PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

HADLIMA®/HADLIMA® PushTouch®

adalimumab injection

40 mg/0.8 mL subcutaneous injection (Pre-filled syringe/Auto-injector)

40 mg/0.4 mL subcutaneous injection (Pre-filled syringe/Auto-injector)

Read this carefully before you/your child start taking **HADLIMA® (or HADLIMA® PushTouch®)** and each time you/your child get a refill. This leaflet is a summary and will not tell you/your child everything about this drug. Talk to your/your child's healthcare professional about your/your child's medical condition and treatment and ask if there is any new information about **HADLIMA® (or HADLIMA® PushTouch®)**.

HADLIMA® (or HADLIMA® PushTouch®) is a biosimilar biologic drug (biosimilar) to the reference biologic drug Humira®. A biosimilar is authorized based on its similarity to a reference biologic drug that was already authorized for sale.

Serious Warnings and Precautions

Before starting, during and after treatment with **HADLIMA® (or HADLIMA® PushTouch®)**, you/your child should be checked for active or inactive tuberculosis infection with a tuberculin skin test. Any medicine can have side effects. Like all medicines that affect your/your child's immune system, HADLIMA® (or HADLIMA® PushTouch®) can cause serious side effects. The possible serious side effects include:

- **Allergic reactions**: If you/your child develop a severe rash, swollen face or difficulty breathing while taking HADLIMA® (or HADLIMA® PushTouch®), call your/your child's doctor right away.
- **Hepatosplenic T-cell lymphoma**: Very rare reports of hepatosplenic T-cell lymphoma (HSTCL), a rare serious lymphoma that is often fatal, have been identified in patients treated with adalimumab injection. Most patients had also been treated with other medications for Crohn's disease and the majority were in adolescent and young adult males. The link between HSTCL and adalimumab injection is not clear.
- **Other cancers:** There have been very rare cases of certain kinds of cancer in patients taking adalimumab injection or other TNF-blockers. Some patients receiving adalimumab injection have developed types of cancer called non-melanoma skin cancer. Tell your/your child's doctor if you/your child 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/your child take HADLIMA®, HADLIMA® PushTouch®, or other TNF-blockers, your/your child's risk may increase. There have been cases of lymphoma and other cancers, including unusual types, in children, adolescents and young adults taking TNF-blocking agents, including adalimumab injection, which sometimes resulted in death. For children and adults taking TNF-blocker medicines, the chances of developing lymphoma or other cancers may increase.

- **Lupus-like symptoms:** Some patients have developed lupus-like symptoms that got better after their treatment was stopped. If you/your child have chest pains that do not go away, shortness of breath, joint pain or a rash on your/your child's cheeks or arms that gets worse in the sun, call your/your child's doctor right away. Your/your child's doctor may decide to stop your/your child's treatment.
- **Nervous system diseases:** There have been rare cases of disorders that affect the nervous system of people taking adalimumab injection or other TNF-blockers. Signs that you/your child could be experiencing a problem affecting your/your child's nervous system include: numbness or tingling, problems with your/your child's vision, weakness in your/your child's legs, and dizziness.
- **Serious infections**: There have been rare cases where patients taking adalimumab injection 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, and bacterial infections that have spread throughout the body (sepsis). Infection causes include tuberculosis, legionellosis (a serious form of bacterial pneumonia), listeriosis (an infection that usually develops after eating food contaminated by bacteria called listeria), 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, such as anemia (low red blood cells) or low platelets. If you/your child develop symptoms such as persistent fever, bleeding, or bruising, you should contact your/your child's doctor right away

What is HADLIMA® (or HADLIMA® PushTouch®) used for?

HADLIMA® (or HADLIMA® PushTouch®) is a medicine that is used in:

