

## PART III: CONSUMER INFORMATION

Pr **REMICADE®**  
(Infliximab)

This leaflet is part III of a three-part "Product Monograph" published when REMICADE® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about REMICADE®. Contact your doctor or pharmacist if you have any questions about the drug.

### ABOUT THIS MEDICATION

#### What the medication is used for:

REMICADE® is a medicine that is used in people with moderate to severe rheumatoid arthritis (in combination with methotrexate) and ankylosing spondylitis. Your doctor has chosen to treat your rheumatoid arthritis with REMICADE® because you have moderately to severely active rheumatoid arthritis. Your doctor has chosen to treat your ankylosing spondylitis with REMICADE® because you have had an inadequate response to other treatments or because you cannot tolerate other treatments.

REMICADE® is also used in people with moderate to severe plaque psoriasis. Your doctor has chosen to treat your plaque psoriasis with REMICADE® because your disease is still active even though you have tried other treatments.

REMICADE® is also used in people with active psoriatic arthritis. Your doctor has chosen to treat your psoriatic arthritis with REMICADE® because your disease is still active even though you have tried other treatments.

REMICADE® is also used in adults, children and teenagers with moderate to severe Crohn's disease or with moderate to severe ulcerative colitis. Your doctor has chosen to treat your Crohn's disease or ulcerative colitis with REMICADE® because your disease is still active even though you have tried other treatments.

#### What it does:

Research has shown that in these diseases the body overproduces a substance known as tumour necrosis factor alpha (TNF alpha). The active ingredient in REMICADE® is called infliximab. Infliximab is a monoclonal antibody, a type of protein that recognises and binds to other unique proteins. Infliximab binds to and neutralises TNF alpha. Infliximab is made from mouse and human proteins.

REMICADE® is a medicine that affects your immune system. REMICADE® can lower the ability of your immune system to fight infections.

#### When it should not be used:

If you have a severe infection, such as sepsis (an infection in the bloodstream), abscess, tuberculosis or other serious infection, you must not take REMICADE®.

If you have heart failure that is moderate or severe, you must not take REMICADE®.

If you are allergic to infliximab or any ingredient in REMICADE® (polysorbate 80, sodium phosphate and sucrose), or if you have a history of allergies to mouse proteins, you should not take REMICADE®.

#### What the medicinal ingredient is:

Infliximab

#### What the important nonmedicinal ingredients are:

Dibasic sodium phosphate dihydrate, monobasic sodium phosphate monohydrate, polysorbate and sucrose. No preservatives are present.

#### What dosage forms it comes in:

REMICADE® is an injectable medicine. It is supplied as lyophilized concentrate for IV injection in individually-boxed single-use vials of 100 mg infliximab. Vial stopper is free of natural rubber latex.

#### Where I may receive the infusion:

Your doctor will decide where you will receive the infusion. The BioAdvance® Network has been established to facilitate the administration of REMICADE®. This network consists of clinics located across Canada that are staffed by qualified healthcare professionals specially trained in the administration of REMICADE® infusions. Contact your doctor if you have any questions.

**Tell all doctors involved in your care that you take REMICADE®.**

**WARNINGS AND PRECAUTIONS****Serious Warnings and Precautions**

Serious infections, including sepsis, tuberculosis, legionellosis (a serious form of bacterial pneumonia), listeriosis (an infection that usually develops after eating food contaminated by bacteria called listeria) and opportunistic infections (such as systemic fungal, viral, and bacterial infections), have been reported in patients, especially those 65 years and older, receiving REMICADE® and other similar medicines. Some patients with these infections have died. Prior to treatment with REMICADE®, you should tell your doctor if you have a chronic infection, a history of recurrent infection, or if you have lived in or traveled to an area where infections called histoplasmosis, coccidioidomycosis or blastomycosis are common. These infections are caused by fungus that can affect the lungs or other parts of your body. Ask your doctor if you don't know if these infections are common in the area in which you have lived or traveled. If you develop an infection during treatment with REMICADE®, you should tell your doctor right away.

Prior to treatment with REMICADE®, you should tell your doctor if you have had tuberculosis, or if you have been exposed recently to anyone who might have tuberculosis, or if you have any other reason to believe you may be at risk for tuberculosis. Your doctor will evaluate you for tuberculosis and may begin treatment for tuberculosis before you are treated with REMICADE®.

