

## READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

### PATIENT MEDICATION INFORMATION

PrEnbrel®

etanercept injection

#### Single-use Prefilled Syringe

Read this carefully before you start taking **ENBREL** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ENBREL**.

#### Serious Warnings and Precautions

- **Serious infections.** There have been cases where patients taking ENBREL or other TNF-blocking agents have developed serious infections, including tuberculosis (TB) and infections caused by bacteria, viruses or fungi that have spread throughout their body. Some patients have died from these infections. In very rare cases, hepatitis B recurred in patients with previous hepatitis. If you tend to get infections easily or if you develop an infection while taking ENBREL, you should tell your doctor right away.
- **Malignancies.** There have been cases, sometimes fatal, of unusual cancers in children and teenagers who started using TNF-blocking agents, including ENBREL, at less than 18 years of age.

#### What is ENBREL used for?

ENBREL is a medicine for treating people with moderate to severe forms of rheumatoid arthritis (RA), juvenile idiopathic arthritis (JIA) and a type of disease called psoriatic (sore-ee-ah-tick) arthritis (PsA). ENBREL is also for treating adults with a type of arthritis called ankylosing spondylitis (ank-e-low-sing spond-e-lie-tis) (AS). ENBREL is also for adults with moderate to severe psoriasis (sore-l-ah-sis) (PsO) and children with severe psoriasis (PsO). RA, JIA, PsA and AS are inflammatory diseases that affect the joints in your body. PsO is an inflammatory disease that affects the skin and can cause raised, thick, red and scaly patches (“psoriatic skin lesions”) that can appear anywhere on the body. PsA is usually seen in patients with PsO and affects both the joints and the skin.

#### How does ENBREL work?

ENBREL is a type of protein called a tumour necrosis factor (TNF) blocker that blocks the action of a substance your body makes called TNF-alpha. TNF-alpha is made by your body’s immune system. People with immune diseases like RA, JIA, PsA and PsO, as well as patients with AS, have too much TNF-alpha in their bodies, which can cause inflammation and lead to painful, swollen joints and raised thick, red, scaly patches (“psoriatic skin lesions”) that can appear anywhere on the body. ENBREL can reduce the amount of TNF in the body to normal levels, helping to treat joint damage and skin lesions. In patients with inflammatory arthritis, ENBREL may be effective in reducing signs and symptoms of inflammatory arthritis (such as pain, morning stiffness and fatigue), may help improve your ability to do simple daily activities (such as dressing, walking and climbing stairs), and may help prevent damage to your bones and joints. In patients with psoriatic skin conditions, ENBREL may be effective in clearing skin and improving quality of life (such as personal relationships, work and daily activities, and treatment satisfaction).

## When can I expect to see results from taking ENBREL?

Improvement may be seen as early as 1 week after starting ENBREL in adults, and within 2 weeks in children with JIA and 4 weeks with PsO. In clinical trials, full effect was usually seen by 3 months in both adults and children and was sustained with continued treatment.

In clinical trials with PsA, one quarter of patients saw improvement in their joint symptoms within 1 month, one half of patients saw improvement within 3 months, and three quarters of patients saw improvement within 9 months of treatment with ENBREL.

During the PsA clinical trials, approximately 2% of patients treated with ENBREL stopped taking ENBREL due to side effects and up to 5% of ENBREL-treated patients stopped taking ENBREL due to lack of improvement.

## What are the ingredients in ENBREL?

Medicinal ingredients: etanercept

Non-medicinal ingredients: L-arginine hydrochloride, sodium chloride, sucrose, and Water for Injection, USP.

## ENBREL comes in the following dosage forms:

**Single-use prefilled syringes** are available in 25 mg\* (0.51 mL of a 50 mg/mL solution of etanercept, minimum deliverable volume of 0.47 mL) and 50 mg (0.98 mL of a 50 mg/mL solution of etanercept, minimum deliverable volume of 0.94 mL) dosage strengths.

**Single-use prefilled SureClick® autoinjectors** are available in a 50 mg (0.98 mL of a 50 mg/mL of etanercept, minimum deliverable volume of 0.94 mL) dosage strength.

## Do not use ENBREL if you:

- have ever had an allergic reaction to ENBREL or any of the ingredients in ENBREL.
- have an infection that has spread through your body (sepsis).

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ENBREL. Talk about any health conditions or problems you may have, including if you:**

- have an infection. This could put you at risk for serious side effects from ENBREL.
- have symptoms of an infection such as fever, sweats or chills, cough or flu-like symptoms, shortness of breath, blood in your phlegm, weight loss, muscle aches, warm, red, or painful areas on your skin, sores on your body, diarrhea or stomach pain, burning when you urinate or urinate more often than normal, and feel very tired.
- have a history of infections that keep coming back or other conditions — like diabetes, HIV, or a weak immune system — that might increase your risk of infections.
- have tuberculosis (TB), or have been in close contact with someone who has or has had TB. You will need to be evaluated for TB. Your doctor should test you for TB before starting ENBREL.
- were born in, lived in, or traveled to countries where there is a risk for getting TB. Ask your doctor if you are not sure.

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- live in, have lived in or have traveled to, areas where there is a greater risk for certain kinds of fungal infections (histoplasmosis, coccidioidomycosis, blastomycosis). These infections may develop or become more severe if you take ENBREL. If you don't know if you have lived in an area where these infections are common, ask your doctor.
- have or have had hepatitis B.
- have or have had persistent numbness, tingling and muscle weakness or a disease such as multiple sclerosis, Guillain-Barré or a Guillain-Barré-like syndrome, which causes inflammation of the nervous system, either in the brain and spinal cord or nerves going to your hands and feet.
- have been newly diagnosed or are being treated for congestive heart failure.
- are scheduled to have major surgery.
- have recently received or are scheduled to receive a vaccine. All vaccines should be brought up-to-date before starting ENBREL. Patients taking ENBREL should not receive live vaccines.
- use the medication Kineret® (anakinra), Orencia® (abatacept) or cyclophosphamide (see The following may interact with ENBREL below).
- have been around someone with varicella zoster (chicken pox, shingles).

Know the medicines you take. Keep a list of them to show your doctor and pharmacist each time you get a new medicine.

Your doctor should monitor you closely for signs and symptoms of TB during treatment with ENBREL even if you have tested negative for TB. If you develop any of the symptoms of TB (a dry cough that doesn't go away, weight loss, fever, night sweats) call your doctor.

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

### **Other warnings you should know about:**

All medicines have side effects. Medicines, like ENBREL, that affect your immune system can cause serious side effects. The possible serious side effects include:

- **Nervous system diseases.** There have been rare cases of disorders that affect the nervous system of people taking ENBREL or other TNF-blockers, such as multiple sclerosis, seizures or inflammation of the nerves of the eyes. Signs that you could be experiencing a problem affecting your nervous system include: numbness or tingling throughout your body, problems with your vision, weakness in your arms and/or legs, and dizziness.
- **Blood problems.** In some patients the body may fail to produce enough of the blood cells that can help your body fight infections or help you to stop bleeding. This can lead to death. If you develop a fever that doesn't go away, bruise or bleed very easily or look very pale or feel faint, call your doctor right away. Your doctor may decide to stop treatment. Some people have also had symptoms that resemble lupus (rash on your face and arms that gets worse in the sun) that may go away when you stop taking ENBREL.
- **Heart problems.** You should also tell your doctor if you have ever been treated for heart failure. If you have, your doctor may choose not to start you on ENBREL, or may want to monitor you more closely. Symptoms include shortness of breath or swelling of your ankles and feet.