- adults with rheumatoid arthritis, which is an inflammatory disease of the joints.
- adults with psoriatic arthritis, which is an inflammatory disease of the joints and skin.
- adults with ankylosing spondylitis, which is a form of arthritis.
- adults with Crohn's disease, which is an inflammatory disease of the digestive tract.
- pediatrics with polyarticular juvenile idiopathic arthritis who are 2 years of age and older and require a full 40 mg dose based on body weight.
- adults with ulcerative colitis, which is an inflammatory disease of the bowel (colon).
- adults or adolescents (12 to 17 years of age, weighing ≥ 30 kg) with moderate to severe hidradenitis suppurativa (HS) who have not responded to antibiotics. HS is a painful, progressive, chronic inflammatory skin disease that causes nodules, abscesses, sinus tracts and fistulas under the breasts, underarms, buttocks and groin.
- adults with psoriasis, which is an inflammatory disease of the skin. The doctor prescribed HADLIMA® (or HADLIMA® PushTouch®) to reduce the signs and symptoms of your plaque psoriasis.
- adults with uveitis, which is an inflammatory disease of the eye.
- children (weighing ≥ 30 kg) with chronic non-infectious uveitis from 2 years of age with inflammation affecting the front of the eye.

- children 5 to 17 years of age, weighing ≥ 40 kg who have ulcerative colitis

Patients with rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, hidradenitis suppurativa, psoriasis, or uveitis may be given other medicines for their disease before they are given HADLIMA® (or HADLIMA® PushTouch®). If you have ulcerative colitis or Crohn's disease, you will first be given other medicines. If you do not respond well enough to these medicines, you will be given HADLIMA® (or HADLIMA® PushTouch®) to reduce the signs and symptoms of your disease.

How does HADLIMA® (or HADLIMA® PushTouch®) work?

HADLIMA® (or HADLIMA® PushTouch®) is a fully human monoclonal antibody produced by cultured cells. Monoclonal antibodies are proteins that recognize and bind to other unique proteins. HADLIMA® (or HADLIMA® PushTouch®) 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, ulcerative colitis, hidradenitis suppurativa or psoriasis have too much of TNF-alpha in their bodies. The extra TNF-alpha in your/your child's body can attack normal healthy body tissues and cause inflammation, especially in the tissues of your /your child's bones, cartilage, joints, digestive tract and skin. By binding to TNF-alpha, HADLIMA® (or HADLIMA® PushTouch®) decreases the inflammation process of these diseases.

HADLIMA® (or HADLIMA® PushTouch®) helps reduce the signs and symptoms of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis and psoriatic arthritis (such as pain and swollen joints), may help improve your/your child's ability to perform daily activities (such as getting dressed, walking and climbing stairs), and may help prevent further damage to your/your child's bones and joints. In addition, HADLIMA® (or HADLIMA® PushTouch®) helps reduce the signs and symptoms of ankylosing spondylitis (back pain and morning stiffness), and adult Crohn's disease or adult and pediatric ulcerative colitis (abdominal pain and diarrhea). HADLIMA® (or HADLIMA® PushTouch®) may help improve the work productivity and activity impairment in caregivers of children with ulcerative colitis.

HADLIMA® (or HADLIMA® PushTouch®) is also used to treat inflammatory lesions (nodules and abscesses) in adults and adolescents (12 to 17 years of age, weighing ≥ 30 kg) with hidradenitis suppurativa.

HADLIMA® (or HADLIMA® PushTouch®) also helps reduce the signs and symptoms of psoriasis (such as pain, itching and scaly patches on skin).

HADLIMA® (or HADLIMA® PushTouch®) helps control uveitis by reducing the risk of inflammation and loss of vision in adult and pediatric patients.

HADLIMA® (or HADLIMA® PushTouch®), however, can also lower your/your child's body's ability to fight infections. Taking HADLIMA® (or HADLIMA® PushTouch®) can make you/your child more prone to getting infections or make any infection you/your child have worse.

What are the ingredients in HADLIMA® (or HADLIMA® PushTouch®)?

Medicinal ingredients (50 mg/mL and 100 mg/mL): adalimumab

Non-medicinal ingredients (50 mg/mL): citric acid monohydrate, sodium citrate dihydrate, L-histidine, L-histidine hydrochloride monohydrate, sorbitol, polysorbate 20, water for injection

Non-medicinal ingredients (100 mg/mL): L-histidine, L-histidine hydrochloride monohydrate, mannitol, polysorbate 20, sodium phosphate monobasic monohydrate, sodium phosphate dibasic heptahydrate, sodium succinate dibasic, succinic acid and water for injections

HADLIMA® (or HADLIMA® PushTouch®) comes in the following dosage forms:

- Single-use, 1 mL auto-injector containing 40 mg adalimumab dissolved in 0.8 mL sterile solution (50 mg/mL) or in 0.4 mL sterile solution (100 mg/mL)
- Single-use, 1 mL pre-filled glass syringe containing 40 mg adalimumab dissolved in 0.8 mL sterile solution (50 mg/mL) or in 0.4 mL sterile solution (100 mg/mL)
- All packaging components are latex-free.

