

PART III: CONSUMER INFORMATION

PrHUMIRA® adalimumab

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

ABOUT THIS MEDICATION

HUMIRA® (adalimumab) treatment should be initiated and supervised by specialist physicians experienced in the diagnosis and treatment of rheumatoid arthritis (RA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), Crohn's Disease (CD), or psoriasis (Ps), and familiar with the HUMIRA® efficacy and safety profile.

What the medication is used for:

HUMIRA® is a medicine that is used in people with moderate to severe rheumatoid arthritis (RA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), Crohn's disease (CD), or psoriasis (Ps). Rheumatoid arthritis (RA) is an inflammatory disease of the joints. Psoriatic arthritis (PsA) is an inflammatory disease of the joints and skin. Ankylosing spondylitis (AS) is a form of arthritis. Psoriasis (Ps) is an inflammatory disease of the skin. Your doctor prescribed HUMIRA® to reduce the signs and symptoms of your plaque psoriasis. People with RA, PsA, AS, or Ps may be given other medicines for their disease before they are given HUMIRA®. Crohn's disease is an inflammatory disease of the digestive tract. If you have Crohn's disease you will first be given other medicines. If you do not respond well enough to these medicines, you will be given HUMIRA® to reduce the signs and symptoms of your disease.

What it does:

HUMIRA® is intended for treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease and psoriasis. It is a medicine that decreases the inflammation process of these diseases. The active ingredient, adalimumab, is a fully human monoclonal antibody produced by cultured cells. Monoclonal antibodies are proteins that recognize and bind to other unique proteins. Adalimumab binds to a specific protein (tumor necrosis factor or TNF-alpha), which is present at increased levels in inflammatory diseases such as rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease and psoriasis. People with RA, PsA, AS, CD, or Ps have too much of TNF-alpha in their bodies. The extra TNF-alpha in your body can attack normal healthy body tissues and cause inflammation especially in the tissues of your bones, cartilage, joints and digestive tract.

HUMIRA® helps reduce the signs and symptoms of RA and PsA (such as pain and swollen joints), may help improve your ability to perform daily activities (such as getting dressed, walking and climbing stairs), and may help prevent further damage to your bones and joints. In addition, HUMIRA® helps reduce the signs and symptoms of AS (back pain and morning stiffness), and CD (abdominal pain and diarrhea). HUMIRA® also helps reduce the signs and symptoms of Ps (such as pain, itching and scaly patches on skin). HUMIRA®, however can also lower your body's ability to fight infections. Taking HUMIRA® can make you more prone to getting infections or make any infection you have worse.

When it should not be used:

You should not take HUMIRA® if you have an allergy to any of the ingredients in HUMIRA® (sodium phosphate, sodium citrate, citric acid, mannitol, and polysorbate 80). The needle cover on the pre-filled syringe contains dry natural rubber (latex). Tell your doctor if you have any allergies to rubber or latex.

You should not take HUMIRA® if you have a serious infection such as tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis).

What the medicinal ingredient is:

adalimumab

What the important non-medicinal ingredients are:

citric acid, mannitol, sodium citrate, sodium phosphate, polysorbate 80, and sodium chloride.

For a full listing of non-medicinal ingredients, see Part 1 of the Product Monograph.

What dosage forms it comes in:

- Single-dose, 1 mL Pre-filled Pen/40 mg adalimumab dissolved in 0.8 mL sterile solution (50 mg/mL).
- Single-dose, 1 mL Pre-filled Glass Syringe/40 mg adalimumab dissolved in 0.8 mL sterile solution (50 mg/mL).
- Sterile Injection Glass Vial/40 mg adalimumab dissolved in 0.8 mL sterile solution (50 mg/mL).

WARNINGS AND PRECAUTIONS

Before initiation, during and after treatment with HUMIRA®, you should be evaluated for active or latent tuberculosis infection with a tuberculin skin test.