- **Allergic reactions.** Some patients have had allergic reactions to ENBREL. If you develop a severe rash, swollen face or difficulty breathing while taking ENBREL, call your doctor right away.
- **Malignancies.** Patients with inflammatory diseases including RA, AS or PsO, particularly those with highly active disease, may be at higher risk for lymphoma (a type of cancer). For children and adults taking TNF-blocker medicines including ENBREL, the chances of getting lymphoma or other cancers may increase. Whether treatment with ENBREL might influence the development and course of malignancies in adults is unknown.
- **Liver problems** (autoimmune hepatitis). Liver problems can happen in people who use TNF-blocker medicines, including ENBREL. These problems can lead to liver failure and death. Call your doctor right away if you have any of these symptoms: feel very tired, skin or eyes look yellow, poor appetite or vomiting, pain on the right side of your stomach (abdomen). These symptoms may occur several months after starting and even after ENBREL has been stopped.
- **Psoriasis.** Some people using ENBREL developed new psoriasis or worsening of psoriasis they already had. Tell your doctor if you develop red scaly patches or raised bumps which may be filled with pus. Your doctor may decide to stop your treatment with ENBREL.
- **Serious infections.** ENBREL can lower the ability of your immune system to fight infections. So, taking ENBREL can make you more prone to getting infections or make any infection that you may have worse. Some people have serious infections while taking ENBREL including infections that spread through the body such as tuberculosis (TB), legionellosis (usually a bacterial pneumonia), and listeriosis (usually from contaminated food). Other infections caused by viruses, fungi, bacteria or parasites may occur. Some people have died from these infections.

### **Can I take ENBREL if I am pregnant or breastfeeding?**

The safe use of ENBREL has not been established in pregnant women.

You should tell your doctor if you are pregnant, become pregnant or are thinking about becoming pregnant. If you took ENBREL during pregnancy, talk to your doctor prior to administration of live vaccines to your infant.

ENBREL can pass into breast milk. ENBREL has not been studied in nursing mothers, and therefore its effects on nursing babies are not known. Talk to your healthcare provider about the best way to feed your baby while taking ENBREL.

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

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

### **The following may interact with ENBREL:**

It is important that you tell your doctor about any other medicines (for example, high blood pressure medicine) you are taking for other conditions before you start taking ENBREL. You should also tell your doctor about any over-the-counter drugs, herbal medicines and vitamin and mineral supplements you are taking.

If you have diabetes and are taking medication to control your diabetes, your doctor may decide you need less anti-diabetic medicine while taking ENBREL.

## General Information about ENBREL

Medicines are sometimes prescribed for purposes not mentioned in the Consumer Information leaflet. **Do NOT** use ENBREL for a condition for which it was not prescribed. **Do NOT** give ENBREL to other people, even if they have the same condition.

### Can I take ENBREL if I am taking other medicines for my RA, JIA, PsA, AS or other conditions?

In adults, ENBREL can be used in combination with methotrexate. However, little is known of the interaction of ENBREL with methotrexate and other drugs in children with JIA.

Taking ENBREL with Kineret® (anakinra) is not recommended because this may increase your risk of getting a serious infection.

Taking ENBREL with Orencia® (abatacept) is not recommended because this may increase your risk for serious side effects.

Taking ENBREL with cyclophosphamide (used to treat cancer or immune diseases) is not recommended. You may have a higher chance for getting certain cancers when taking ENBREL with cyclophosphamide.

### **How to take ENBREL:**

ENBREL is given as an injection under the skin.

You may continue to use other medicines that help treat your condition while taking ENBREL, such as non-steroidal anti-inflammatory drugs (NSAIDs) and prescription steroids, as recommended by your doctor.

### **Usual dose:**

If you have RA, PsA or AS, the recommended dose of ENBREL for adults is 50 mg per week given as one injection using a 50 mg single-use prefilled syringe or two injections using the 25 mg\* single-use prefilled syringe. Your doctor will tell you whether the two injections with the 25 mg\* single-use prefilled syringe should be given on the same day once a week or on two different days (3 or 4 days apart) in the same week.

If you have PsO, the recommended starting dose of ENBREL for adult patients is a 50 mg dose twice a week (3 or 4 days apart) for 3 months. After 3 months, your doctor will tell you to reduce your dose to 50 mg once per week, using one 50 mg single-use prefilled syringe or two 25 mg\* single-use prefilled syringes.

The recommended dose of ENBREL for children with JIA or PsO is based on the child's body weight. Your child's doctor will tell you the correct amount of ENBREL your child should take. **The 50 mg single-use prefilled syringe is only recommended for children weighing 63 kg (138 pounds) or more.** ENBREL should be given by, or under the supervision of, a responsible adult.

Make sure you have been shown how to inject ENBREL before you do it yourself. You can call your doctor or the toll-free information line at 1-877-9ENBREL (1-877-936-2735) if you have any questions about ENBREL or about giving yourself or your child an injection. Someone you know can also help you with your injection. Remember to take this medicine just as your doctor has told you and do not miss any doses.

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\* 25 mg single-use prefilled syringe is not available in Canada

**Overdose:**

Call your doctor if you accidentally inject ENBREL more frequently than instructed.

If you think you have taken too much ENBREL, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

**Missed Dose:**

If you forget to use ENBREL, inject your dose as soon as you remember. Then, take your next dose at your regular(ly) scheduled time. In case you are not sure when to inject ENBREL, call your healthcare provider. A toll-free information service is also available: 1-877-9ENBREL (1-877-936-2735).

**ENBREL Single-Use Prefilled Syringe:**

The following instructions are for preparing and giving an injection of ENBREL using a single-use prefilled syringe.

**Important: The ENBREL prefilled syringe is not made with natural rubber latex.**

**Storage of your ENBREL prefilled syringe**

- Store the ENBREL prefilled syringe in the refrigerator at 36°F to 46°F (2°C to 8°C).
- Store the ENBREL prefilled syringe in the original carton to protect from light or physical damage.
- If needed, you may store your ENBREL prefilled syringe at room temperature, up to 27°C, for up to 60 days.
- Once the ENBREL prefilled syringe has reached room temperature, do not put it back in the refrigerator.
- Throw away any ENBREL prefilled syringe that has been stored at room temperature after 60 days.
- **Do not** store the ENBREL prefilled syringe in extreme heat or cold. For example, avoid storing ENBREL prefilled syringe in your vehicle's glove box or trunk.
- **Do not freeze.**
- **Do not shake.**
- **Keep the Enbrel prefilled syringe and all medicines out of the reach of children.**

If you have any questions about storage, contact your healthcare professional or call 1-877-9ENBREL (1-877-936-2735) for further instructions.