Do not use HADLIMA® (or HADLIMA® PushTouch®) if:

You/your child should not take HADLIMA® (or HADLIMA® PushTouch®) if you/your child have:

- an allergy to any of the ingredients in HADLIMA® (or HADLIMA® PushTouch®) (see **What are the ingredients in HADLIMA® (or HADLIMA® PushTouch®)?** section).
- a serious infection such as tuberculosis, infections caused by bacteria or fungi, and bacterial infections that have spread throughout the body (sepsis).
- moderate to severe heart failure (NYHA class III/IV).

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

- you have or have had 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 HADLIMA® (or HADLIMA® PushTouch®). If you are unsure, ask your doctor.
- you have a history of infections that keep coming back or other conditions that might increase your risk of infections, including fungal infections.
- 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.
- you resided or travelled 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 HADLIMA® (or HADLIMA® PushTouch®) these may become active or more severe. If you don’t know if you have lived in or travelled to an area where these infections are common, ask your doctor.
- you have ever had liver injury or hepatitis B virus infection or are at risk of developing this infection. Signs and symptoms include the following: yellowing of the skin or eyes (jaundice), feeling of sickness, tiredness, loss of appetite, joint pain, fever, dark brown-colored urine, vomiting, 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 HADLIMA® (or HADLIMA® PushTouch®).
- you experience any numbness or tingling or have ever had a disease that affects your nervous system like multiple sclerosis or Guillain-Barré syndrome.
- you have or have had heart failure.
- you are scheduled to have major surgery or dental procedures.
- you are scheduled to be vaccinated for anything. It is recommended that pediatric patients, if possible, be brought up to date with all immunizations according to current guidelines before starting HADLIMA® (or HADLIMA® PushTouch®).
- you are taking other medicines for your rheumatoid arthritis, polyarticular juvenile idiopathic 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 acceptable that you take them while you are taking HADLIMA® (or HADLIMA® PushTouch®). 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 HADLIMA® (or HADLIMA® PushTouch®).
- you are taking any over-the-counter drugs, herbal medicines and vitamin and mineral supplements.
- you are pregnant or could become pregnant
- you are breast-feeding or plan to breast-feed.

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

Other warnings you should know about:

If you received HADLIMA® (or HADLIMA® PushTouch®) while pregnant, your baby may be at higher risk for getting an infection for up to approximately five months after the last dose of HADLIMA® (or HADLIMA® PushTouch®) received during pregnancy. It is important that you tell your baby's doctors and other healthcare professionals about your HADLIMA® (or HADLIMA® PushTouch®) use during pregnancy so they can decide when your baby should receive any vaccine.

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 HADLIMA® (or HADLIMA® PushTouch®):

You should not take HADLIMA® (or HADLIMA® PushTouch®) with:
- other TNF-blockers such as Enbrel®, Remicade®, Cimzia®, or Simponi®
- abatacept (Orencia®)
- anakinra (Kineret®)

If you have questions, ask your doctor.

How to take HADLIMA® (or HADLIMA® PushTouch®):

HADLIMA® (or HADLIMA® PushTouch®) is administered by injection under the skin (by subcutaneous injection).

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.

Patients, aged 2 years and older, with polyarticular juvenile idiopathic arthritis:

- Weighing 30 kg or more: the recommended dose of HADLIMA® (or HADLIMA® PushTouch®) is 40 mg every other week.
- The auto-injector and pre-filled syringe are not designed to deliver a portion of the full 40 mg dose and must not be used in pediatric patients who require < 40 mg dose.

Adults with Crohn's Disease or Ulcerative Colitis:

- The recommended induction dose is 160 mg at Week 0, followed by 80 mg at Week 2 administered by subcutaneous injection. The first dose of 160 mg can be given in one day (four 40 mg injections) or split over two consecutive days (two 40 mg injections each day). The second dose of 80 mg at Week 2 is given as two 40 mg injections in one day. The recommended maintenance dose regimen is 40 mg every other week beginning at Week 4.

