

# Infliximab

## Infliximab 100mg powder for solution for infusion vials When used in rheumatoid arthritis

Infliximab (In-flix-ee-mab) is a medicine which is used in a number of conditions.

### Your medicine

Infliximab is an immunosuppressant which may be given in combination with other medicines. It helps to suppress overactivity of the immune system in inflammatory conditions. It helps to reduce pain and swelling by limiting inflammation.

Due to its effects on the immune system, people who have Infliximab are prone to getting infections. This includes serious infections such as tuberculosis and sepsis. It is for this reason that people who have Infliximab are monitored for infections.

Infliximab stays in the body for up to six months, so the effects of this medicine will persist for some time after you have your last dose.

### Other information about Infliximab:

- while you are having Infliximab you may have an increased chance of getting an infection. You should speak to your prescriber for further information about how you can best avoid getting an infection
- your prescriber will give you an alert card and a package leaflet. It contains important information about Infliximab. If you have any concerns or questions about having Infliximab you should discuss them with your prescriber
- when changing from one biologic to another, you will be monitored continuously by your prescriber for any signs of infection

Infliximab is usually given to you by a healthcare professional. The person responsible for giving you your medicine will make sure that you get the right dose.

If you feel that the medicine is making you unwell or you do not think it is working, then talk to your prescriber or someone involved in your medical care.

### When to take your medicine

The person with responsibility for giving you your medicine will make sure that you have your medicine at the prescribed times.

### How to take your medicine

This medicine will be given to you as an injection. If you have any concerns about this medicine or how this will be given to you, talk to someone who is involved in your medical care.

### Taking too much of your medicine

Having extra doses of some medicines can be harmful. In some cases even one extra dose can cause you problems.

In the case of Infliximab, the person who is responsible for giving you your medicine will make sure that you are given the correct dose.

### Stopping your medicine

The person in charge of your care will make the decision about when you should stop this medicine. If you experience any problems while having this medicine, talk to someone who is involved in your medical care.

### Looking after your medicine

As Infliximab will be given to you as an injection, it will usually be stored by the medical team.

### Whether this medicine is suitable for you

Infliximab is not suitable for everyone and some people should never use it. Other people should only use it with special care. It is important that the person prescribing this medicine knows your full medical history.

*Your prescriber may only prescribe this medicine with special care or may not prescribe it at all if you:*

- have sepsis
- have heart problems
- are allergic or sensitive to or have had a reaction to any of the ingredients in the medicine
- are immunosuppressed
- have demyelinating disorders
- have kidney problems
- have liver problems
- have intestinal strictures due to Crohn's disease
- are a carrier of hepatitis B infection
- have or have had cancer
- have been in close contact with somebody with tuberculosis
- are or have been a heavy smoker
- have psoriasis and have or have had PUVA treatment for a long time
- have primary sclerosing cholangitis
- are about to have surgery or have had an arthroplasty
- have or have had tuberculosis
- have had recurrent infections
- were last given Infliximab for Crohn's disease or rheumatoid arthritis more than sixteen weeks ago
- have ulcerative colitis
- have infections, abscesses or infected fistulas

- have come into contact with someone who has a fungal infection
- have recently had a vaccination or are having a vaccination soon
- are allergic or sensitive to or have had a bad reaction to mouse proteins in the past
- are aged over 65 years

Furthermore the prescriber may only prescribe this medicine with special care or may not prescribe it at all for someone under 18 years of age.

*As part of the process of assessing suitability to take this medicine a prescriber may also arrange tests:*

- to determine whether or not the medicine is suitable and whether it must be prescribed with extra care
- to check that this medicine is not having any undesired effects

Over time it is possible that Infliximab can become unsuitable for some people, or they may become unsuitable for it. If at any time it appears that Infliximab has become unsuitable, it is important that the prescriber is contacted immediately.

### Side-effects

A medicine is only made available to the public if the clinical trials have shown that the benefits of taking the medicine outweigh the risks.

Once a medicine has been licensed, information on the medicine's effects, both intended and unintended, is continuously recorded and updated.

Some side-effects may be serious while others may only be a mild inconvenience.

Everyone's reaction to a medicine is different. It is difficult to predict which side-effects you will have from taking a particular medicine, or whether you will have any side-effects at all. The important thing is to tell your prescriber or pharmacist if you are having problems with your medicine.

