Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Ixifi®

Powder for concentrate for solution for intravenous (I.V.) infusion.

Each Ixifi vial contains 100 mg of infliximab. After solution preparation, each ml contains 10 mg of infliximab.
Inactive ingredients and allergens: see section 2 under "Important information about some of this medicine's ingredients" and section 6 "Further information".

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

Ixifi is a biosimilar product. In addition to the patient information leaflet, Ixifi also has a patient safety information card.
This card contains important safety information that you need to know and that you should follow before you start and during the treatment with Ixifi.
Carefully read the patient safety information card and patient information leaflet before using this medicine. Keep the card in case you need to read it again.

For your attention,
Each time you get this medicine at the pharmacy, it is important that you confirm that you have received the same medicine that your doctor has prescribed you.
If the medicine you are given looks different from what you usually get, or if the instructions for use have changed, please refer to the pharmacist immediately to verify you have received the right medicine. Only your doctor can switch your medicine or change the dosage of medicine that contains infliximab. Please check that the medicine that your specialist prescribed you has the same brand name as the medicine you received from the pharmacist.

1. WHAT IS THE MEDICINE INTENDED FOR?

Ixifi is used in adults for treatment of the following inflammatory diseases:
• Rheumatoid arthritis
• Ankylosing spondylitis
• Psoriatic arthritis
• Psoriasis
• Crohn's disease
• Ulcerative colitis

Therapeutic group: TNFα blockers

Ixifi contains the active substance infliximab.
Infliximab is a monoclonal antibody - a type of protein that binds to a specific target in the body, to a protein called TNF (tumor necrosis factor) alpha.
Ixifi works by selectively attaching to TNF alpha protein and blocking its action. TNF alpha is involved in inflammatory processes of the body, therefore blocking it can reduce the inflammation in your body.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- You are sensitive (allergic) to infliximab or to any of the other ingredients in this medicine (listed in section 6).
- You are allergic to proteins of murine origin.
- You have tuberculosis (TB) or another severe infection such as an abscess (bacterial infection) or sepsis (severe bacterial infection of the blood), and opportunistic infection.
- You suffer from moderate or severe heart failure.

Do not use Ixifi if you suffer from any of the conditions listed above. If you are not sure, contact your doctor before taking Ixifi.

Special warnings regarding use of the medicine
Before treatment with Ixifi, tell your doctor if:

<u>You have been previously treated with any medicine containing infliximab</u>

• Tell your doctor if you have received treatment with medicines containing infliximab in the past and are now starting treatment with Ixifi again.
• If you stopped treatment with infliximab for more than 16 weeks, there is a higher risk for allergic reactions occurring when you start the treatment again.

<u>Infections</u>

• Tell your doctor before starting treatment with Ixifi if you have any infection, even if it is a minor infection.
• Tell your doctor before starting treatment with Ixifi if you have ever lived in or travelled in 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 Ixifi. If you are 65 years of age or older, you have a greater risk.
• The following potentially severe infections include tuberculosis, infections caused by viruses, fungi, bacteria or other organisms in the environment and sepsis, that may be life-threatening. Tell your doctor immediately if you experience signs of infection during treatment with Ixifi. Signs include fever, cough, flu-like signs, generally unwell feeling, hot or red skin, wounds or dental problems. Your doctor may recommend temporary discontinuation of the treatment with Ixifi.

<u>Tuberculosis</u>

• 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 or has had tuberculosis in the past.
• Your doctor will test you to see if you have tuberculosis. Cases of tuberculosis have been reported in patients treated with infliximab, even in patients who have already been treated with medicines for tuberculosis. Your doctor will record the test results on your "Patient Safety Information Card".
• If your doctor is concerned that you are at risk for tuberculosis, you may be treated with medicines for tuberculosis before you start treatment with Ixifi.
Tell your doctor immediately if you notice signs of tuberculosis during treatment with Ixifi. These signs include persistent cough, weight loss, feeling tired, fever, night sweats.

<u>Hepatitis B virus</u>

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

<u>Heart problems</u>

• Tell your doctor if you have any heart problems, such as mild heart failure.
• Your doctor will closely monitor your heart.

Tell your doctor immediately if you experience new or worsening symptoms of heart failure during treatment with Ixifi. The symptoms include shortness of breath or swelling of the feet.

