

PART III: CONSUMER INFORMATION

PrHUMIRA[®] subcutaneous injection adalimumab

This leaflet is PART III of a three-part “Product Monograph” published when HUMIRA[®] (Hu-MARE-ah) 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[®] 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, psoriatic arthritis, ankylosing spondylitis, Crohn’s disease, or psoriasis.

- Rheumatoid arthritis is an inflammatory disease of the joints.
- Psoriatic arthritis is an inflammatory disease of the joints and skin.
- Ankylosing spondylitis is a form of arthritis.
- Crohn’s disease is an inflammatory disease of the digestive tract.
- Psoriasis is an inflammatory disease of the skin. Your doctor prescribed HUMIRA[®] to reduce the signs and symptoms of your plaque psoriasis.

People with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, or psoriasis may be given other medicines for their disease before they are given HUMIRA[®]. 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 a fully human monoclonal antibody produced by cultured cells. Monoclonal antibodies are proteins that recognize and bind to other unique proteins. HUMIRA[®] binds to a specific protein called TNF-alpha (also known as tumor necrosis factor). People with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn’s disease, or psoriasis 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. By

binding to TNF-alpha, HUMIRA[®] decreases the inflammation process of these diseases.

HUMIRA[®] helps reduce the signs and symptoms of rheumatoid arthritis and psoriatic arthritis (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 ankylosing spondylitis (back pain and morning stiffness), and Crohn’s disease (abdominal pain and diarrhea). HUMIRA[®] also helps reduce the signs and symptoms of psoriasis (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[®] (see **What the important non-medicinal ingredients are** section). The needle cover of the syringe contains dry natural rubber (latex). Tell your doctor if you have any allergies to rubber or latex.
- 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 monohydrate, dibasic sodium phosphate dihydrate, mannitol, monobasic sodium phosphate dihydrate, polysorbate 80, sodium citrate, sodium chloride

For a full listing of non-medicinal ingredients see PART I of the Product Monograph.

What dosage forms it comes in:

- Single-use, 1 mL pre-filled Pen containing 40 mg adalimumab dissolved in 0.8 mL sterile solution (50 mg/mL)
- Single-use, 1 mL pre-filled glass syringe containing 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

- **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 HUMIRA[®]. Most of the patients had prior infliximab therapy as well as concomitant azathioprine or 6-mercaptopurine used for Crohn's disease. The causal association of HSTCL with HUMIRA[®] is not clear.
- **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.
- **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 rheumatoid arthritis 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.
- **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.
- **Pediatric Cancer:** Lymphoma and other cancers, which may result in death, have been reported in children and teenage patients taking TNF-blockers, including HUMIRA[®].
- **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, infections caused by bacteria or fungi, bacterial infections that have spread throughout the body (sepsis), and very rare cases of hepatitis B infection relapse.

- **Blood Problems:** In some instances, patients treated with TNF-blocking agents may develop low blood counts. If you develop symptoms such as persistent fever, bleeding, or bruising, you should contact your doctor right away.
- **Pediatric Cancer:** 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 developing lymphoma or other cancers may increase.

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, 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, 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 tuberculosis 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, blastomycosis, or parasitic infections. 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 infection or are at risk of developing this infection. Signs and symptoms of hepatitis B virus 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 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 rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn’s disease, psoriasis, 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 taking any over-the-counter drugs, herbal medicines and vitamin and mineral supplements.
- you are pregnant, thinking of becoming pregnant, or are breast-feeding. HUMIRA® has not been studied in pregnant women or nursing mothers, so the effects on pregnant women or nursing babies are unknown.

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®)
- anakinra (Kineret®)

If you have questions, ask your doctor.

PROPER USE OF THIS MEDICATION

Usual Dose:

Adults with Rheumatoid Arthritis, Psoriatic Arthritis or Ankylosing Spondylitis:

- The recommended dose is 40 mg administered every other week as a subcutaneous injection.

Adults with Crohn’s Disease:

- The recommended induction dose 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 is 40 mg every other week beginning at Week 4.