*Very common: More than 1 in 10 people who have Infliximab*

- production of antibodies to Infliximab

*Common: More than 1 in 100 people who have Infliximab*

- abnormal laboratory test results
- chest pain
- diarrhoea
- dry skin
- feeling dizzy
- fever
- flushing
- headaches

- indigestion
- infusion-related reactions such as difficulty in breathing, urticaria and headache
- itching
- nausea
- respiratory tract infection such as bronchitis or pneumonia
- serum-sickness or serum-sickness like reaction
- sinusitis
- skin rash or rashes
- stomach pain
- sweating
- tiredness
- urticaria
- vertigo

*Uncommon: More than 1 in 1000 people who have Infliximab*

- abscess
- allergic reactions
- anaphylactic reactions such as laryngeal oedema, pharyngeal oedema, bronchospasm or seizures
- apathy
- autoimmune problems
- bruising
- cellulitis
- chills
- collection of blood under the skin
- confusion
- constipation
- cyanosis
- demyelinating problems such as multiple sclerosis and Guillain Barré syndrome or worsening of such existing disorders
- depression
- difficulty sleeping
- eye or eyesight problems
- fainting or brief loss of consciousness
- feeling agitated
- feeling nervous
- gallbladder problems
- gastro-oesophageal reflux
- hair loss
- healing problems
- heart problems or worsening of heart problems - these may be fatal
- hot flushes
- inflammation or cracking of the lips
- injection site problems
- irregular heart rate
- irritation or inflammation of the vagina
- kidney problems

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- liver problems - some of these liver problems may be fatal. Seek immediate medical advice if you develop jaundice
- lowered blood pressure
- lung problems
- lupus or lupus-like problem
- lymphadenopathy
- memory problems
- muscle pain or tenderness
- nail problems
- nose bleed
- oedema
- pain including back pain or joint pain
- palpitations
- petechiae
- pulmonary oedema
- raised blood pressure
- sarcoid-like reaction
- sepsis
- skin problems such as skin colour changes, boils, eczema, seborrhea, rosacea, certain types of dermatitis or thickening of the outer layer of the skin
- sleepiness
- slower heart rate
- swelling around the eyes
- thrombophlebitis
- tuberculosis - some of the tuberculosis infections caused by Infliximab may be fatal. Seek immediate medical advice if you get a persistent cough, fever or weight loss
- urinary tract infection
- vasospasm

*Rare: More than 1 in 10,000 people who have Infliximab*

- circulation problems
- faster heart rate
- gastrointestinal problems such as gastrointestinal bleeding
- granulomatous lesion
- lymphoma - this may be fatal
- meningitis

*The frequency of these side-effects is unknown*

- anaphylactic shock
- cancer
- changes in vision - this may happen during or within two hours of infusion
- delayed hypersensitivity reactions - seek immediate medical advice if you get any of the following: painful muscles and joints that occur with fever and rashes, itching, swelling of the face, swelling of the hands, or swelling of the lips, swallowing difficulties, urticaria, sore throat or headache

- erythema multiforme
- heart attack - this may happen during or within two hours of infusion
- hiding symptoms of infection such as fever
- hypoaesthesia
- inflammation of the spinal cord
- leukaemia
- neuropathies
- pancreatitis
- paraesthesia
- psoriasis or psoriasis-like rash or worsening of psoriasis
- reactivation of hepatitis B - this may be fatal. You must seek medical advice if your symptoms return or if they become worse
- reduced resistance to infection
- seizures
- Stevens-Johnson syndrome
- toxic epidermal necrolysis
- unexplained or easy bruising of the skin or mucous membranes
- vasculitis

*The following side effects have also been reported in people who have Infliximab. The reported frequency of these side-effects varies so the frequency is not included here.*

- blood and bone marrow problems - seek immediate medical advice if you develop persistent fever, bleeding, bruising or paleness
- hypersensitivity reactions
- infections - some of the infections caused by Infliximab may be fatal. Seek immediate medical advice if you get any symptoms of an infection whilst you are having Infliximab

If you feel unwell or if you have concerns about a side-effect, you will need to seek advice. If you feel very ill, get medical help straight away. Contact your prescriber, pharmacist, nurse or call NHS Direct on 0845 46 47.

### Taking other medicines

If you are taking more than one medicine they may interact with each other. At times your prescriber may decide to use medicines that interact, in other cases this may not be appropriate.