Cancer and lymphoma
• Tell your doctor before you are given Ixifi if you have or have ever had lymphoma (a type of blood cancer) or any other type of cancer.
• Patients with severe rheumatoid arthritis may be at a higher risk of developing lymphoma.
• Adults taking Ixifi may be at a higher risk of developing lymphoma or another type of cancer.
• Some patients who have been treated with 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 of them had either Crohn's disease or ulcerative colitis. This type of cancer has usually resulted in death. Almost all patients had also taken medicines containing azathioprine or 6-mercaptopurine in addition to TNF blockers.
• Some patients treated with infliximab have developed certain types 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 treated with infliximab for rheumatoid arthritis have developed cervical cancer. For women taking Ixifi, including women aged over 60 years, the doctor may recommend regular screening tests for cervical cancer.

Lung disease or heavy smoking
• Tell your doctor before you are given Ixifi 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 be at a higher risk of developing cancer during Ixifi treatment.

Nervous system diseases
• Tell your doctor before you are given Ixifi if you have or have ever had problems affecting your nervous system. These problems include multiple sclerosis, Guillain-Barre syndrome, if you have fits or have been diagnosed with optic neuritis. Tell your doctor immediately if you develop symptoms of a nerve disease during treatment with Ixifi. Signs include changes in your vision, weakness in your arms or legs, numbness or tingling in any part of the body.

Abnormal skin openings (fistulae)
• Tell your doctor if you have any abnormal skin openings (fistulae) before you are given Ixifi.

Vaccinations
• Tell your doctor if you have recently received or are due to receive a vaccine.
• You should receive recommended vaccines before starting Ixifi treatment. You may receive some vaccines during the treatment with Ixifi, but you should not receive live vaccines (vaccines containing a living but weakened infectious agent) during the treatment with Ixifi because they may cause infections.
• If you received Ixifi while you were pregnant, your baby may also be at a 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 healthcare professionals about your Ixifi use, so they can decide when your baby should receive any vaccine, including 'live' vaccines such as BCG (for prevention of tuberculosis).
• If you are breast-feeding, it is important that you tell your baby's doctors and other healthcare professionals about your Ixifi use before your baby is given any vaccine.
For more information see section on "Pregnancy breast-feeding and fertility".

Therapeutic infectious agents
• Tell your doctor if you have recently received or are scheduled to receive treatment with a therapeutic infectious agent (such as BCG vaccine used for treatment of cancer).

Operations or dental procedures
• Tell your doctor if you are going to undergo any operation or dental procedure.

Tell the surgeon or dentist that you are receiving treatment with Ixifi and show them your "patient safety information card".

Liver problems
• Some patients receiving infliximab have developed serious liver problems.
• Tell your doctor immediately if you experience symptoms of liver problems during treatment with Ixifi. 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 rash, or fever.

Low blood count
• 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 immediately if you experience symptoms of low blood count during treatment with Ixifi. 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 immediately if you develop symptoms of lupus during treatment with Ixifi. Signs include joint pain or a rash on the cheeks or arms, which is sensitive to the sun.

If you are not sure whether any of the above conditions applies to you, talk to your doctor before you receive treatment with Ixifi.

Children and adolescents
This medicine is not intended for use in children and adolescents.

Drug interactions
If you are taking or have recently taken, other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist. Particularly tell your doctor or pharmacist if you are taking or have previously taken:
• Medicines for treatment of inflammatory diseases. These medicines may cause side effects. Your doctor will advise you what other medicines you must keep using while you are receiving treatment with Ixifi.
• Medicines for treatment of Crohn’s disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, psoriasis.

In particular, tell your doctor if you are using any of the following medicines:
• Medicines that affect your immune system.
• Kineret (containing anakinra). Do not use Ixifi and Kineret together.
• Orencia (containing abatacept). Do not use Ixifi and Orencia together.
• You must not receive live vaccines during the treatment with Ixifi
• If you are breast-feeding or pregnant, it is important that you tell your baby’s doctors and other healthcare professionals about your Ixifi use before your baby is given any vaccine.

Pregnancy, breast-feeding and fertility
• If you are pregnant or breast-feeding, think that you may be pregnant or are planning to become pregnant, do not use this medicine before you consult your doctor. Ixifi should only be used during pregnancy or while breast-feeding if your doctor feels it is necessary for you.
• You should avoid getting pregnant during treatment with Ixifi and for 6 months after stopping the treatment. Consult your doctor regarding the use of contraceptives during this period.
• If you received Ixifi during pregnancy, your baby may be at a higher risk for getting an infection.
• It is important that you inform your baby’s doctor and other health care professionals about your use of Ixifi before your baby receives any vaccine. If you received Ixifi while pregnant, do not give the BCG vaccine (used to prevent tuberculosis) to your baby in the 12 months following birth.