Adults with Psoriasis:

- The recommended dose is an initial dose of 80 mg, followed by 40 mg given every other week starting one week after the initial dose.

Overdose:

If you accidentally inject HUMIRA® more frequently than instructed, contact your doctor or local poison control center right away.

Missed Dose:

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

Administration:

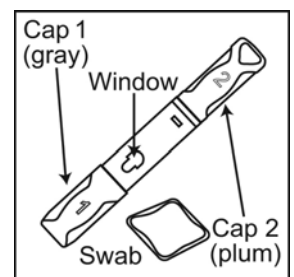
The following instructions explain how to inject HUMIRA®. Please read the instructions carefully and follow them step-by-step. You will be instructed by your doctor or his/her assistant on the technique of self-injection. Do not attempt to self-inject until you are sure that you understand how to prepare 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.

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

Step 1. Setting Up

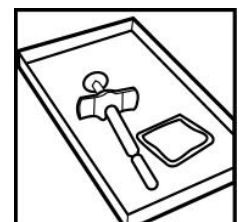
- Remove one dose tray containing a HUMIRA® Pen or pre-filled syringe from the refrigerator.
 - Do not shake or drop the Pen or pre-filled syringe.
 - Do not use the Pen or pre-filled syringe if it is frozen or if it has been left in direct sunlight.
 - If you are using the Pen, only remove the caps **immediately** before injection.
- Set up the following on a clean, flat working surface:

- One HUMIRA® Pen
- One alcohol pad (swab)



-OR-

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

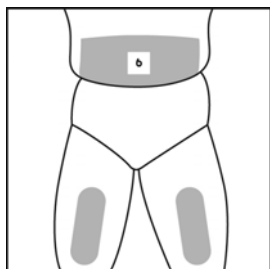


- If you do not have all of the pieces you need to give yourself an injection, call your pharmacist. Use only the items provided in the box your HUMIRA[®] prescription comes in.
- Make sure that the name HUMIRA[®] appears on the dose tray and Pen or pre-filled syringe label.
- Check the expiry date on the Pen or pre-filled syringe. Do not use the product if the date has passed the month and year shown.
- Make sure the liquid in the Pen or pre-filled syringe is clear and colourless. Do not use the Pen or pre-filled syringe 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, needles and syringe.

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

Step 2. Choosing and Preparing The 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.

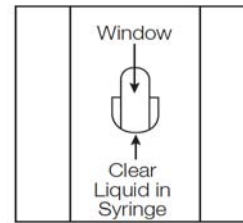


- Wipe the injection site where HUMIRA[®] is to be injected with an alcohol pad (swab), using a circular motion. Do **NOT** touch this area again before giving the injection.

Step 3. Preparing The Dose for Injection

HUMIRA[®] Pen

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



HUMIRA[®] Pre-Filled Syringe

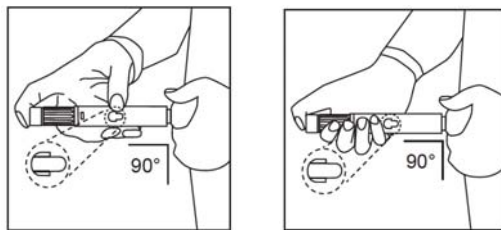
- Remove the needle cover from the syringe, taking care not to touch the needle with your fingers or allowing it to touch any surface.
- Turn the syringe so the needle is facing up and slowly push the plunger in to push the air in the syringe out through the needle. If a small drop of liquid comes out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

Step 4. Injecting HUMIRA[®]