Any medicine can have side effects. Like all medicines that affect your immune system, HUMIRA® can cause serious side effects. The possible serious side effects include:

Serious Warnings and Precautions

- **Serious infections:** There have been rare cases where patients taking HUMIRA® or other TNF-blocking agents have developed serious infections. Some of these cases have been life-threatening. Such infections include tuberculosis (TB), infections caused by bacteria or fungi, bacterial infections that have spread throughout the body (sepsis), and very rare cases of hepatitis B infection relapse.
- **Nervous system diseases:** There have been rare cases of disorders that affect the nervous system of people taking HUMIRA® or other TNF blockers. Signs that you could be experiencing a problem affecting your nervous system include: numbness or tingling, problems with your vision, weakness in your legs, and dizziness.
- **Malignancies:** There have been very rare cases of certain kinds of cancer in patients taking HUMIRA® or other TNF blockers. Some patients receiving HUMIRA® have developed types of cancer called non-melanoma skin cancer. Tell your doctor if you have a bump or open sore that does not heal. People with more serious RA that have had the disease for a long time may have a higher than average risk of getting a kind of cancer that affects the lymph system, called lymphoma. If you take HUMIRA® or other TNF blockers, your risk may increase.
- **Lupus-like symptoms:** Some patients have developed lupus-like symptoms that got better after their treatment was stopped. If you have chest pains that do not go away, shortness of breath, joint pain or a rash on your cheeks or arms that is sensitive to the sun, call your doctor right away. Your doctor may decide to stop your treatment.
- **Allergic reactions:** If you develop a severe rash, swollen face or difficulty breathing while taking HUMIRA®, call your doctor right away.
- **Hepatosplenic T-cell lymphoma:** Very rare post-marketing reports of hepatosplenic T-cell lymphoma (HSTCL), a rare aggressive lymphoma that is often fatal, have been identified in patients treated with adalimumab. Most of the patients had prior infliximab therapy as well as concomitant azathioprine or 6-mercaptopurine use for Crohn’s disease. The causal association of HSTCL with adalimumab is not clear.

Before you start taking HUMIRA®, you should tell your doctor if you have or have had any of the following:

- Any kind of infection including an infection that is in only one place in your body (such as an open cut or sore), or an infection that is in your whole body (such as the flu). Having an infection could put you at risk for serious side effects from HUMIRA®. If you are unsure, please ask your doctor.
- A history of infections that keep coming back or other conditions that might increase your risk of infections, including fungal infections.

- If you have ever had tuberculosis (TB), or if you have been in close contact with someone who has had tuberculosis. If you develop any of the symptoms of tuberculosis (a dry cough that doesn't go away, weight loss, fever, night sweats) call your doctor right away. Your doctor will need to examine you for TB and perform a skin test.
- If you resided or traveled to areas where there is a greater risk for certain kinds of infections such as tuberculosis, histoplasmosis, coccidioidomycosis, or blastomycosis. These infections are caused by a bacteria or a fungus that can affect the lungs or other parts of your body. If you take HUMIRA® these may become active or more severe. If you don't know if you have lived in an area where these infections are common, ask your doctor.
- If you have ever had hepatitis B virus (HBV) infection or are at risk of developing this infection. Signs and symptoms of HBV infection include the following: yellowing of the skin or eyes (jaundice), feeling of sickness, tiredness, loss of appetite, joint pain, and abdominal pain. If you experience any of these signs and symptoms, contact your doctor immediately. These symptoms may occur several months after starting therapy with HUMIRA®.
- If you experience any numbness or tingling or have or have ever had a disease that affects your nervous system like multiple sclerosis.
- If you are scheduled to have major surgery.
- If you are scheduled to be vaccinated for anything.
- You are taking other medicines for your RA, PsA, AS, CD, Ps or other conditions. You can take other medicines provided your doctor has prescribed them, or has told you it is ok to take them while you are taking HUMIRA®. It is important that you tell your doctor about any other medicines you are taking for other conditions (for example, high blood pressure medicine) before you start taking HUMIRA®.
- You are pregnant or breast-feeding. HUMIRA® has not been studied in pregnant women or nursing mothers, so we don't know what the effects are on pregnant women or nursing babies. You should tell your doctor if you are pregnant, become pregnant or are thinking about becoming pregnant.
- You should also tell your doctor about any over-the-counter drugs, herbal medicines and vitamin and mineral supplements you are taking.

If you are not sure or have any questions about any of this information, ask your doctor.

INTERACTIONS WITH THIS MEDICATION

You should not take HUMIRA® with other TNF blockers, abatacept (Orencia®), and anakinra (Kineret®). If you have questions, ask your doctor.