Live vaccines should not be given to your baby for the 6 months following birth unless your baby's doctor recommends otherwise. For more information see "Vaccination" section.
• If you are breast-feeding, it is important that you tell your baby's doctors and other healthcare professionals about your Ixifi use before your baby is given any vaccine. Live vaccines may be given to your baby while you are breast-feeding, subject to monitoring of the level of the medicine in the blood.
• 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 infections or fevers, contact your baby's doctor immediately.

Driving and using machines
Ixifi is not likely to affect your ability to drive, use tools or operate machines. If you feel tired, dizzy or unwell after receiving Ixifi treatment, do not drive or use any tools or machines.

Important information about some of this medicine's ingredients
The medicine contains less than 23 mg sodium per dose, that is to say essentially 'sodium-free'. However, before Ixifi is given to you, it is mixed with a solution that contains sodium. Tell your doctor if you are on a low salt diet.

3. HOW TO USE THIS MEDICINE?
• Ixifi will be given to you by your doctor or nurse, in a hospital or clinic.
• Your doctor or nurse will prepare the medicine solution for infusion.
• Ixifi solution will be given to you as an infusion (drip) (over 2 hours) into one of your veins, usually in the arm. After the third treatment, your doctor may decide to give you the solution dose over 1 hour period only.
• You will be under medical follow up while you receive Ixifi, as well as for 1 to 2 hours afterwards.
• Your doctor will determine your dosage (in mg) and how often you will receive Ixifi in accordance with your disease, weight and your response to Ixifi treatment.

If you received an overdose of Ixifi
As this medicine is being given by a doctor or nurse, it is unlikely that you will receive an overdose of this medicine. There are no known side effects associated with receiving an overdose of Ixifi.

If you forget or miss your Ixifi infusion
If you forget or miss an appointment scheduled for receiving Ixifi, schedule another appointment as soon as possible.
Adhere to the treatment as recommended by your doctor.
Even if your health improves, do not stop taking this medicine without consulting your doctor.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS
As with any medicine, use of Ixifi may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of 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 the treatment with Ixifi has stopped.

Consult your doctor immediately if you notice any of the following signs:
• **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 can occur within 2 hours of receiving the injection or later. Additional signs of allergic side effects that may occur up to 12 days after receiving the 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, light-headedness, dizziness, fainting, sweating, nausea (feeling sick), vomiting, sensation of fluttering or pounding in your chest, a fast or slow heartbeat, and swelling of the feet.
• **Signs of infection (including tuberculosis),** 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 during urination.
• **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 lung problems,** such as coughing, breathing difficulties or tightness in the chest.
• **Signs of nervous system problems (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 liver problems** (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 rash, or fever.
• **Signs of an immune system disorder,** 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 upper part of the body, large areas of peeling and shedding (exfoliating) skin, ulcers in the 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.

The following side effects have been observed with Ixifi:
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 the infusion
• Pain

Common side effects (may affect up to 1 in 10 people)
• Changes in liver function, increase in liver enzymes (diagnosed 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
• Hives (nettle-type rash), itchy rash or dry skin
• Balance problems or feeling dizzy
• Fever, increased sweating
• Circulation problems such as low or high blood pressure
• Bruising, hot flushes or nosebleed, warm and 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, accumulation 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, vein swelling
• Collection of blood outside the blood vessels (hematoma) or bruising
• Skin problems such as blistering, warts, abnormal skin colouration or pigmentation, or swelling of the 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 gallbladder, 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 the 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 lungs, causing sharp chest pain worsening with breathing (pleurisy)
• Tuberculosis
• Kidney infections
• Low platelet count, excess of white blood cells
• Vaginal infections
• 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 side effects (may affect up to 1 in 1,000 people)
• Lymphoma (a type of blood cancer)
• Insufficient supply of oxygen from the blood to the body, circulation problems such as narrowing of blood vessels
• 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 may be life-threatening (anaphylactic shock)
• Swelling of small blood vessels (vasculitis)
• Immune system 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 Lyell's disease (toxic epidermal necrolysis), Stevens-Johnson Syndrome and Acute Generalised Exanthematous Pustulosis (AGEP)
• Other skin problems such as erythema multiforme, skin reactions (lichenoid reactions) (itchy reddish-purple skin rash and/or threadlike white-grey lines on mucous membranes), blisters and peeling skin, or boils (furunculosis)