Adults with Hidradenitis Suppurativa:

- The recommended initial dose is 160 mg, followed by 80 mg two weeks later administered by subcutaneous injection. The first dose of 160 mg at Week 0 can be given in one day (four 40 mg injections) or split over two consecutive days (two 40 mg injections each day). The second dose of 80 mg at Week 2 is given as two 40 mg injections in one day.
- The recommended maintenance dose regimen is 40 mg every week beginning four weeks after the initial dose.

Adults with Psoriasis or Uveitis:

- 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 administered by subcutaneous injection. The first dose of 80 mg can be given as two 40 mg injections.

Adolescents, 12 to 17 years of age weighing ≥ 30 kg, with Hidradenitis Suppurativa:

- The recommended initial dose is 80 mg administered by subcutaneous injection, followed by 40 mg every other week starting one week later. Depending on your/your child's response, the doctor may increase the dose to 40 mg every week.

Children, from 2 years of age with Uveitis:

- weighing 30 kg or more: the usual dose of HADLIMA® (or HADLIMA® PushTouch®) is 40 mg every other week with methotrexate. Your child's doctor may also prescribe an initial dose of 80 mg to be administered one week prior to the start of the usual dose.
- The auto-injector and pre-filled syringe are not designed to deliver a portion of the full 40 mg dose and must not be used in pediatric patients who require < 40 mg dose.

Children, from 5 to 17 years of age with Ulcerative Colitis:

- weighing 40 kg or more: the induction dose of HADLIMA® (or HADLIMA® PushTouch®) is 160 mg at Week 0, followed by 80 mg at Week 2. The recommended HADLIMA® (or HADLIMA® PushTouch®) maintenance dose regimen is 80 mg every other week or 40 mg every week beginning at Week 4.

Overdose:

If you/your child accidentally inject HADLIMA® (or HADLIMA® PushTouch®) more frequently than instructed, contact your/your child's doctor or local poison control centre right away.

If you/your child think you/your child have taken too much HADLIMA® (or HADLIMA® PushTouch®), contact your/your child's healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

If you/your child forget to give yourself/your child an injection, you/your child should inject the missed dose of HADLIMA® (or HADLIMA® PushTouch®) as soon as you/your child remember. Then administer the next dose as you/your child would have on the originally scheduled date.

What are possible side effects from using HADLIMA® (or HADLIMA® PushTouch®)?

These are not all the possible side effects you/your child may feel when taking HADLIMA® (or HADLIMA® PushTouch®). If you experience any side effects not listed here, contact your healthcare professional.

Like all medicines, HADLIMA® (or HADLIMA® PushTouch®) can cause side effects. Most side effects are mild to moderate. However, some may be serious and require treatment.

You may feel less injection site pain when using HADLIMA® (or HADLIMA® PushTouch®) 40 mg/0.4 mL compared to HADLIMA® (or HADLIMA® PushTouch®) 40 mg/0.8 mL.

Tell your doctor immediately if you/your child 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 could mean a blood problem such as low red blood cells (anemia) or low platelets

Tell the doctor as soon as possible if you notice 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
- arm or leg pain, swelling or redness
- bump or open sore that does not heal
- red scaly patches or raised bumps that are filled with pus (this could be new or worsening hidradenitis suppurativa, new or worsening psoriasis or a skin infection)
- alopecia (loss of hair)
- changes in the colour of the skin
- changes in the colour of your urine (dark or red)
- worsening of the appearance of a scar
- night sweats
- weight loss
- pain in the abdomen or chest

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**	
VERY COMMON			
Injection site reaction		✓	
COMMON			
Cough and cold symptoms, including sore throat		✓	
Headache	✓		
Rash		✓	
Nausea		✓	
Pneumonia		✓	✓
Fever		✓	
Abdominal pain	✓		
UNCOMMON			
Tuberculosis		✓	✓
Other serious infections		✓	✓
Nerve disorder		✓	✓
Appendicitis		✓	✓
Blood clots: abdominal pain, chest pain, leg or arm pain with redness and swelling		✓	✓
Bladder infection (painful urination)		✓	✓
Hepatitis (jaundice [yellow skin, dark urine], abdominal pain, tiredness]		✓	✓

If you/your child 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.