Treatment with REMICADE® must be interrupted if you develop a serious infection or sepsis. Tell your doctor if you have any symptoms of an infection (for example, fever, fatigue, cough, flu-like symptoms, or pain) while you are taking REMICADE® and for 6 months after you receive the medicine. If you need surgery, tell your doctor that you have taken REMICADE®.

Lymphoma and other cancers, which may result in death, have been reported in children and teenage patients taking TNF-blockers, including REMICADE®. Some patients who have received TNF-blockers, including REMICADE® have developed a rare type of cancer called hepatosplenic T-cell lymphoma. Of these patients, most were teenage or young adult males and most had either Crohn's disease or ulcerative colitis. This type of cancer often results in death. Almost all patients had also received drugs known as azathioprine or 6-mercaptopurine in addition to TNF-blockers. You should also tell your doctor if you have had or develop lymphoma or other cancers while you are taking REMICADE®.

Reports of a type of blood cancer called lymphoma in patients on REMICADE® or other TNF-blockers are rare but occur more often than expected for people in general. People who have been treated for rheumatoid arthritis, Crohn's disease or ankylosing spondylitis for a long time, particularly those with highly active disease may be more prone to develop lymphoma. Cancers, other than lymphoma, have also been reported. There have been cases

of cancers, including unusual types, in children and teenage patients taking TNF-blocking agents, which sometimes resulted in death. For children and adults taking TNF-blocker medicines, the chances of getting lymphoma or other cancers may increase. Some patients treated with REMICADE® 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 REMICADE® have developed cervical cancer. For women taking REMICADE®, including those over 60 years of age, your doctor may recommend that you continue to be regularly screened for cervical cancer. Patients with a specific type of lung disease called COPD (Chronic Obstructive Pulmonary Disease) may be at increased risk for cancer with REMICADE® treatment. If you have COPD you should discuss with your doctor whether REMICADE® is appropriate for you.

**Before you start taking REMICADE®, you should tell your doctor if you have any of the following:**

- Congestive heart failure: If you have mild heart failure and you are being treated with REMICADE®, your heart failure status must be closely monitored by your doctor. If you develop new or worsening symptoms of heart failure (such as shortness of breath or swelling of your feet), you must contact your doctor immediately.
- Other heart problems: Some patients have experienced a heart attack (some of which led to death), low blood flow to the heart, or abnormal heart rhythm within 24 hours of beginning their infusion of REMICADE®. Symptoms may include chest discomfort or pain, arm pain, stomach pain, shortness of breath, anxiety, lightheadedness, dizziness, fainting, sweating, nausea, vomiting, fluttering or pounding in your chest, and/or a fast or a slow heartbeat. Tell your doctor right away if you have any of these symptoms
- Immediate allergic reactions: Some patients who have received REMICADE® have developed allergic reactions, including anaphylaxis. Some reactions can happen while you are getting your infusion or shortly afterwards. Some of these reactions have been serious. The symptoms include hives, difficulty breathing, chest pain and high or low blood pressure. Your doctor may decide to stop REMICADE® treatment for severe reactions. Your doctor can prescribe medicines to treat these effects.
- Delayed allergic reactions: Some allergic reactions can occur 3 to 12 days after REMICADE® retreatment. The symptoms of this type of delayed reaction include muscle or joint pain with fever or rash. Tell your doctor if you notice any of these symptoms.
- Nervous system diseases: Tell your doctor if you have a disease that affects your nervous system, like multiple sclerosis, neuropathies, Guillain-Barré syndrome, or seizures, or you have been diagnosed with optic neuritis, or if you experience any numbness, tingling, or visual disturbances. Some patients have reported that their nervous system disease got worse after receiving REMICADE®.
- Autoimmune disease: Some patients treated with REMICADE® have developed symptoms that suggest an autoimmune disease called lupus-like syndrome. Tell your doctor if you notice symptoms of lupus-like syndrome, such

as, prolonged chest discomfort or pain, shortness of breath, joint pain, or sun-sensitive rash on the cheeks or arms. Your doctor will evaluate your condition and may decide to stop your treatment with REMICADE®.