**STEP 1: Setting up for an injection**

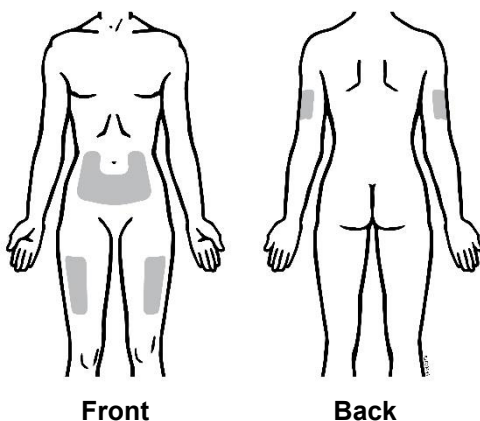
1. Select a clean, well-lit, flat working surface, such as a table.
2. Take the ENBREL carton containing the prefilled syringes out of the refrigerator and place it on your flat work surface. Remove one prefilled syringe and place it on your work surface. Carefully lift the prefilled syringe straight up out of the box. **Do NOT shake** the prefilled syringe of ENBREL. Place the carton containing any remaining prefilled syringes back into

the refrigerator (2°C to 8°C). You may also store the carton of unused prefilled syringes at room temperature, up to 27°C for up to 60 days.

3. Check the expiration date on the prefilled syringe. If the expiration date has passed, or if it has been stored at room temperature beyond 60 days (whichever comes first), **do NOT** use the prefilled syringe and contact your pharmacist or call 1-877-9ENBREL (1-877-936-2735) for assistance.
4. **Do NOT** use the prefilled syringe if the needle cover is missing or not securely attached. Call 1-877-9ENBREL (1-877-936-2735).
5. For a more comfortable injection, leave the prefilled syringe to reach room temperature for about 15 to 30 minutes. **Do NOT** remove the needle cover while allowing it to reach room temperature. **Do NOT** warm ENBREL in any other way (for example, **do NOT** warm it in a microwave oven or in hot water).
6. Assemble the additional supplies you will need for your injection. These include an alcohol swab, a cotton ball or gauze, and a sharps disposal container (see “**Step 4: Disposing of Supplies**”).
7. Wash your hands thoroughly with soap and warm water.
8. Make sure the solution in the prefilled syringe is clear and colourless. You may notice small white particles in the solution. These particles are formed from ENBREL and this is acceptable. However, **do NOT inject the solution if it is cloudy or discoloured, or contains large or coloured particles**, call 1-877-9ENBREL (1-877-936-2735).

## STEP 2: Choosing and Preparing an Injection Site

1. Recommended injection sites for ENBREL using a prefilled syringe include:
  - The front of the middle thigh
  - the stomach area (abdomen), except for the **5-centimetre (2-inch)** area right around the navel (belly button)
  - the outer area of the upper arm (only if someone else is giving you the injection).



2. Rotate the site for each injection. **Do NOT** inject into areas where the skin is tender, bruised, red, or hard. Avoid areas with scars or stretch marks.
3. If you have psoriasis, you should try not to inject directly into any raised, thick, red, or scaly skin patches or lesions.
4. To prepare the area of skin where ENBREL is to be injected, wipe the injection site with an alcohol swab. **Do not touch this area again before giving the injection.**

### STEP 3: Injecting ENBREL Using a Prefilled Syringe

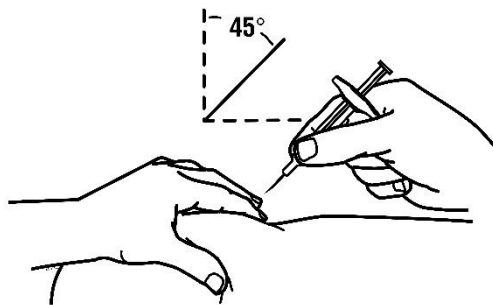
**Do NOT** remove the needle cover from the prefilled syringe until you are ready to inject.

1. Pick up the prefilled syringe from your flat work surface. Hold the barrel of the prefilled syringe with one hand and pull the needle cover straight off, only when you are ready to inject. **Do not** leave the needle cover off for more than 5 minutes. This can dry out the medicine.

To avoid damaging the needle, **do not** twist or bend the needle cover while you are removing it, and **do not** try to put the needle cover back onto the prefilled syringe.

When you remove the needle cover, there may be a drop of liquid at the end of the needle; this is normal. **Do not** touch the needle or allow it to touch any surface. **Do not** touch or bump the plunger. Doing so could cause the liquid to leak out.

2. Holding the syringe with the needle pointing up, check the syringe for air bubbles. If there are bubbles, **gently** tap the syringe with your finger until the air bubbles rise to the top of the syringe. Slowly push the plunger up to force the air bubbles out of the syringe.
3. Holding the syringe in one hand like a pencil, use the other hand to gently pinch a fold of skin at the cleaned injection site and hold it firmly.
4. With a quick and “dart like” motion, insert the needle at a 45-degree angle into the skin.



5. When the needle is completely inserted into the skin, let go of the skin that you are holding. With your free hand, hold the syringe near its base to stabilize it. Then push the plunger to inject all of the ENBREL solution at a slow steady rate.
6. When the syringe is empty, pull the needle out of the skin, being careful to keep it at the same angle as inserted. There may be a little bleeding at the injection site. You can press a cotton ball or gauze over the injection site for 10 seconds. **Do not** rub the injection site. If needed, you may cover the injection site with a bandage.

## STEP 4: Disposing of Supplies

The syringe should **never** be reused. **Never** recap a needle.

Put the used prefilled syringes in a sharps disposal container right away after use. **Do not** throw away (dispose of) the prefilled syringes in your household trash.

If you do not have a sharps disposal container, you may use a household container that is:

- made of a heavy-duty plastic,
- can be closed with a tight-fitting, puncture-resistant lid without sharps being able to come out,
- upright and stable during use,
- leak-resistant, and
- properly labeled to warn of hazardous waste inside the container.

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be local laws about how you should throw away used needles and syringes.

- **Do not** reuse the syringe.
- **Do not** recycle the syringe or sharps disposal container or throw them into household trash.

**Important:** Always keep the sharps disposal container out of the reach of children.

A healthcare professional familiar with ENBREL should answer all questions. Call 1-877-9ENBREL (1-877-936-2735) for more information about ENBREL.

## What are possible side effects from using ENBREL?

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

### What are the common side effects?

In studies comparing ENBREL to placebo (inactive injection), side effects that occurred more frequently in patients treated with ENBREL were:

- Reactions where the injection was given. These reactions are usually mild and include redness, swelling, itching, or bruising. These usually go away within 3 to 5 days. If you have pain, redness or swelling around the injection site that doesn't go away or gets worse, call your doctor.
- Upper respiratory infections (sinus infections)
- Headaches

These are not all the possible side effects you may feel when taking ENBREL. If you experience any side effects not listed here, contact your healthcare professional.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>VERY COMMON</b>			
Injection site reactions		X	
<b>COMMON</b>			
Upper respiratory tract infections (sinus infections)		X	
Headaches	X		
<b>UNCOMMON</b>			
Serious infections		X	X
Tuberculosis		X	
Nerve disorders		X	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on [Adverse Reaction Reporting \(http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php\)](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### Storage:

Keep out of the reach and sight of children.