The decision to use medicines that interact depends on your specific circumstances. Your prescriber may decide to use medicines that interact, if it is believed that the benefits of taking the medicines together outweigh the risks. In such cases, it may be necessary to alter your dose or monitor you more closely.

Tell your prescriber the names of all the medicines that you are taking so that they can consider all possible interactions. This includes all the medicines which have been prescribed by your GP, hospital doctor, dentist, nurse, health visitor, midwife or pharmacist. You must also tell your prescriber about medicines which you have bought over the counter without prescriptions.

*The following medicines may interact with Infliximab:*

- anakinra
- azathioprine
- 6-mercaptopurine
- abatacept
- methotrexate

*The following types of medicine may interact with Infliximab:*

- live vaccines
- immunomodulators
- Tumour Necrosis Factor antagonists

If you are taking Infliximab and one of the above medicines or types of medicines, make sure your prescriber knows about it.

### Complementary preparations and vitamins

Medicines can interact with complementary preparations and vitamins. In general, there is not much information available about interactions between medicines and complementary preparations or vitamins.

If you are planning to take or are already taking any complementary preparations and vitamins you should ask your prescriber whether there are any known interactions with Infliximab.

Your prescriber can advise whether it is appropriate for you to take combinations that are known to interact. They can also discuss with you the possible effect that the complementary preparations and vitamins may have on your condition.

If you experience any unusual effects while taking this medicine in combination with complementary preparations and vitamins, you should tell your prescriber.

### Driving and operating machinery

When taking any medicine you should be aware that it might interfere with your ability to drive or operate machinery safely.

*In the case of Infliximab:*

- as this medicine is only normally used in hospitals, its impact on someone driving or operating machinery may not be relevant

You should see how this medicine affects you before you judge whether you are safe to drive or operate machinery. If you are in any doubt about whether you should drive or operate machinery, talk to your prescriber.

### Diet

Medicines can interact with certain foods. In some cases, this may be harmful and your prescriber may advise you to avoid certain foods.

*In the case of Infliximab:*

- there are no specific foods that you must exclude from your diet when having Infliximab

### Alcohol

Alcohol can interact with certain medicines.

*In the case of Infliximab:*

- there are no known interactions between alcohol and Infliximab

### Family planning and pregnancy

Most medicines, in some way, can affect the development of a baby in the womb. The effect on the baby differs between medicines and also depends on the stage of pregnancy that you have reached when you take the medicine.

*In the case of Infliximab:*

- you must not become pregnant while you are having it and for at least six months after you have the last dose of Infliximab. If you could become pregnant, you must use effective contraception or abstain from penetrative sex. You must contact your prescriber if you become pregnant, or you think you may be pregnant, while having Infliximab
- the use of this medicine during pregnancy is not recommended. You should only have this medicine during pregnancy if your doctor thinks that you need it

You should discuss your personal circumstances with your doctor if you are pregnant or want to become pregnant. This is so that together you can make a decision about what treatment you may need during your pregnancy.

You should discuss whether there are any other medicines which you could take during pregnancy which would treat your condition.

### Breast-feeding

Certain medicines can pass into breast milk and may reach your baby through breast-feeding.

*In the case of Infliximab:*

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- do not breast-feed for at least six months after you have the last dose of Infliximab
- women who are having Infliximab should not breast-feed

Before you have your baby you should discuss breast-feeding with your doctor or midwife. They will help you decide what is best for you and your baby based on the benefits and risks associated with this medicine. If you wish to breast-feed you should discuss with your prescriber whether there are any other medicines you could take which would also allow you to breast-feed. You should not stop this medicine without taking advice from your doctor.

### Ingredients of your medicine

Medicines contain active ingredients. They may also contain other, additional ingredients that help ensure the stability, safety and effectiveness of the medicine. They may also be used to prolong the life of the medicine.

This medicine contains infliximab.

We are unable to list all of the ingredients for your medicine here. For a full list, you should refer to the patient information leaflet that comes with this medicine or ask your prescriber. You should check that you are able to take the ingredients of your medicine, especially if you have any allergies.

If you are not able to take any of the ingredients in your medicine, talk to your prescriber or pharmacist to see if they can suggest an alternative medicine. If you have reacted badly to Infliximab before, do not take Infliximab. Talk to your prescriber, pharmacist or nurse as soon as possible.