- **Liver injury:** There have been cases where people taking REMICADE® have developed liver problems. Signs that you could be having a problem include: jaundice (skin and eyes turning yellow), dark brown-colored urine, right-sided abdominal pain, fever, and severe fatigue (tiredness). You should contact your doctor immediately if you develop any of these symptoms.

- **Previous phototherapy:** Tell your doctor if you have had phototherapy (treatment with ultraviolet light or sunlight along with a medicine to make your skin sensitive to light) for psoriasis. In clinical trials, skin cancers were more common in patients who received prior phototherapy.

- **Blood Problems:** In some instances, patients treated with TNF-blocking agents may develop low blood counts, including a severely decreased number of white blood cells. If you develop symptoms such as persistent fever or infections, bleeding, or bruising, you should contact your doctor right away.

- **Stroke:** Some patients have experienced a stroke within approximately 24 hours of their infusion of REMICADE®. Tell your doctor right away if you have symptoms of a stroke which may include: numbness or weakness of the face, arm or leg, especially on one side of the body; sudden confusion, trouble speaking or understanding; sudden trouble seeing in one or both eyes, sudden trouble walking, dizziness, loss of balance or coordination or a sudden, severe headache.

- **Hepatitis B:** Treatment with TNF-blocking agents such as REMICADE® may result in a reactivation of the hepatitis B virus in people who carry this virus. If you have or have had hepatitis B infection or know or suspect you may be a carrier of hepatitis B virus, be sure to tell your doctor about this as this may impact the decision to start or continue treatment with REMICADE®. Your doctor should do a blood test for hepatitis B virus before you start treatment with REMICADE®.

- **Vaccination:** Tell your doctor that you have received REMICADE® if you need to get a vaccination. It is not known if medicines like REMICADE® can interfere with vaccinations. You should not receive live vaccines while you are taking REMICADE®. The use of a 'live' vaccine may result in an infection caused by the 'live' vaccine or bacteria contained in the vaccine (when you have a weakened immune system). It is recommended that you be brought up to date with all vaccinations in agreement with current guidelines prior to starting REMICADE®.

- **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 instillation used for the treatment of cancer).

- **Pregnancy, breast-feeding and ability to have children:**

If you are being treated with REMICADE®, you must avoid becoming pregnant by using adequate contraception during your treatment and for 6 months after your last REMICADE® injection. Tell your doctor if you think you may be pregnant, are breastfeeding, or planning to conceive a child. Your doctor will help you decide whether or not to use REMICADE®.

If you have a baby and you were using REMICADE® during your pregnancy, it is important to tell your baby's doctor and other healthcare professionals about your REMICADE® use so they can

decide when your baby should receive their vaccinations, including live vaccines, such as BCG (used to prevent tuberculosis).

If you received REMICADE® while you were pregnant, your baby may be at higher risk for getting an infection. It is important that you tell your baby's doctors and other health care professionals about your REMICADE® use before the baby receives any vaccine. Administration of BCG vaccine within 6 months after birth to the baby whose mother received REMICADE® while pregnant may result in infection in the newborn with severe complications, including death. For other types of vaccines, discuss with your doctor.

Breast feeding is not recommended during treatment and for 6 months after the last dose of REMICADE®. Your doctor will help you decide whether or not to use REMICADE®.

Severely decreased numbers of white blood cells have also been reported in infants born to women treated with REMICADE® during pregnancy. If your baby has continual fevers or infections, contact your baby's doctor immediately.

It is not known if REMICADE® can affect your ability to have children in the future.

## INTERACTIONS WITH THIS MEDICATION

Tell your doctor about all medicines that you have recently taken or are taking during your treatment with REMICADE®. These include any other medicines to treat Crohn's disease, ulcerative colitis, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis or psoriasis. Drugs that may interact with REMICADE® include: prescription and non-prescription medicines, vitamins, and herbal supplements.

Patients with rheumatoid arthritis or Crohn's disease often take other medicines that can cause side effects. Special studies have not been done to determine whether other medicines will react with REMICADE®. In studies of REMICADE®, patients were also taking antibiotics, antivirals, corticosteroids, mercaptopurine (6MP), azathioprine (AZA), methotrexate (MTX), and aminosalicylates along with REMICADE®. Patients who took immunosuppressants, such as methotrexate, corticosteroids, mercaptopurine, azathioprine, had a lower risk of allergic reactions during infusion.