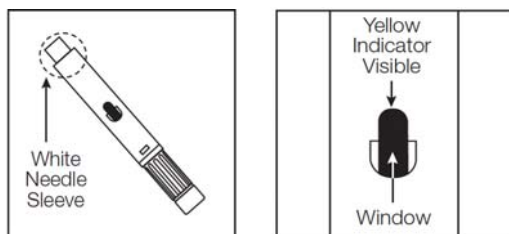
HUMIRA[®] Pen

- Only remove the caps **immediately** before injection.
- Hold the gray body of the Pen with one hand.
 - Place your hand on the middle of the Pen so that neither the gray cap (Cap 1) nor the plum cap (Cap 2) is covered.
 - Hold the Pen with the gray cap (Cap 1) pointing up.
- With your other hand, pull the gray cap (Cap 1) straight off (without twisting) and discard the cap.
 - Check that the small gray needle cover of the syringe has been removed with the cap.
 - If a few small drops of liquid come out of the needle, this is okay.
 - The white needle sleeve, which covers the needle, will now be exposed. Do not try to touch the needle housed in the barrel.
 - **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.
- Pull the plum safety cap (Cap 2) straight off (without twisting) to expose the plum-coloured activation button. 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 plum-coloured activation button until properly positioned.
 - **DO NOT RECAP as this could cause the unit to discharge.**
- Hold the Pen so that the window is in view. The presence of one or more bubbles in the window is normal.
- With your free hand, gently squeeze a sizable area of the cleaned skin at the injection site and hold firmly. You will inject into this raised area of skin.

- Place the white end of the Pen straight (a 90° angle) and flat against the raised area of skin. Position the Pen so that it will not inject the needle into your fingers.
- With your index finger or thumb, press the plum-coloured button to begin the injection.
 - Try not to cover the window.
 - Note that you will hear a loud ‘click’ when you press the button, which indicates the start of the injection. You will feel a small prick as the needle advances.
 - Keep pressing and continue to hold the Pen with steady pressure in place for about **10 seconds to ensure complete injection**. (A way to remember is simply ‘click and count to 10’.) Do not remove the Pen while the injection is being given.
 - It is important to maintain steady pressure at the injection site for the entire period of time.



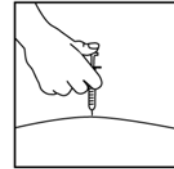
- You will see a yellow indicator move into the windows during the injection. The injection is complete when the yellow indicator stops moving.
- Lift the Pen straight up from the injection site. The white needle sleeve will move down over the needle and lock into place over the needle tip. Do not try to touch the needle. The white needle sleeve is there to protect you from touching the needle.



- Press a cotton ball or gauze pad over the injection site and hold it for 10 seconds. Do **NOT** rub the injection site. If you have slight bleeding, this is normal.
- Dispose of the Pen immediately into your special sharps container.

HUMIRA® Pre-Filled Syringe

- 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, however do **NOT** use the same syringe (discard the syringe 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 or gauze pad 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 into your special sharps container.

Step 5. Disposing of Supplies

- You should always check with your healthcare provider (e.g., doctor, nurse, or pharmacist) for instructions on how to properly dispose of used needles and syringes (including the Pen). 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 (including the Pen) in the household trash or recycling bin.**
- Dispose of used needles and syringes (including the Pen) 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 RECYCLING BIN.**

- The 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 recycled.



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
- sudden weight gain (this is possibly indicative of new or worsening heart failure)
- bruising or bleeding very easily, looking very pale (this is possibly indicative of a blood problem)

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
- red scaly patches or raised bumps that are filled with pus (this is possibly indicative of new or worsening psoriasis or infection)
- alopecia (loss of hair)
- changes in the pigmentation of the skin
- worsening of the appearance of a scar
- night sweats
- weight loss

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 disorder		✓	✓

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

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. **DO NOT FREEZE HUMIRA®.** Protect from light. Refrigerated HUMIRA® remains stable until the expiration date printed on the Pen or pre-filled syringe. 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).

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 on line at:
www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789
 - Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701C
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 <http://www.healthcanada.gc.ca/medeffect>

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

This document plus the full Product Monograph, prepared for health professionals can be found at:

<http://www.abbott.ca>

or by contacting the sponsor, Abbott Laboratories, Limited, Saint-Laurent, Qc H4S 1Z1 at:
1-866-8HUMIRA (1-866-848-6472)

This leaflet was prepared by Abbott Laboratories, Limited.

Last revised: July 21, 2011

Orencia® and Kineret® are trademarks of their respective owners and are not trademarks of Abbott Laboratories, Limited.