The ENBREL prefilled syringe should be refrigerated at 2°C to 8°C. **Do NOT freeze ENBREL.** Refrigerated ENBREL remains stable until the expiration date printed on the syringe.

ENBREL may be transferred to room temperature storage (up to 27°C). Upon removal from the refrigerator, it must be used within 60 days. Protect from direct sunlight, sources of heat, and humidity until ready to use.

**If you want more information about ENBREL:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website](#); the manufacturer's website [www.amgen.ca](http://www.amgen.ca), or by contacting the ENLIVEN<sup>®</sup> Services information support line, toll free at: 1-877-9ENBREL (1-877-936-2735). Additional information can be found at [www.enbrel.ca](http://www.enbrel.ca).

This leaflet was prepared by AMGEN CANADA INC. for IMMUNEX CORPORATION

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- **Malignancies.** There have been cases, sometimes fatal, of unusual cancers in children and teenagers who started using TNF-blocking agents, including ENBREL, at less than 18 years of age.

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#### How does ENBREL work?

ENBREL is a type of protein called a tumour necrosis factor (TNF) blocker that blocks the action of a substance your body makes called TNF-alpha. TNF-alpha is made by your body’s immune system. People with immune diseases like RA, JIA, PsA and PsO, as well as patients with AS, have too much TNF-alpha in their bodies, which can cause inflammation and lead to painful, swollen joints and raised thick, red, scaly patches (“psoriatic skin lesions”) that can appear anywhere on the body. ENBREL can reduce the amount of TNF in the body to normal levels, helping to treat joint damage and skin lesions. In patients with inflammatory arthritis, ENBREL may be effective in reducing signs and symptoms of inflammatory arthritis (such as pain, morning stiffness and fatigue), may help improve your ability to do simple daily activities (such as dressing, walking and climbing stairs), and may help prevent damage to your bones and joints. In patients with psoriatic skin conditions, ENBREL may be effective in clearing skin and improving quality of life (such as personal relationships, work and daily activities, and treatment satisfaction).

## When can I expect to see results from taking ENBREL?

Improvement may be seen as early as 1 week after starting ENBREL in adults, and within 2 weeks in children with JIA and 4 weeks with PsO. In clinical trials, full effect was usually seen by 3 months in both adults and children and was sustained with continued treatment.

In clinical trials with PsA, one quarter of patients saw improvement in their joint symptoms within 1 month, one half of patients saw improvement within 3 months, and three quarters of patients saw improvement within 9 months of treatment with ENBREL.

During the PsA clinical trials, approximately 2% of patients treated with ENBREL stopped taking ENBREL due to side effects and up to 5% of ENBREL-treated patients stopped taking ENBREL due to lack of improvement.

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- have ever had an allergic reaction to ENBREL or any of the ingredients in ENBREL.
- have an infection that has spread through your body (sepsis).

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ENBREL. Talk about any health conditions or problems you may have, including if you:**

- have an infection. This could put you at risk for serious side effects from ENBREL.
- have symptoms of an infection such as fever, sweats or chills, cough or flu-like symptoms, shortness of breath, blood in your phlegm, weight loss, muscle aches, warm, red, or painful areas on your skin, sores on your body, diarrhea or stomach pain, burning when you urinate or urinate more often than normal, and feel very tired.
- have a history of infections that keep coming back or other conditions — like diabetes, HIV, or a weak immune system — that might increase your risk of infections.
- have tuberculosis (TB), or have been in close contact with someone who has or has had TB. You will need to be evaluated for TB. Your doctor should test you for TB before starting ENBREL.
- were born in, lived in, or traveled to countries where there is a risk for getting TB. Ask your doctor if you are not sure.

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- live in, have lived in or have traveled to, areas where there is a greater risk for certain kinds of fungal infections (histoplasmosis, coccidioidomycosis, blastomycosis). These infections may develop or become more severe if you take ENBREL. If you don't know if you have lived in an area where these infections are common, ask your doctor.
- have or have had hepatitis B.
- have or have had persistent numbness, tingling and muscle weakness or a disease such as multiple sclerosis, Guillain-Barré or a Guillain-Barré-like syndrome, which causes inflammation of the nervous system, either in the brain and spinal cord or nerves going to your hands and feet.
- have been newly diagnosed or are being treated for congestive heart failure.
- are scheduled to have major surgery.
- have recently received or are scheduled to receive a vaccine. All vaccines should be brought up-to-date before starting ENBREL. Patients taking ENBREL should not receive live vaccines.
- use the medication Kineret® (anakinra), Orencia® (abatacept) or cyclophosphamide (see the following may interact with ENBREL below).
- have been around someone with varicella zoster (chicken pox, shingles).

Know the medicines you take. Keep a list of them to show your doctor and pharmacist each time you get a new medicine.

Your doctor should monitor you closely for signs and symptoms of TB during treatment with ENBREL even if you have tested negative for TB. If you develop any of the symptoms of TB (a dry cough that doesn't go away, weight loss, fever, night sweats) call your doctor.

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

### **Other warnings you should know about:**

All medicines have side effects. Medicines, like ENBREL, that affect your immune system can cause serious side effects. The possible serious side effects include:

- **Nervous system diseases.** There have been rare cases of disorders that affect the nervous system of people taking ENBREL or other TNF-blockers, such as multiple sclerosis, seizures or inflammation of the nerves of the eyes. Signs that you could be experiencing a problem affecting your nervous system include: numbness or tingling throughout your body, problems with your vision, weakness in your arms and/or legs, and dizziness.
- **Blood problems.** In some patients the body may fail to produce enough of the blood cells that can help your body fight infections or help you to stop bleeding. This can lead to death. If you develop a fever that doesn't go away, bruise or bleed very easily or look very pale or feel faint, call your doctor right away. Your doctor may decide to stop treatment. Some people have also had symptoms that resemble lupus (rash on your face and arms that gets worse in the sun) that may go away when you stop taking ENBREL.
- **Heart problems.** You should also tell your doctor if you have ever been treated for heart failure. If you have, your doctor may choose not to start you on ENBREL, or may want to monitor you more closely. Symptoms include shortness of breath or swelling of your ankles and feet.