PROPER USE OF THIS MEDICATION

Usual dose:

The recommended dose of HUMIRA® (adalimumab) for adult patients with rheumatoid arthritis (RA), psoriatic arthritis (PsA), or ankylosing spondylitis (AS) is 40 mg administered every other week as a subcutaneous (s.c.) injection.

The recommended induction dose of HUMIRA® (adalimumab) for adult patients with Crohn's disease (CD) is 160 mg at Week 0 (dose can be administered as four injections in one day or as two injections per day for two consecutive days), followed by 80 mg at Week 2.

The recommended maintenance dose regimen of HUMIRA® for adult patients with Crohn's disease is 40 mg every other week beginning at Week 4.

The recommended dose for adults with psoriasis (Ps) is an initial dose of 80 mg, followed by 40 mg given every other week starting one week after the initial dose.

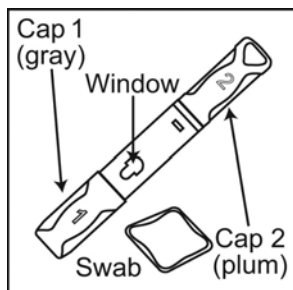
Instructions for preparing and giving an injection of HUMIRA®:

The following instructions explain how to inject HUMIRA®. Please read the instructions carefully and follow them step-by-step. You will be instructed by your doctor or his/her assistant on the technique of self-injection. Do not attempt to self-inject until you are sure that you understand how to prepare and give the injection. After proper training, the injection can be self-administered or given by another person; for example, a family member or friend.

IF YOU ARE USING THE HUMIRA® PEN

1) Setting up

- Wash your hands thoroughly.
- Remove one dose tray containing a HUMIRA® Pen from the refrigerator. Do not use a Pen if it is frozen or if it has been left in direct sunlight.
- Set up the following on a clean, flat working surface
 - One HUMIRA® Pen
 - One alcohol pad (swab)



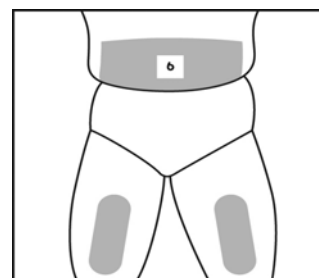
If you do not have all of the pieces you need to give yourself an injection, call your pharmacist. Use only the items provided in the box your HUMIRA® prescription comes in.

- Make sure that the name HUMIRA® appears on the dose tray and Pen label.
- Make sure that the expiration date on the dose tray and Pen has not passed. Do not use a Pen if the date has passed.
- Make sure the liquid in the Pen is clear and colourless. Do not use a Pen if the liquid is cloudy or discoloured or if flakes or particles can be seen.
- Have a puncture-proof container nearby for disposing of the used Pen.

FOR YOUR PROTECTION, IT IS IMPORTANT THAT YOU FOLLOW THESE INSTRUCTIONS.

2) Choosing and preparing an injection site

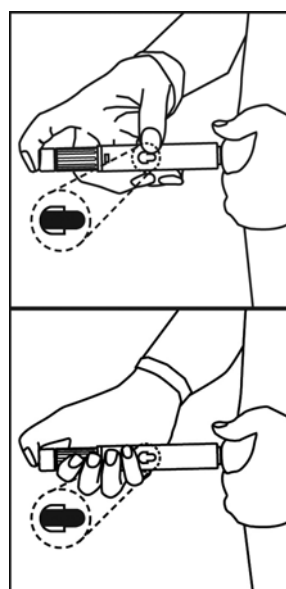
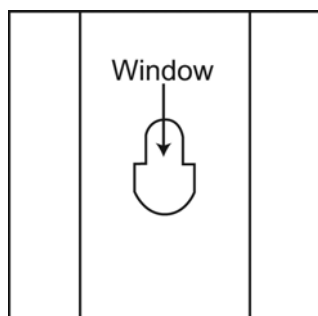
- Wash your hands thoroughly.
- Choose a site on the front of your thighs or your abdomen. If you choose your abdomen, you should avoid the area 2 inches around your navel.
 - Choose a different site each time you give yourself an injection. Each new injection should be given at least one inch from a site you used before. Do **NOT** inject into areas where the skin is tender, bruised, red or hard or where you have scars or stretch marks.
 - You may find it helpful to keep notes on the location of previous injections.



- Wipe the injection site where HUMIRA® is to be injected with an alcohol pad (swab), using a circular motion. Do **NOT** touch this area again before giving the injection.