General Advice About Prescription Medicines

Talk to your doctor or other healthcare provider if you/your child have any questions about this medicine or your condition. Medicines are sometimes prescribed for purposes other than those listed in a **PATIENT MEDICATION INFORMATION** leaflet. If you/your child have any concerns about this medicine, ask the doctor. The doctor or pharmacist can give you/your child 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 1-844-820-5468.

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 (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) 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:

Store between 2 and 8ºC (in a refrigerator) in the original carton until ready to use. **DO NOT FREEZE HADLIMA® and HADLIMA® PushTouch®.** Protect from light. Refrigerated HADLIMA® and HADLIMA® PushTouch® remain stable until the expiration date printed on the auto-injector or pre-filled syringe. Do not use beyond the expiration date.

When needed, for example when you are travelling, a HADLIMA® PushTouch® or HADLIMA® 40 mg/0.8 mL can be stored at room temperature (up to 25ºC/77ºF) for a single maximum period of 28 days. When needed, for example when you are travelling, a HADLIMA® PushTouch® or HADLIMA® 40 mg/0.4 mL can be stored at room temperature (up to 25ºC/77ºF) for a single maximum period of 31 days.

Once taken out of the refrigerator for room temperature storage, a HADLIMA® PushTouch® or HADLIMA® 40 mg/0.8 mL must be used within 28 days, even if it is put back in the refrigerator. If not used within 28 days, the HADLIMA® PushTouch® or HADLIMA® 40 mg/0.8 mL must be discarded. You should record the date when the HADLIMA® PushTouch® or HADLIMA® 40 mg/0.8 mL is first removed from the refrigerator. Once taken out of the refrigerator for room temperature storage, a HADLIMA® PushTouch® or HADLIMA® 40 mg/0.4 mL must be used within 31 days, even if it is put back in the refrigerator. If not used within 31 days, the HADLIMA® PushTouch® or HADLIMA® 40 mg/0.4 mL must be discarded. You should record the date when the HADLIMA® PushTouch® or HADLIMA® 40 mg/0.4 mL is first removed from the refrigerator.

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

If you want more information about HADLIMA® (or HADLIMA® PushTouch®):

- Talk to your healthcare professional

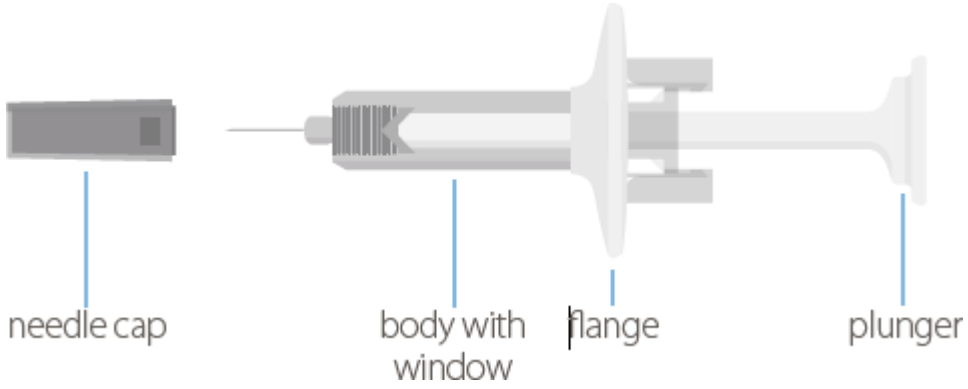
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (https://www.canada.ca/en/health-canada.html); the Canadian distributor (Organon Canada Inc.) website www.organon.ca, or by calling 1-844-820-5468.

This leaflet was prepared by SAMSUNG BIOEPIS.

Last Revised MON DD, YYYY

Instructions for Use:
The following instructions are for preparing and giving a dose of HADLIMA® using a single-use pre-filled syringe 40 mg/0.8 mL, 40 mg/0.4 mL (or HADLIMA® PushTouch® using a single-use auto-injector 40 mg/0.8 mL, 40 mg/0.4 mL).

Your pre-filled syringe (40 mg/0.8 mL):



Step 1: Gather supplies

- Place your syringe and unopened alcohol swabs on a clean, dry surface.
- Remember to wash your hands!
- Don't remove the cap just yet!

Step 2: Wait 15-30 minutes

- Wait 15-30 minutes for your syringe to warm-up to room temperature, which helps reduce your pain during injection.
- Don't remove the cap just yet!