Especially, tell your doctor if you take KINERET® (anakinra) or ORENCIA® (abatacept). REMICADE® should not be taken together with anakinra or abatacept.

If you have a baby while you are using REMICADE®, tell your baby's doctor about your REMICADE® use before the baby receives any live vaccines.

## PROPER USE OF THIS MEDICATION

### Usual dose:

#### Rheumatoid Arthritis

The recommended dose of REMICADE® is 3 mg/kg given as an intravenous infusion followed by additional 3 mg/kg doses

at 2 and 6 weeks after the first infusion then every 8 weeks thereafter. REMICADE® should be given in combination with methotrexate.

#### Ankylosing Spondylitis

The recommended dose of REMICADE® is one initial infusion followed by infusions at 2 and 6 weeks after the first dose. Then you will receive an infusion every 6 to 8 weeks thereafter.

#### Crohn's Disease and Fistulising Crohn's Disease

##### Adults

The recommended dose of REMICADE® is 5 mg/kg given as an induction regimen at 0, 2 and 6 weeks followed by a maintenance regimen of 5 mg/kg every 8 weeks thereafter for the treatment of moderate to severe, active Crohn's disease. For patients who have an incomplete response, consideration may be given to adjusting the dose up to 10 mg/kg. Your doctor may consider doing a blood test (therapeutic drug monitoring) to determine how much infliximab is in your blood stream in order to optimize your dose of REMICADE®.

##### Children (9 years of age or older)

The recommended dose of REMICADE® for children with moderately to severely active Crohn's disease is 5 mg/kg given as an induction regimen of 0, 2 and 6 weeks followed by a maintenance regimen of 5 mg/kg every 8 weeks.

#### Ulcerative Colitis

##### Adults:

If you are receiving REMICADE® for ulcerative colitis, you will receive your first 5 mg/kg dose followed by additional 5 mg/kg doses at 2 and 6 weeks after the first dose. You will then receive a dose every 8 weeks thereafter. Your doctor will monitor your response to REMICADE® and may change your dose. Your doctor may consider doing a blood test (therapeutic drug monitoring) to determine how much infliximab is in your blood stream in order to optimize your dose of REMICADE®.

##### Children (6 years of age or older):

The recommended dose of REMICADE® for children with moderately to severely active ulcerative colitis is 5 mg/kg given as an induction regimen of 0, 2 and 6 weeks followed by a maintenance regimen of 5 mg/kg every 8 weeks.

#### Psoriatic Arthritis:

The recommended dose of REMICADE® is 5 mg/kg as an intravenous infusion followed with additional doses at 2 and 6 weeks after the first infusion then every 8 weeks thereafter. If you show no response at 24 weeks, no additional treatment with REMICADE® should be given.

#### Plaque Psoriasis:

The recommended dose of REMICADE® is 5 mg/kg given as an intravenous infusion followed with additional 5 mg/kg doses at 2 and 6 weeks after the first infusion then every 8 weeks thereafter. If you do not show an adequate response at Week 14, after infusions at Weeks 0, 2, and 6, no additional treatment with REMICADE® should be given.

#### Overdose:

Single doses up to 20 mg/kg have been administered without any direct toxic effect. In case of overdosage, it is recommended that the patient be monitored for any signs or symptoms of adverse reactions or effects and appropriate symptomatic treatment instituted immediately.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

#### **How to give this medication:**

REMICADE® will be given to you by a healthcare professional. The medicine will be given to you through a needle placed in a vein in your arm. This is called an infusion. If you have Crohn's disease, ulcerative colitis, ankylosing spondylitis, psoriatic arthritis, or plaque psoriasis, the infusion will take about 2 hours. If you have rheumatoid arthritis, the first 3 infusions will be given to you over a period of about 2 hours, after the third infusion your doctor may decide to give you the infusion over a 1 hour period. During the infusion you will be monitored for side effects. You must stay for 1 to 2 hours after the infusion so that you can continue to be watched for any reactions to the medicine.

Your doctor may ask you to take other medicines along with REMICADE®.