• Serious nervous system disorders such as transverse myelitis, multiple sclerosis-like disease, optic neuritis and Guillain-Barre 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

Side effects of unknown frequency (the frequency of these effects cannot be estimated from the available data)
• Cancer
• 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 accompanied by muscle weakness)
• Heart attack
• Stroke
• Temporary vision loss during or within 2 hours of infusion
• Infection due to a live vaccine because of a weakened immune system

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects:
You can report side effects to the Ministry of Health by following the link ‘Reporting Side Effects of Drug Treatment’ on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects or by using the link:
https://sideeffects.health.gov.il

5. HOW TO STORE THE MEDICINE?
Ixifi will be stored by the healthcare professionals at the hospital or clinic. The storage details, should you need them, are as follows:
• Prevent poisoning! This and any other medicine should be kept in a closed place, out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.
• Do not use the medicine after the expiry date (exp. date) which is stated on the label and package. The expiry date refers to the last day of that month. Even if stored according to the recommended storage conditions, medicines are kept only for a limited period. Please pay attention to the medicine's expiry date! In case of any doubt, consult the pharmacist who dispensed the medicine to you.
• Keep refrigerated (2°C-8°C). An unopened package can be stored at a temperature of up to 30°C for a period of up to 6 months (but not beyond the expiry date indicated on the package). After removing the medicine from the refrigerator, do not return it to the refrigerator.
• Once Ixifi is prepared for infusion, it is recommended to use it as soon as possible (within 3 hours).
• Do not use the solution if you notice that it is discoloured or if there are particles in it.
• Do not throw away the medicine via wastewater or household waste. Ask the pharmacist how to throw away this medicine. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, this medicine also contains:
Sucrose, disodium succinate hexahydrate, succinic acid, polysorbate 80

What the medicine looks like and contents of the pack:
Ixifi is supplied in a glass vial containing white powder for concentrate for solution for infusion.
Ixifi is marketed in a pack containing 1 vial.

Registration holder and address: Pfizer PFE Pharmaceuticals Israel Ltd., 9 Shenkar St, Herzliya Pituach 46725.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
162-94-35522-00

Guidelines for healthcare professionals:

Special instruction for handling
1. Calculate the dose and the number of Ixifi vials needed. Each Ixifi vial contains 100 mg infliximab. Calculate the total volume of reconstituted Ixifi solution required.

2. Under aseptic conditions, reconstitute each Ixifi vial with 10 ml of water for injections, using a syringe equipped with a 21-gauge (0.8 mm) or smaller needle. Remove flip-top from the vial and wipe the top with a 70% alcohol swab. Insert the syringe needle into the vial through the centre of the rubber stopper and direct the stream of water for injections to the glass wall of the vial. Gently swirl the solution by rotating the vial to dissolve the lyophilised powder. Avoid prolonged or vigorous agitation. DO NOT SHAKE. Foaming of the solution on reconstitution is not unusual. Allow the reconstituted solution to stand for 5 minutes. Check that the solution is colourless to light brown and opalescent. The solution may develop a few fine translucent particles, as infliximab is a protein. Do not use if opaque particles, discolouration, or other foreign particles are present.

3. Dilute the total volume of the reconstituted Ixifi solution dose to 250 ml with sodium chloride 9 mg/ml (0.9%) solution for infusion. Do not dilute the reconstituted Ixifi 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 Ixifi. Slowly add the total volume of reconstituted Ixifi solution to the 250 ml infusion bottle or bag. Gently mix.

4. Administer the infusion solution over a period of not less than the infusion time recommended. Use only an infusion set with an in-line, sterile, non-pyrogenic, low protein-binding filter (pore size 1.2 micrometre or less). 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, Ixifi infusion solution can be used within 24 hours if stored at 2°C – 8°C. Do not store any unused portion of the infusion solution for reuse.

5. No physical biochemical compatibility studies have been conducted to evaluate the co-administration of Ixifi with other agents. Do not infuse Ixifi concomitantly in the same intravenous line with other agents.

6. Visually inspect Ixifi for particulate matter or discolouration prior to administration. Do not use if visibly opaque particles, discolouration or foreign particles are observed.

7. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Revised in 08/2024.