Step 3: Inspect medicine & date

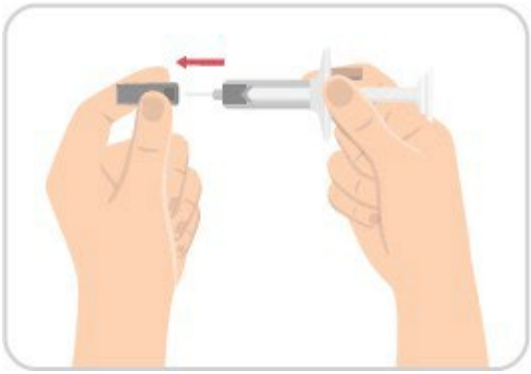
- Make sure your medicine is clear to opalescent, free of particles, and colorless to pale brown and hasn't expired.
- You may see one or more bubbles, and that's okay. There is no need to remove it.
- Don't remove the cap just yet!

Step 4: Choose site & clean skin

- Choose an injection site on your body. Your abdomen or thighs are best.
- Wipe your skin at the injection site with an alcohol swab.
- Avoid skin that's sore, bruised, scarred, scaly or has red patches.

Step 5: Pull off needle cap

- Carefully pull off the needle cap.



Step 6: Pinch skin & insert needle

- Gently pinch your skin and insert the needle all the way.

Step 7: Push plunger all the way

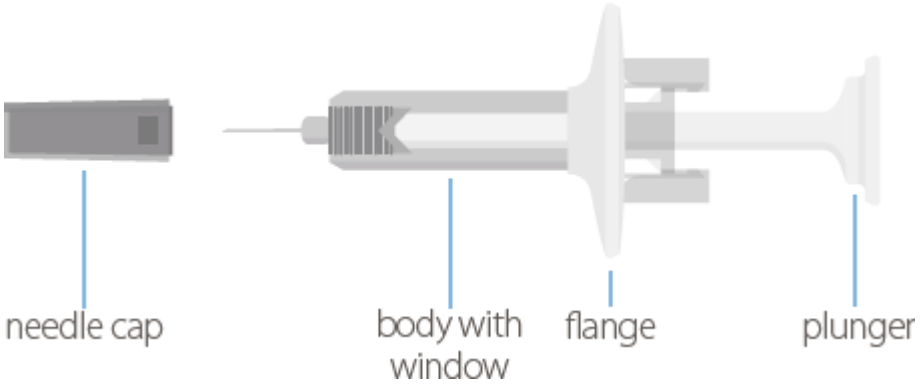
- Hold the syringe steady and press the plunger all the way down.
- Then lift your thumb to let the needle retract into the body of the syringe.

Step 8: Remove syringe & dispose

- Pull the syringe away from your skin.
- Confirm that the needle has retracted and discard the syringe in a sharps container.


You got your dose if...
✓ Needle retracted
✓ No medicine leaked out
(a small drop is okay)
SHARPS
CONTAINER

Your pre-filled syringe (40 mg/0.4 mL):



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- Remember to wash your hands!
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Step 2: Wait 15-30 minutes

- Wait 15-30 minutes for your syringe to warm-up to room temperature, which helps reduce your pain during injection.
- Don't remove the cap just yet!

Step 3: Inspect medicine & date

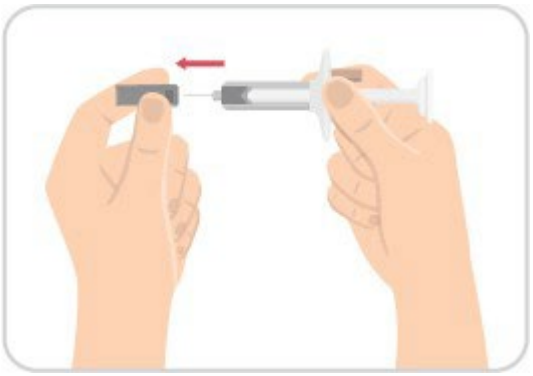
- Make sure your medicine is clear to opalescent, free of particles, and colorless to pale brown and hasn't expired.
- You may see one or more bubbles, and that's okay. There is no need to remove it.
- Don't remove the cap just yet!

Step 4: Choose site & clean skin

- Choose an injection site on your body. Your abdomen or thighs are best.
- Wipe your skin at the injection site with an alcohol swab.
- Avoid skin that's sore, bruised, scarred, scaly or has red patches.