- **Allergic reactions.** Some patients have had allergic reactions to ENBREL. If you develop a severe rash, swollen face or difficulty breathing while taking ENBREL, call your doctor right away.
- **Malignancies.** Patients with inflammatory diseases including RA, AS or PsO, particularly those with highly active disease, may be at higher risk for lymphoma (a type of cancer). For children and adults taking TNF-blocker medicines including ENBREL, the chances of getting lymphoma or other cancers may increase. Whether treatment with ENBREL might influence the development and course of malignancies in adults is unknown.
- **Liver problems** (autoimmune hepatitis). Liver problems can happen in people who use TNF-blocker medicines, including ENBREL. These problems can lead to liver failure and death. Call your doctor right away if you have any of these symptoms: feel very tired, skin or eyes look yellow, poor appetite or vomiting, pain on the right side of your stomach (abdomen). These symptoms may occur several months after starting and even after ENBREL has been stopped.
- **Psoriasis.** Some people using ENBREL developed new psoriasis or worsening of psoriasis they already had. Tell your doctor if you develop red scaly patches or raised bumps which may be filled with pus. Your doctor may decide to stop your treatment with ENBREL.
- **Serious infections.** ENBREL can lower the ability of your immune system to fight infections. So, taking ENBREL can make you more prone to getting infections or make any infection that you may have worse. Some people have serious infections while taking ENBREL including infections that spread through the body such as tuberculosis (TB), legionellosis (usually a bacterial pneumonia), and listeriosis (usually from contaminated food). Other infections caused by viruses, fungi, bacteria or parasites may occur. Some people have died from these infections.

### **Can I take ENBREL if I am pregnant or breastfeeding?**

The safe use of ENBREL has not been established in pregnant women.

You should tell your doctor if you are pregnant, become pregnant or are thinking about becoming pregnant. If you took ENBREL during pregnancy, talk to your doctor prior to administration of live vaccines to your infant.

ENBREL can pass into breast milk. ENBREL has not been studied in nursing mothers, and therefore its effects on nursing babies are not known. Talk to your healthcare provider about the best way to feed your baby while taking ENBREL.

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

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

### **The following may interact with ENBREL:**

It is important that you tell your doctor about any other medicines (for example, high blood pressure medicine) you are taking for other conditions before you start taking ENBREL. You should also tell your doctor about any over-the-counter drugs, herbal medicines and vitamin and mineral supplements you are taking.

If you have diabetes and are taking medication to control your diabetes, your doctor may decide you need less anti-diabetic medicine while taking ENBREL.

## General Information about ENBREL

Medicines are sometimes prescribed for purposes not mentioned in the Consumer Information leaflet. **Do NOT** use ENBREL for a condition for which it was not prescribed. **Do NOT** give ENBREL to other people, even if they have the same condition.

### Can I take ENBREL if I am taking other medicines for my RA, JIA, PsA, AS or other conditions?

In adults, ENBREL can be used in combination with methotrexate. However, little is known of the interaction of ENBREL with methotrexate and other drugs in children with JIA.

Taking ENBREL with Kineret<sup>®</sup> (anakinra) is not recommended because this may increase your risk of getting a serious infection.

Taking ENBREL with Orencia<sup>®</sup> (abatacept) is not recommended because this may increase your risk for serious side effects.

Taking ENBREL with cyclophosphamide (used to treat cancer or immune diseases) is not recommended. You may have a higher chance for getting certain cancers when taking ENBREL with cyclophosphamide.

### **How to take ENBREL:**

ENBREL is given as an injection under the skin.

You may continue to use other medicines that help treat your condition while taking ENBREL, such as non-steroidal anti-inflammatory drugs (NSAIDs) and prescription steroids, as recommended by your doctor.

### **Usual dose:**

If you have RA, PsA or AS, the recommended dose of ENBREL for adults is 50 mg per week given as one injection using a 50 mg single-use prefilled SureClick<sup>®</sup> autoinjector.

If you have PsO, the recommended starting dose of ENBREL for adult patients is a 50 mg dose twice a week (3 or 4 days apart) for 3 months. After 3 months, your doctor will tell you to reduce your dose to 50 mg once per week using one 50 mg single-use prefilled SureClick<sup>®</sup> autoinjector.

The recommended dose of ENBREL for children with JIA or PsO is based on the child's body weight. Your child's doctor will tell you the correct amount of ENBREL your child should take.

**The 50 mg single-use prefilled SureClick<sup>®</sup> autoinjector is only recommended for children weighing 63 kg (138 pounds) or more.** ENBREL should be given by, or under the supervision of, a responsible adult.

Make sure you have been shown how to inject ENBREL before you do it yourself. You can call your doctor or the toll-free information line at 1-877-9ENBREL (1-877-936-2735) if you have any questions about ENBREL or about giving yourself or your child an injection. Someone you know can also help you with your injection. Remember to take this medicine just as your doctor has told you and do not miss any doses.

### **Overdose:**

Call your doctor if you accidentally inject ENBREL more frequently than instructed.

If you think you have taken too much ENBREL, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

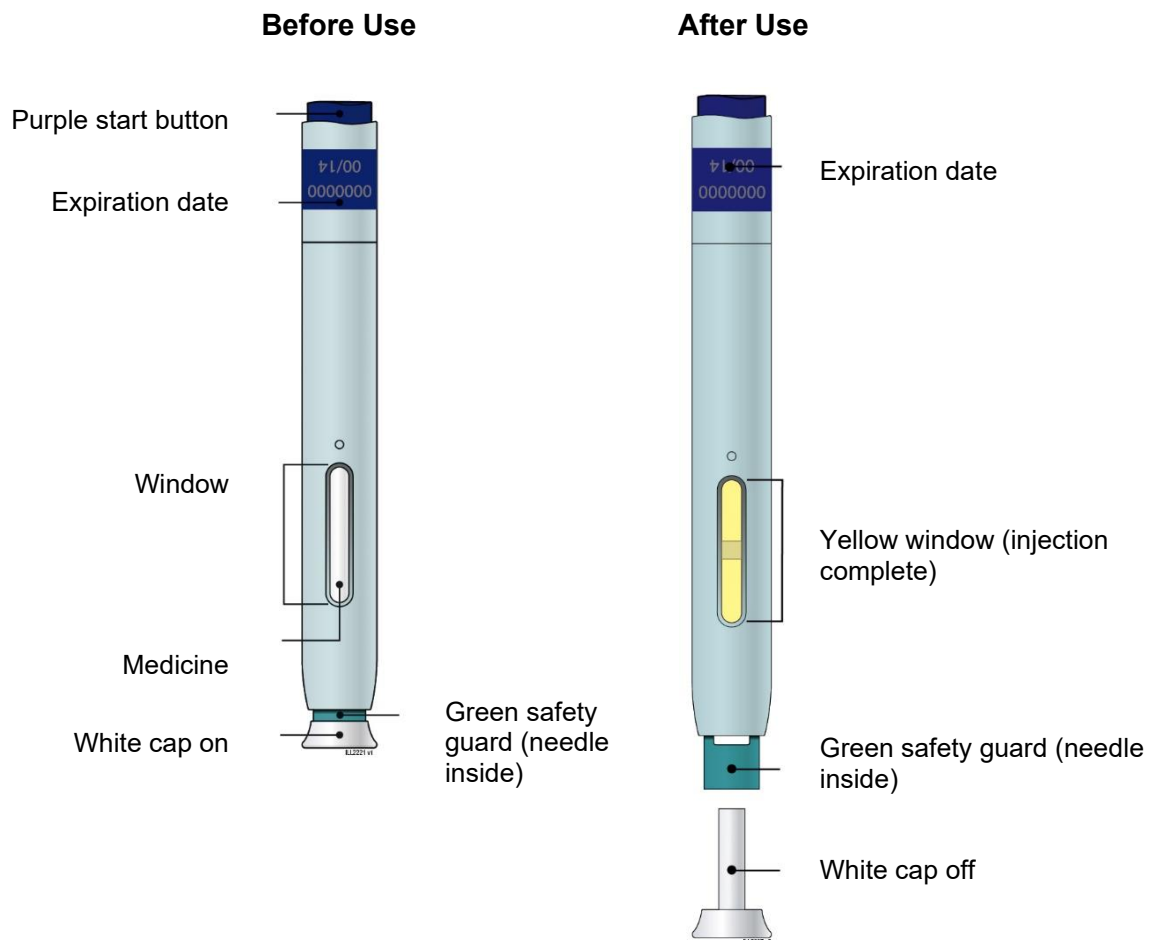
### Missed Dose:

If you forget to use ENBREL, inject your dose as soon as you remember. Then, take your next dose at your regular(ly) scheduled time. In case you are not sure when to inject ENBREL, call your healthcare provider. A toll-free information service is also available: 1-877-9ENBREL (1-877-936-2735).

### ENBREL Single-Use Prefilled SureClick® Autoinjector

The following instructions are for preparing and giving an injection of ENBREL using a single-use prefilled SureClick® autoinjector.

#### Guide to Parts



**Important:** Needle is inside the green safety guard.

### Important

#### Important Information You Need to Know Before Injecting ENBREL:

- It is important that you **do not** try to give yourself or someone else the injection unless you have received training from your healthcare professional.

### Storing your ENBREL SureClick® autoinjector:

- Keep the autoinjector and all medicines out of the reach of children.
- Keep the autoinjector in the original carton to protect from light.
- Keep the autoinjector in the refrigerator at 2°C to 8°C.
- After removing from the refrigerator, the autoinjector may be kept at room temperature, up to 27°C, for up to 60 days.
- Once ENBREL has reached room temperature, do not put it back in the refrigerator.
- Throw away ENBREL that has been stored at room temperature for more than 60 days.
- **Do not** store the autoinjector in extreme heat or cold. For example, avoid storing the autoinjector in your vehicle's glove box or trunk.
- **Do not** freeze or use the autoinjector if it has been frozen.

### Using your ENBREL SureClick® autoinjector:

- **Do not** use the autoinjector after the expiration date on the label, or if it has been stored at room temperature beyond 60 days (whichever comes first).
- **Do not** shake the autoinjector.
- **Do not** remove the white cap from the autoinjector until you are ready to inject. Leaving the cap off for more than 5 minutes can dry out the medicine.
- **Do not** use the autoinjector if it has been dropped on a hard surface. Part of the autoinjector may be broken even if you cannot see the break. Use a new autoinjector, and call 1-877-9ENBREL (1-877-936-2735).
- The autoinjector is not made with natural rubber latex.
- **Children must weigh at least 63 kg (138 pounds) to use ENBREL SureClick® autoinjector. Children who weigh less than 63 kg (138 pounds) should use a different form of ENBREL.**

For more information or help, contact your healthcare professional, or call 1-877-9ENBREL (1-877-936-2735).

### STEP 1: Preparing to inject ENBREL

#### A. Remove the autoinjector from the carton.

Carefully lift the autoinjector straight up out of the carton.

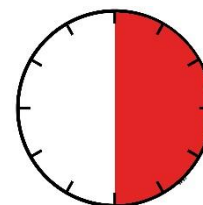
Before you inject, always check the label of the autoinjector to make sure you have the correct medicine and the correct dose of ENBREL

Put the original package with any unused autoinjectors back in the refrigerator.

You may also store the unused autoinjectors at room temperature, up to 27°C for up to 60 days.

Wait at least **30** minutes for the autoinjector to reach room temperature before injecting.

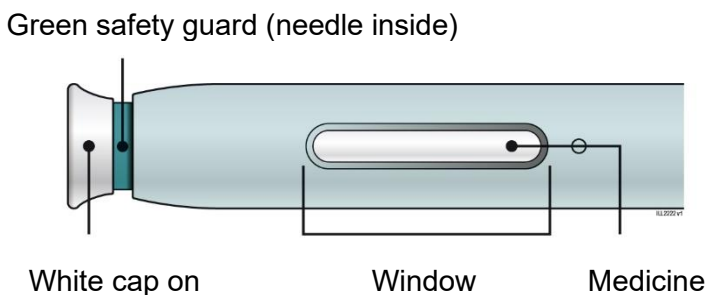
This is important for administering the entire dose and helps minimize discomfort. ENBREL may take longer to inject if it has



not reached room temperature. **Do not** heat the autoinjector. Let it come to room temperature naturally

- **Do not** put the autoinjector back in the refrigerator after it has reached room temperature.
- **Do not** try to warm the autoinjector by using a heat source such as hot water or microwave.
- **Do not** leave the autoinjector in direct sunlight.
- **Do not** shake the autoinjector.
- **Do not** remove the white cap from the autoinjector yet.

**B. Inspect the ENBREL SureClick® autoinjector.**



**Make sure the medicine in the window is clear and colourless.**

**It is okay if you see small white particles in the medicine.**

- **Do not** use the autoinjector if the medicine is cloudy or discoloured or contains large lumps, flakes, or coloured particles.
- **Do not** use the autoinjector if any part appears cracked or broken.
- **Do not** use the autoinjector if the autoinjector has been dropped.
- **Do not** use the autoinjector if the white cap is missing or not securely attached.
- **Do not** use the autoinjector if the expiration date printed on the label has passed.

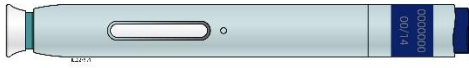
In all cases, use a new autoinjector, and call 1-877-9ENBREL (1-877-936-2735).

**C. Gather all materials needed for your injection.**

Wash your hands thoroughly with soap and water.

On a clean, well-lit work surface, place the:

- New autoinjector
- Alcohol wipes
- Cotton balls or gauze pads
- Adhesive bandages
- Sharps disposal container (see “**Step 4: Finish**”)



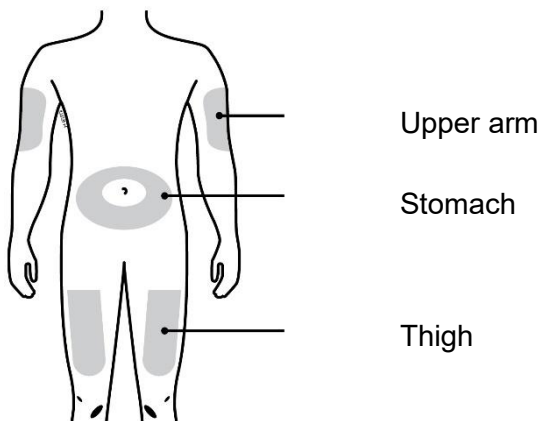
D. Prepare and clean your injection site.