#### **SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

Some patients had side effects that caused them to stop REMICADE® treatment. The most common reasons were shortness of breath, rash, and headache.

Other common side effects besides the ones already mentioned in this leaflet include abdominal pain, back pain, coughing, diarrhea, dizziness, fatigue, itchiness, pain, upper respiratory infections (such as bronchitis, sinusitis, cold, sore throat), upset stomach, and urinary tract infections. REMICADE® may have a minor influence on the ability to drive and use machines. Dizziness may occur following administration of REMICADE®.

Children and teenagers who took REMICADE® in studies for ulcerative colitis had similar side effects as adults with ulcerative colitis. The most common side effects observed in children with ulcerative colitis include: cough and cold symptoms including sore throat, stomach pain, fever, headache and anemia (low red blood cell count). Among patients who took REMICADE® for ulcerative colitis in clinical studies, more children had infections as compared with adults, including bladder infections, skin infections, and bronchitis.

Some of the side effects of REMICADE® can be serious and may require treatment.

Tell your doctor if you experience any of the effects listed in this leaflet or any other side effects.

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom/effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
Common	Serious infections: symptoms of fever, feel very tired, have a cough or develop flu-like symptoms or develop an abscess.		√	
	Allergic reactions: symptoms, while you are getting your REMICADE® infusion or shortly afterwards, of hives (red, raised, itchy patches of skin), difficulty breathing, chest pain and high or low blood pressure or symptoms 3 to 12 days after receiving REMICADE® including fever, rash, headache and muscle or joint pain.		√	
Uncommon	Liver injury: signs that you could be having a problem include: jaundice (skin and eyes turning yellow), dark brown-colored urine, right sided abdominal pain, fever and severe fatigue (tiredness).		√	
	Heart failure: If you have been told that you have a heart problem called congestive heart failure, you will need to be closely monitored by your doctor. New or worse symptoms that are related to your heart condition, including shortness of breath or swelling of your ankles or feet.		√	
	Blood problems: symptoms of fever that doesn't go away, bruising or bleeding very easily or looking very pale.		√	
	Nervous system disorders: signs include changes in your vision (including blindness), seizures, weakness in your arms and/or legs, and numbness or tingling in any part of your body.		√	
	Malignancy: if you have had or develop lymphoma or other cancers, including skin cancers, while you are taking REMICADE®.		√	

**SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM**

Symptom/effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		Only if severe	In all cases	
	Lupus: symptoms may include chest discomfort or pain that doesn't go away, shortness of breath, joint pain, or a rash on the cheeks or arms that gets worse in the sun.		√	
Rare	Skin problems: skin rashes including redness, itching, skin peeling and blistering; Small pus-filled bumps that can spread over the body, sometimes with a fever (acute generalized exanthematous pustulosis).		√	
	Lung problems: symptoms of new or worsening shortness of breath.		√	

*This is not a complete list of side effects. For any unexpected effects while taking REMICADE®, contact your doctor or pharmacist.*

**HOW TO STORE IT**

REMICADE® is stored in the original package in the refrigerator before use. Do not use beyond the refrigerated expiration date printed on the carton. Only at the location of reconstitution, REMICADE® can also be stored in the original carton outside of refrigerated storage up to a maximum of 30°C for a single period of up to 6 months; but not exceeding the refrigerated expiration date printed on the carton. In this situation, write the non-refrigerated expiry date on the carton including month/year and do not return to refrigerated storage again. Discard this medicine if not used by the new expiry date or the expiry date printed on the carton, whichever is earlier. It must be kept out of the reach and sight of children. The vial must be kept sealed. Only a healthcare professional should prepare the medicine before use and administer it to you. It should not be used beyond the expiration date.

**REPORTING SUSPECTED SIDE EFFECTS**

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at [www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting](http://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting)
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program  
Health Canada  
Postal Locator 1908C  
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect® Canada Web site at [www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting](http://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting).

***NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.***

**MORE INFORMATION**

For questions, concerns, or the full Product Monograph go to: [www.janssen.com/canada](http://www.janssen.com/canada) or contact the manufacturer, Janssen Inc. at 1-800-567-3331.

Information about the BioAdvance® Network can be obtained by contacting Janssen Inc. at: 1-800-567-3331.

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