Step 5: Pull off needle cap

- Carefully pull off the needle cap.



Step 6: Pinch skin & insert needle

- Gently pinch your skin and insert the needle all the way.

Step 7: Push plunger all the way

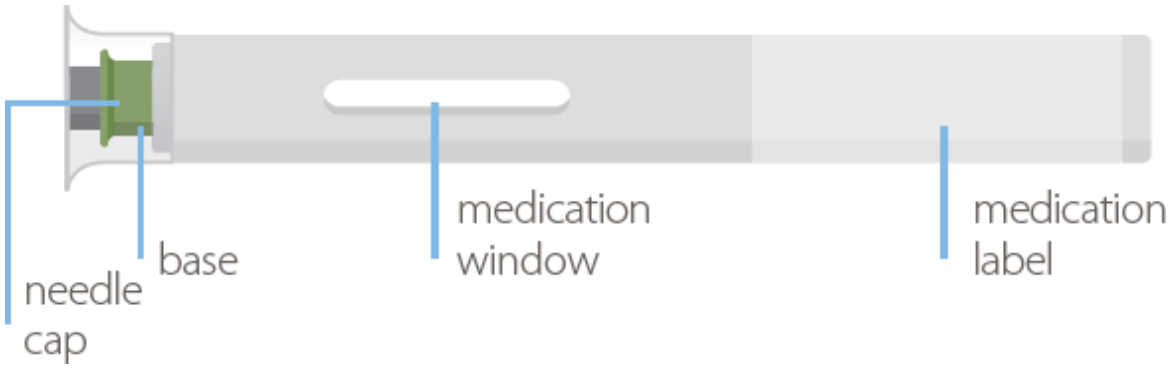
- Hold the syringe steady and press the plunger all the way down.
- Then lift your thumb to let the needle retract into the body of the syringe.

Step 8: Remove syringe & dispose

- Pull the syringe away from your skin.
- Confirm that the needle has retracted and discard the syringe in a sharps container.

Your single-dose auto-injector (40 mg/0.8 mL):

- There is no button on your auto-injector!
- The needle is hidden below the green base. When you push the device firmly onto your skin, the injection will start automatically.



Step 1: Gather supplies

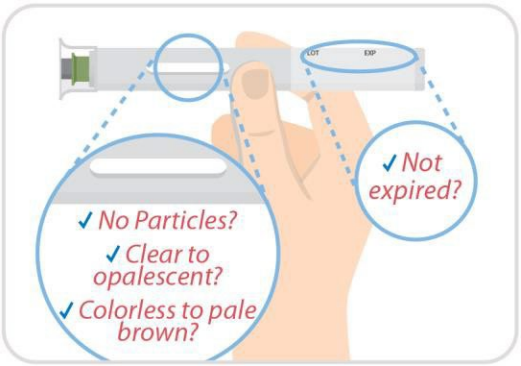
- Place your auto-injector and unopened alcohol swabs on a clean, dry surface.
- Remember to wash your hands!
- Don't remove the cap just yet!

Step 2: Wait 15-30 minutes

- Wait 15-30 minutes for your auto-injector to warm-up to room temperature, which helps to reduce pain during injection.
- Don't remove the cap just yet!

Step 3: Inspect medicine & date

- Always make sure your medicine is clear to opalescent, free of particles, and colorless to pale brown and hasn't expired.
- You may see an air bubble, and that's okay.
- Don't remove the cap just yet!

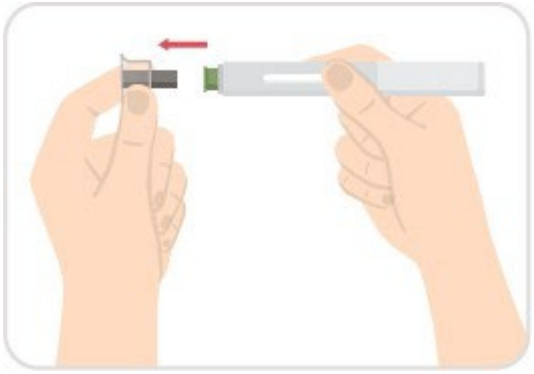


Step 4: Choose site & clean skin

- Choose an injection site on your body.
- Your abdomen or thighs are best.
- Wipe the injection site with an alcohol swab.
- Avoid skin that's sore, bruised, scarred, scaly, or has red patches.