**Only use these injection sites:**

- Thigh
- Stomach (abdomen), except for a **5-centimetre (2 inch)** area around your navel (belly button)
- Outer area of upper arm (only if someone else is giving you the injection)

Clean injection site with an alcohol wipe. Let your skin dry.

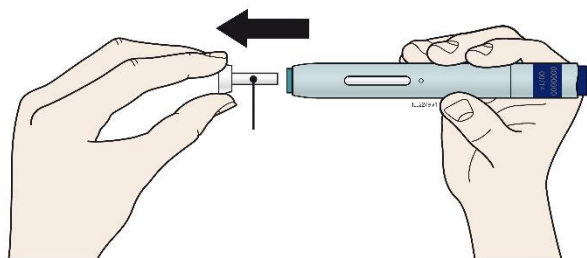
- **Do not** touch this area again before injecting.
- Choose a different site each time you give yourself an injection. If you need to use the same injection site, just make sure it is not the same spot on that site you used for the last time.
  - **Do not** inject into areas where the skin is tender, bruised, red, or hard. Avoid injecting into areas with scars or stretch marks.
- If you have psoriasis, you should avoid injecting directly into raised, thick, red, or scaly skin patch or lesion.



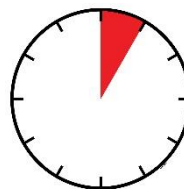
**Step 2: Get ready**

E. Pull white cap straight off, only when you're ready to inject.

**Do not** leave the white cap off for more than **five minutes**. This can dry out the medicine.



5 minutes



### White Cap

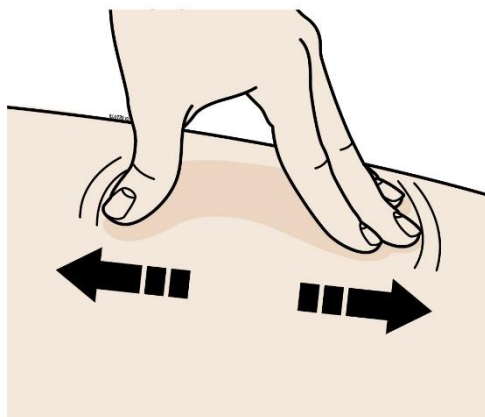
It is normal to see a drop of liquid at the end of the needle or green safety guard.

- **Do not** twist, bend, or wiggle the white cap.
- **Do not** put the white cap back onto the autoinjector.
- **Do not** put fingers into the green safety guard.
- **Do not** remove the white cap from the autoinjector until you are ready to inject.

If you are unable to inject, please contact your health care provider.

**F.** Create a firm surface at the selected injection site (thigh, stomach, or outer areas of the upper arm), by using **either** the Stretch method **or** the Pinch method.

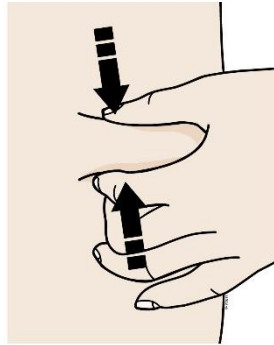
### Stretch method:



Stretch skin firmly by moving your thumb and fingers in opposite directions, creating an area about **5** centimetres (2 inches) wide.

**OR**

**Pinch method:**

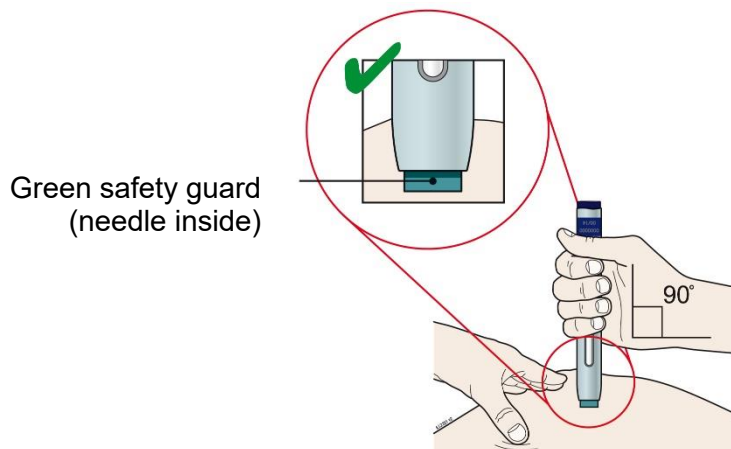


Pinch the skin firmly between your thumb and fingers, creating an area about 5 centimetres (2 inches) wide.

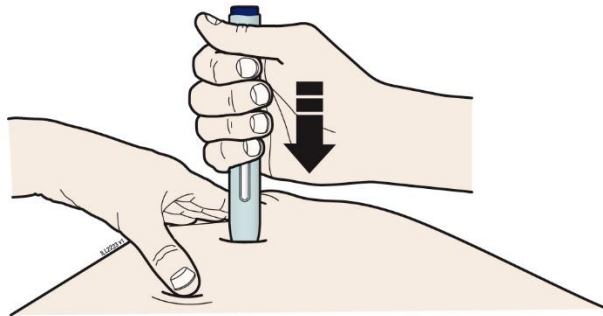
**Important:** Keep skin stretched or pinched while injecting.

**STEP 3: Inject**

**G.** Keep holding the stretched or pinched skin. With the white cap off, **put** the green safety guard on your skin at 90 degrees. The **needle is inside** the green safety guard. Do not push the purple start button yet.



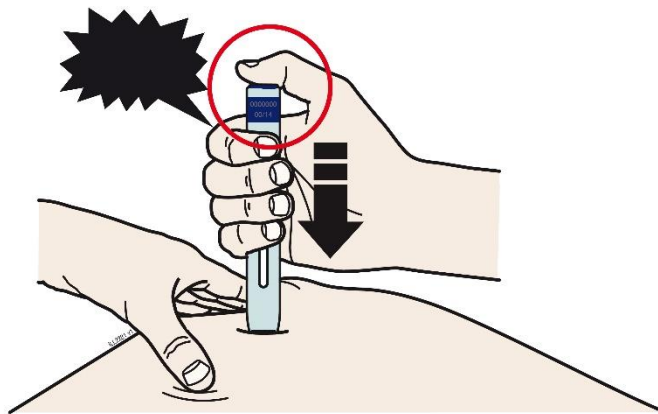
H. Firmly **push** down the autoinjector onto the skin until it stops moving.