3) How to prepare your HUMIRA® dose for injection with a HUMIRA® Pen

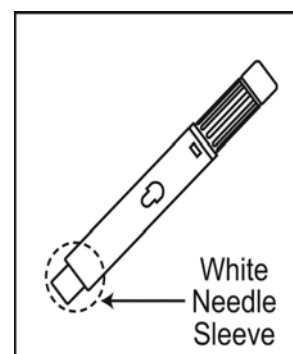
- Hold the Pen with the gray cap pointing up. Examine the solution through the windows on the sides of the Pen to make sure the liquid is clear and colourless. Do not use a Pen if the liquid is cloudy or discoloured or has flakes or particles in it. Do not use if frozen.



4) Injecting HUMIRA®

- Hold the Pen with one hand.
- With your other hand, remove the gray cap (1) and discard cap. Pull the cap straight off. Do not twist the cap. Check that the small gray needle cover of the syringe has come off with the cap. After removal, the needle cover is held in the cap. Do not try to touch the needle housed in the barrel. The white needle sleeve will now be exposed. **DO NOT RECAP as you may damage the needle.** Care should be taken to avoid dropping or crushing the product as it contains a glass syringe.
- Remove the plum safety cap (2) to expose the plum-coloured activation button at the top. Pull the cap straight off. Do not twist the cap. The Pen is now ready to use. Please note that the Pen is activated after removing cap 2 and that pressing the button under cap 2 will immediately result in discharge of medication. Do not press the button until properly positioned. **DO NOT RECAP as this could cause the unit to discharge.**
- Position the Pen so that the window is in view.
- With your free hand, gently squeeze a sizable area of the cleaned skin at the injection site, creating a platform on which to position the Pen.
- Position the white end of the Pen at a 90° angle flush against the platform of skin. Position the Pen so that it will not inject the needle into your fingers.
- With your index finger, press the plum-coloured button to begin the injection. You may also use your thumb to press the plum colored button to begin the injection. Try not to cover the window. Note that you will hear a 'click' when you press the button, which indicates the start of the injection. Keep pressing and continue to hold the Pen with steady pressure on the injection site until the process is finished. This can take up to 10 seconds. It is important to maintain steady pressure at the injection site for the entire period of time.

- You will know that the injection has finished when the yellow indicator in the side window appears in full view and stops.
- When the injection is finished, pull the Pen from the skin. The white needle sleeve will automatically advance over the needle tip.



- Press a cotton ball over the injection site and hold it for 10 seconds. Do **NOT** rub the injection site. If you have slight bleeding, do not be alarmed.
- Dispose of the Pen immediately.
- Do not try to touch the needle. The white needle sleeve is there to prevent you from touching the needle. (See **How do I dispose of supplies?**)

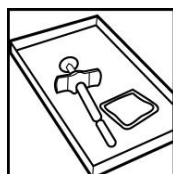
IF YOU ARE USING THE HUMIRA® PRE-FILLED SYRINGE OR VIAL

This injection should not be mixed in the same syringe or vial with any other medicine.

1) Setting up

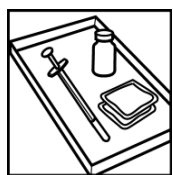
- Wash your hands thoroughly
- Remove one dose tray containing a HUMIRA® syringe or vial from the refrigerator. Do not use a syringe or vial if it is frozen or if it has been left in direct sunlight.
- Set up the following items on a clean, flat working surface

- One pre-filled syringe of HUMIRA® for injection
- One alcohol pad



-OR-

- One vial of HUMIRA® for injection
- Syringe
- 2 alcohol pads



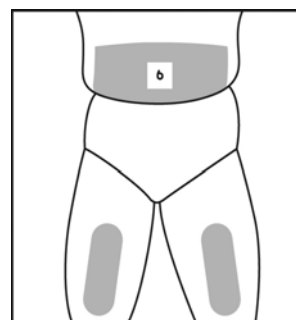
If you do not have all of the pieces you need to give yourself an injection, call your pharmacist. Use only the items provided in the box your HUMIRA® prescription comes in.

- Make sure that the name HUMIRA® appears on the dose tray and pre-filled syringe or vial label.
- Make sure that the expiration date on the dose tray and pre-filled syringe or vial has not passed. Do not use a pre-filled syringe or vial if the date has passed.
- Make sure the liquid in the pre-filled syringe or vial is clear and colourless. Do not use a pre-filled syringe or vial if the liquid is cloudy or discoloured or if flakes or particles can be seen.
- Have a puncture-proof container nearby for disposing of used needles and syringes.