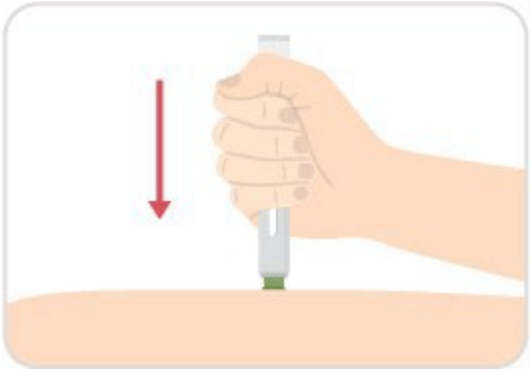
Step 5: Pull off the clear needle cap

- Carefully pull off the clear needle cap with a metal center from the auto-injector.



Step 6: Place green base, press down, and hold

- Place the green base straight on your skin, and push the entire device down firmly to start the injection.
- When you push down, the injection starts.
- You may hear a first click.



Step 7: Continue to hold

- Hold the auto-injector against your skin until the yellow indicator fills the medication window and stops moving.
- Several seconds later you may hear a second click.

Step 8: Confirm completion & dispose auto-injector

- Confirm that the entire medication window is yellow.
- Discard your auto-injector in a sharps container.

Your single-dose auto-injector (40 mg/0.4 mL):

- There is no button on your auto-injector!
- The needle is hidden below the green base. When you push the device firmly onto your skin, the injection will start automatically.

Step 1: Gather supplies

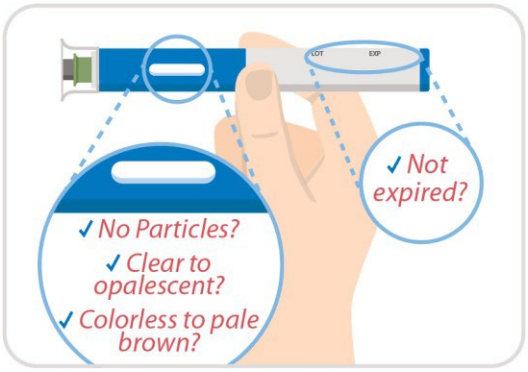
- Place your auto-injector and unopened alcohol swabs on a clean, dry surface.
- Remember to wash your hands!
- Don't remove the cap just yet!

Step 2: Wait 15-30 minutes

- Wait 15-30 minutes for your auto-injector to warm-up to room temperature, which helps to reduce pain during injection.
- Don't remove the cap just yet!

Step 3: Inspect medicine & date

- Always make sure your medicine is clear to opalescent, free of particles, and colorless to pale brown and hasn't expired.
- You may see one or more bubbles, and that's okay.
- Don't remove the cap just yet!



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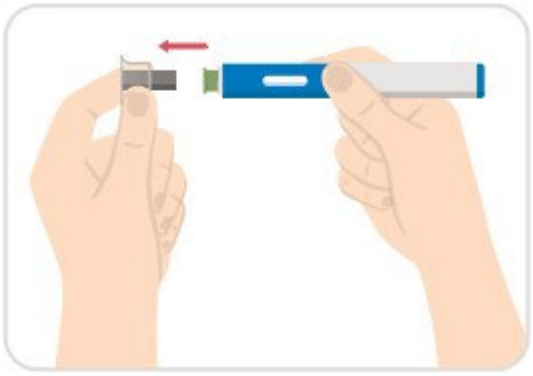

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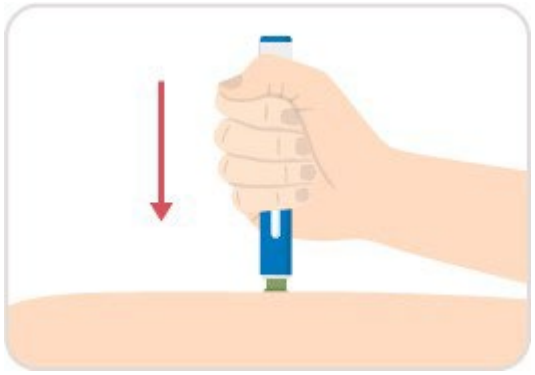

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This leaflet was prepared by Samsung Bioepis Co., Ltd.

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