body, or weakness in arms or legs, changes in eyesight such as double vision or other eye problems.

- **Signs of a liver problem** (including hepatitis B infection when you have had hepatitis B in the past) such as yellowing of the skin or eyes, dark-brown coloured urine, pain or swelling in the upper right side of the stomach area, joint pain, skin rashes, or 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 (lupus) or cough, shortness of breath, fever or skin rash (sarcoidosis).
- **Signs of low blood counts** such as persistent fever, bleeding or bruising more easily, small red or purple spots caused by bleeding under the skin, or looking pale.
- **Signs of serious skin problems** such as reddish-target-like spots or circular patches often with central blisters on the trunk, large areas of peeling and shedding (exfoliating) skin, ulcers of mouth, throat, nose, genitals and eyes or small pus-filled bumps that can spread over the body. These skin reactions can be accompanied by fever.

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

The following side effects have been observed with Remsima:

Very common: 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: 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)
- Infection of the skin due to a fungus
- 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: may affect up to 1 in 100 people
- Shortage of blood supply, swelling of a vein
- Collection of blood outside the blood vessels (haematoma) or bruising
- Skin problems such as blistering, warts, abnormal skin colouration or pigmentation, or swollen lips, or thickening of the skin, or red, scaly, and flaky skin

- 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, or fungal infection of the nails
- Lung problems (such as oedema)
- Fluid around the lungs (pleural effusion)
- Narrowed airway in the lungs, causing difficulty breathing
- Inflamed lining of the lung, causing sharp chest pains that feel worse with breathing (pleurisy)
- Tuberculosis
- Kidney infections
- Low platelet count, too many white blood cells
- Infections of the vagina
- Blood test result showing 'antibodies' against your own body.
- Changes in cholesterol and fat levels in the blood.
- Weight gain (for most patients, the weight gain was small).

Rare: 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
- Inflamed liver caused by a problem with the immune system (autoimmune hepatitis)
- Liver problem that causes yellowing of the skin or eyes (jaundice)
- Abnormal tissue swelling or growth
- Severe allergic reaction that may cause loss of consciousness and could be life-threatening (anaphylactic shock)
- Swelling of small blood vessels (vasculitis)
- Immune disorders that could affect the lungs, skin and lymph nodes (such as sarcoidosis)
- Collections of immune cells resulting from an inflammatory response (granulomatous lesions)
- Lack of interest or emotion
- Serious skin problems such as toxic epidermal necrolysis, Stevens-Johnson syndrome and acute generalised exanthematous pustulosis
- Other skin problems such as erythema multiforme, blisters and peeling skin, or boils (furunculosis)
- Serious nervous system disorders such as transverse myelitis, multiple sclerosis-like disease, optic neuritis and Guillain-Barré syndrome
- Inflammation in the eye that may cause changes in the vision, including blindness
- 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
- Small red or purple spots caused by bleeding under the skin

- Abnormal values of a blood protein called 'complement factor' which is part of the immune system
- Lichenoid reactions (itchy reddish-purple skin rash and/or threadlike white-grey lines on mucous membranes).

Not known: frequency cannot be estimated from the available data
- Cancer in children and adults
- A rare blood cancer affecting mostly teenage boys or young men (hepatosplenic T-cell lymphoma)
- Liver failure
- 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.
- Worsening of a condition called dermatomyositis (seen as a skin rash accompanying muscle weakness)
- Heart attack
- Stroke
- Temporary loss of sight during or within 2 hours of infusion
- Infection due to a live vaccine because of 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 overall levels of white blood cells (leukopenia), redness or blushing (flushing), viral infections, low levels of 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 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 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 – 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, but not beyond the original expiry date. 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 – 8°C up to 60 days and for an additional 24 hours at 25 °C after removal from the refrigerator.
- 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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The following information is intended for healthcare professionals only:

Patients treated with Remsima should be given the patient reminder card.

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

In order to improve the traceability of biological medicinal products, the tradename and batch number of the administered medicinal product should be clearly recorded.

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. The dilution 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. For volumes greater than 250 ml, either use a larger infusion bag (e.g. 500 ml, 1000 ml) or use multiple 250 ml infusion bags to ensure that the concentration of the infusion solution does not exceed 4 mg/ml. If stored refrigerated after reconstitution and

dilution, the infusion solution must be allowed to equilibrate at room temperature to 25 °C for 3 hours prior to Step 4 (infusion). Storage beyond 24 hours at 2 °C - 8 °C applies to preparation of Remsima in the infusion bag only.

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 micrometre 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. If not used immediately, in use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2°C – 8°C, unless reconstitution/dilution has been taken place in controlled and validated aseptic conditions. 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.