FOR YOUR PROTECTION, IT IS IMPORTANT THAT YOU FOLLOW THESE INSTRUCTIONS.

2) Choosing and preparing an injection site

- Wash your hands thoroughly.
- Choose a site on the front of your thighs or your abdomen. If you choose your abdomen, you should avoid the area 2 inches around your navel.
- Choose a different site each time you give yourself an injection. Each new injection should be given at least one inch from a site you used before. Do **NOT** inject into areas where the skin is tender, bruised, red or hard or where you have scars or stretch marks.
- You may find it helpful to keep notes on the location of previous injections.



- Wipe the injection site where HUMIRA® is to be injected with an alcohol pad, using a circular motion. Do **NOT** touch this area again before giving the injection.

3a) How to prepare your HUMIRA® dose for injection with a HUMIRA® Pre-filled Syringe

- Remove the needle cover from the syringe, taking care not to touch the needle with your fingers or allowing it to touch any surface.
- Turn the syringe so the needle is facing up and slowly push the plunger in to push the air in the syringe out through the needle. If a small drop of liquid comes out of the needle, this is acceptable.

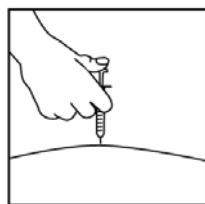
3b) How to prepare your HUMIRA® dose for injection with a HUMIRA® Vial

- Remove the plastic cap from the HUMIRA® vial and clean the gray rubber stopper on the top of the vial with a new alcohol pad. Do not touch the stopper with your hands after cleaning.
- Do **NOT** shake the vial. Shaking the vial can damage the medicine so it does not work properly.
- Before removing the syringe, make sure that the packaging is not damaged.
- Remove the syringe from its package, and make sure that it is not damaged.
- Remove the cover from the needle, taking care not to touch the needle with your fingers or allow it to touch any surface.

- Pull the plunger back to the 0.8 mL mark to draw air into the syringe.
- Keeping the vial upright on your flat working surface, insert the needle straight through the center ring of the gray stopper. You should feel a slight resistance and then a “pop” as the needle goes through the center of the stopper. If the needle is not correctly lined up with the center of the stopper, you will feel constant resistance as it goes through the stopper and no “pop.” If the needle is not lined up correctly, it may bend or break and prevent you from being able to remove the contents of the vial. If this happens, do not use the syringe or vial and call your pharmacist.
- Slowly inject the air from the syringe into the vial of HUMIRA[®].
- Keeping the needle in the vial, turn the vial upside down and make sure the tip of the needle is in the liquid. Slowly pull the plunger back to draw all of the solution into the syringe. The amount of liquid in the syringe should come up to the 0.8 mL mark on the barrel of the syringe. You may not be able to pull all of the liquid out of the vial. You may find some liquid may be remaining in the vial; that is ok as long as the liquid is up to the 0.8 mL mark. If there is not enough liquid in the vial to draw out 0.8 mL into the syringe, call your pharmacist.
- With the needle still in the vial, check the syringe for air bubbles. If there are air bubbles, gently tap the syringe with your fingers to make any bubble rise to the top of the syringe near the needle. Slowly press the plunger in to push the bubbles out of the syringe and into the vial. If you accidentally push some solution back into the vial, pull slowly back on the plunger to draw the contents of the vial back into the syringe.
- Take the needle completely out of the vial and hold it upright in the hand you will use to give yourself an injection. Do **NOT** touch the needle or let it touch any surface.
- Discard any unused product.

4) Injecting HUMIRA[®]

- With one hand, gently pinch the cleaned area of skin and hold it firmly. With the other hand, hold the syringe like a pencil at about a 90° angle to the skin.



- With a quick, short, “dart-like” motion, push the needle into the skin.
- After the needle is in, let go of the skin. If blood appears in the syringe, it means that you have entered a blood vessel. Do not inject HUMIRA[®]. Withdraw the needle and repeat the steps to choose and clean a new injection site. (Do **NOT** use the same

syringe; discard it in your puncture-proof container.) If no blood appears, slowly push the plunger all the way in until all of the HUMIRA[®] is injected.