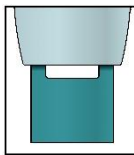
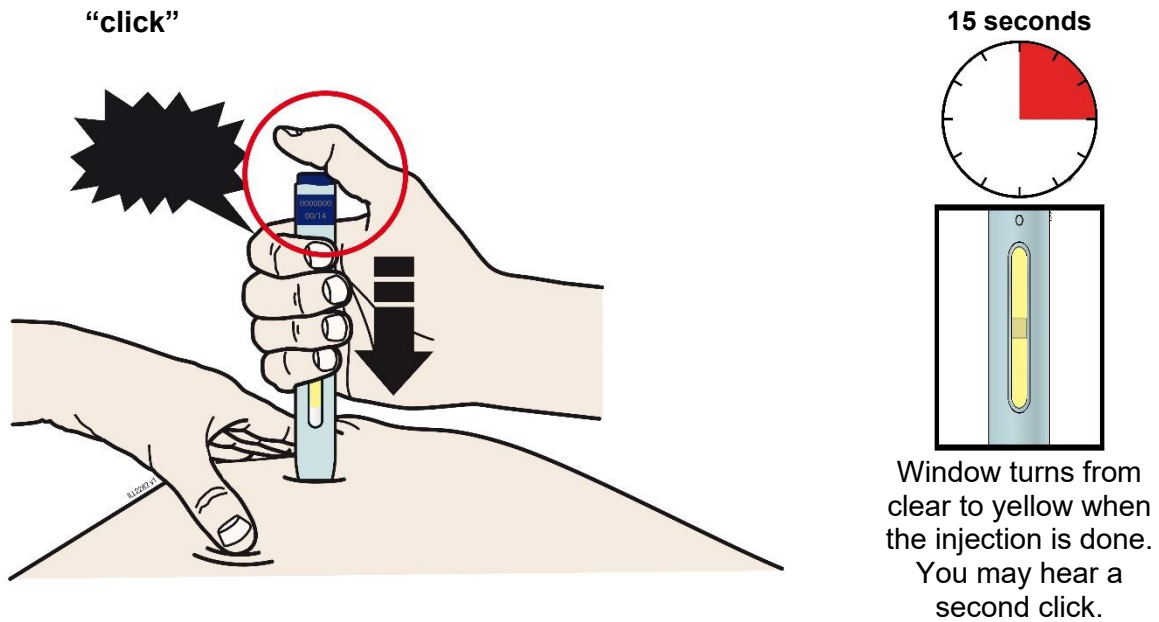
**Important:** You must push all the way down but do not touch the purple start button until you're ready to inject.

I. When you're ready to inject, **press** the purple start button. You will hear a click.

“click”



J. Keep **pushing** the autoinjector down on your skin. Then lift your thumb while still holding the autoinjector on your skin. Your injection could take about **15** seconds to complete.



**Note:** After you remove autoinjector from your skin, the needle will be automatically covered.

**Important:** When you remove the autoinjector, if the window has not turned yellow, or if it looks like the medicine is still injecting, this means you have not received a full dose. Call your healthcare professional immediately.

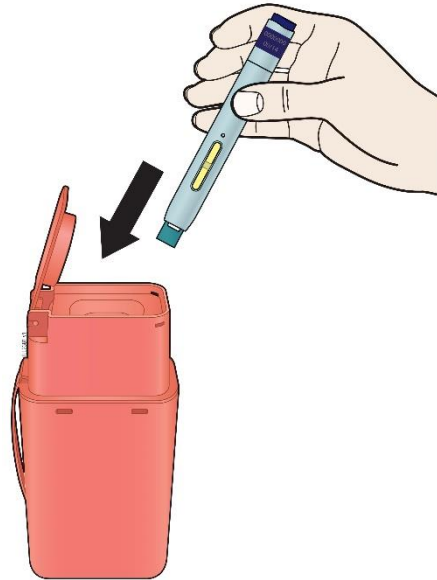
## Step 4: Finish

**K.** Throw away the used autoinjector and white needle cap.

Put the used autoinjector and white needle cap in a sharps disposal container right away after use. **Do not** throw away (dispose of) the SureClick® autoinjector in your household trash.

If you do not have a sharps disposal container, you may use a household container that is:

- made of a heavy-duty plastic,
- can be closed with a tight-fitting, puncture-resistant lid without sharps being able to come out,
- upright and stable during use,
- leak-resistant, and
- properly labeled to warn of hazardous waste inside the container.



When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be local laws about how you should throw away used needles and syringes.

Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

- **Do not** reuse the autoinjector
- **Do not** recap the autoinjector or put fingers into the green safety guard.

**Important:** Always keep the sharps disposal container out of the reach of children.

**L.** Check the injection site.

If there is blood, press a cotton ball or gauze pad on your injection site. Apply an adhesive bandage if needed.

**Do not** rub the injection site.

### **Commonly asked questions**

**What will happen if I press the purple start button before I am ready to do the injection on my skin?**

Even when you press the purple start button, the injection will only happen when the green safety guard is also pushed into the autoinjector.

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**Can I move the autoinjector around on my skin while I am choosing an injection site?**

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It is okay to move the autoinjector around on the injection site as long as you **do not** press the purple start button. However, if you press the purple start button and the green safety guard is pushed into the autoinjector, the injection will begin.

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**Can I release the purple start button after I start my injection?**

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You can release the purple start button, but continue to hold the autoinjector firmly against your skin during the injection.

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**Will the purple start button pop up after I release my thumb?**

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The purple start button may not pop up after you release your thumb if you held your thumb down during the injection. This is okay.

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**What do I do if I didn't hear a second click?**

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If you didn't hear a second click, you can confirm a complete injection by checking that the window has turned yellow.

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**Whom do I contact if I need help with the autoinjector or my injection?**

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If you have any questions about the autoinjector or about your injection, ask your doctor, nurse, or pharmacist, or call 1-877-9ENBREL (1-877-936-2735) for help.

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**What are possible side effects from using ENBREL?**

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

**What are the common side effects?**

In studies comparing ENBREL to placebo (inactive injection), side effects that occurred more frequently in patients treated with ENBREL were:

- Reactions where the injection was given. These reactions are usually mild and include redness, swelling, itching, or bruising. These usually go away within 3 to 5 days. If you have pain, redness or swelling around the injection site that doesn't go away or gets worse, call your doctor.
- Upper respiratory infections (sinus infections)
- Headaches

These are not all the possible side effects you may feel when taking ENBREL. If you experience any side effects not listed here, contact your healthcare professional.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>VERY COMMON</b>			
Injection site reactions		X	
<b>COMMON</b>			
Upper respiratory tract infections (sinus infections)		X	
Headaches	X		
<b>UNCOMMON</b>			
Serious infections		X	X
Tuberculosis		X	
Nerve disorders		X	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

#### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on [Adverse Reaction Reporting \(http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php\)](http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

#### Storage:

The ENBREL single-use prefilled SureClick® autoinjector should be refrigerated at 2°C to 8°C. **Do not freeze. Do not shake.** Refrigerated ENBREL remains stable until the expiration date printed on the syringe.

ENBREL may be transferred to room temperature storage (up to 27°C). Upon removal from the refrigerator, it must be used within 60 days. Protect from direct sunlight, sources of heat, and humidity until ready to use.

Keep out of the reach of children.

**If you want more information about ENBREL:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website](#); the manufacturer's website [www.amgen.ca](http://www.amgen.ca), or by contacting the ENLIVEN<sup>®</sup> Services information support line, toll free at: 1-877-9ENBREL (1-877-936-2735). Additional information can be found at [www.enbrel.ca](http://www.enbrel.ca).

This leaflet was prepared by AMGEN CANADA INC. for IMMUNEX CORPORATION

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