- When the syringe is empty, remove the needle from the skin, being careful to keep it at the same angle as it was when it was inserted.
- Immediately press a cotton ball over the injection site and hold for 10 seconds. Slight bleeding may occur. Do **NOT** rub the injection site. A bandage is optional. Dispose of the syringe immediately. (See **How do I dispose of supplies?**)

5) How do I dispose of supplies?

You should always check with your healthcare provider for instructions on how to properly dispose of used needles and syringes. Do **NOT** use the same needle and syringe more than once. You should follow any special provincial or local laws regarding the proper disposal of needles and syringes. **DO NOT throw used needles or syringes in the household trash or recycle.**

- Dispose of used needles and syringes in a container made specially for this purpose (“Sharps” container), or a hard plastic container with a screw-on cap or metal container with a plastic lid labelled “*Used Syringes*”. Do not use glass or clear plastic containers.
- Always keep the container out of the reach of children.
- When the container is about two-thirds full, tape the cap or lid down so it does not come off and dispose of it as instructed by your doctor, nurse or pharmacist. **DO NOT THROW THE CONTAINER IN THE HOUSEHOLD TRASH OR RECYCLE.**
- The HUMIRA[®] vials and used alcohol pads may be placed in the trash, unless otherwise instructed by your doctor, nurse or pharmacist. The dose tray and cover may be recyclable.



What should I do if I take too much HUMIRA[®]?

Call your doctor if you accidentally inject HUMIRA[®] more frequently than instructed.

What should I do if I miss a dose of HUMIRA[®]?

If you forget to give yourself an injection, you should inject the next dose of HUMIRA[®] as soon as you remember. Then take your next dose as you would have on your originally scheduled date.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, HUMIRA[®] can cause side effects. Most side effects are mild to moderate. However, some may be serious and require treatment.

Tell your doctor immediately if you experience any of the following:

- Severe rash, hives or other signs of allergic reaction
- Swollen face, hands, feet
- Trouble breathing, swallowing

Tell your doctor as soon as possible if you experience any of the following:

- Signs of infection such as fever, malaise, wounds, dental problems, burning on urination
- Feeling weak or tired
- Coughing
- Tingling
- Numbness
- Double vision
- Arm or leg weakness
- Bump or open sore that does not heal

pre-filled syringe, pre-filled Pen or vial. Do not use beyond the expiration date.

Care should be taken to avoid dropping or crushing the product as it contains a glass syringe.

GENERAL ADVICE ABOUT PRESCRIPTION MEDICINES:

Talk to your doctor or other health care provider if you have any questions about this medicine or your condition. Medicines are sometimes prescribed for purposes other than those listed in a **CONSUMER INFORMATION** Leaflet. If you have any concerns about this medicine, ask your doctor. Your doctor or pharmacist can give you information about this medicine that was written for health care professionals. Do not use this medicine for a condition for which it was not prescribed. Do not share this medicine with other people. A toll-free information service is also available at **1-866-8HUMIRA® (1-866-848-6472)**.

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	
Very Common	▶ injection site reaction		✓	
Common	▶ upper respiratory tract infections		✓	
	▶ headache	✓		
	▶ rash		✓	
	▶ nausea		✓	
Uncommon	▶ tuberculosis		✓	✓
	▶ other serious infections		✓	✓
	▶ nerve disorders		✓	✓

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

HOW TO STORE IT

HOW DO I STORE HUMIRA®?

Keep HUMIRA® and all other medicines out of the reach of children.

Store between 2 and 8°C (in a refrigerator) in the original container until ready to use. Keep the vial in the outer carton. **DO NOT FREEZE HUMIRA®**. Protect from light. Refrigerated HUMIRA® remains stable until the expiration date printed on the

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug, you may notify Canada Vigilance by:

Online: www.healthcanada.gc.ca/medeffect
Toll-free telephone: 1-866-234-2345
Toll-free fax: 1-866-678-6789

Postage Paid mail:
Canada Vigilance Program
Health Canada
AL 0701C
Ottawa, Ontario K1A 0K9

NOTE: Should you require information related to the management of the side effect, please contact your health care provider. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

Additional information can be found at: www.abbott.ca or by contacting **ABBOTT Laboratories' toll-free information service at 1-866-8HUMIRA (1-866-848-6472)**.

This leaflet was prepared by ABBOTT Laboratories, Limited.

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