

## **PATIENT MEDICATION INFORMATION**

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

**PrAIMOVIG®**

**(erenumab injection)**

**(AIM-oh-vig)**

#### **Single-Dose Pre-filled SureClick® Autoinjector**

Read this carefully before you start taking **Aimovig®** 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 **Aimovig**.

#### **What is Aimovig used for?**

- Aimovig is a medicine used to prevent migraines in adults who have at least 4 migraine days per month.

#### **How does Aimovig work?**

Aimovig works by blocking the activity of a molecule called calcitonin gene-related peptide or CGRP. CGRP has been linked to migraine.

#### **What are the ingredients in Aimovig?**

Medicinal ingredient: erenumab.

Non-medicinal ingredients: acetate, polysorbate 80, sodium hydroxide, sucrose, water for injection.

#### **Aimovig comes in the following dosage forms:**

- Solution for injection in single-dose pre-filled syringe\* (70 mg/mL or 140 mg/mL).
- Solution for injection in single-dose autoinjector (SureClick®) (70 mg/mL or 140 mg/mL).

\*Pre-filled syringes are not available in Canada.

#### **Do not use Aimovig if:**

You should not take Aimovig if you have ever had an allergic reaction to:

- Aimovig or any of the ingredients in Aimovig.
- Rubber or latex. The white or orange cap on the autoinjector contains a needle cover that is composed of natural rubber, which is made from latex.

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

**Tell your healthcare professional or get emergency medical help immediately:**

- If you get any symptoms of a serious allergic reaction, such as rash or swelling usually of the face, mouth, tongue, or throat; or difficulty breathing. Serious allergic reactions can happen within minutes, but some may happen more than one week after using Aimovig.
- If you get severe constipation or constipation associated with symptoms such as severe or constant belly pain, vomiting, swelling of belly, hard and dry stool, tear and bleeding around the anus or bloating. Constipation with serious complications can happen after receiving Aimovig. In some cases, people have been hospitalized or needed surgery.

### **Children and adolescents**

Do not give Aimovig to children under 18 years of age since the use of Aimovig has not been studied in children under 18 years of age.

### **Pregnancy and Breast-feeding**

Aimovig has not been studied in pregnant women. It is not known if Aimovig will harm your unborn baby. Talk to your healthcare professional if you are trying to get pregnant or think you may be pregnant before taking Aimovig. Your healthcare professional will discuss with you the potential risks of taking Aimovig during pregnancy.

It is not known if Aimovig passes through breast milk. It is important to tell your healthcare professional if you are breastfeeding or plan to breastfeed. Your healthcare professional will then help you decide if you should stop breast-feeding, or stop taking Aimovig.

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

### **How to take Aimovig:**

See the detailed “Instructions for preparing and giving an injection of Aimovig” below about the right way to prepare and give your Aimovig injections at home.

Always use Aimovig exactly as your healthcare professional has told you. Check with your healthcare professional if you are not sure.

Do not exceed the recommended dose prescribed by your healthcare professional.

Aimovig comes in a pre-filled syringe or autoinjector (SureClick). Your healthcare professional will prescribe the type that is best for you. Each pre-filled syringe or autoinjector is for a single injection.

Each syringe or each autoinjector contains 70 mg or 140 mg Aimovig. Make sure that you inject the entire contents of the syringe or the autoinjector.

Your healthcare professional will give you or your caregiver training in the right way to prepare and inject. Do not try to inject Aimovig until you or your caregiver have been shown the right way by your healthcare professional.

Before injection, let Aimovig sit at room temperature (up to 25°C) for at least 30 minutes. This will make the injection more comfortable.

Aimovig is given as an injection under the skin (subcutaneous or SC). You or your caregiver can administer the injection into your abdomen, thigh or (only if someone else is giving you the injection) into the outer area of the upper arm.

Do not give an injection in an area of the skin that is tender, bruised, red or hard. Also do not use the same spot as used for a previous injection.

#### **Usual dose:**

The usual dose for Aimovig is 70 mg once a month. Your healthcare professional might also decide you need 140 mg once a month. Take Aimovig exactly as instructed by your healthcare professional.

Continue taking Aimovig once a month for as long as your healthcare professional tells you.

Do not stop using Aimovig, without talking to your healthcare professional first. Your symptoms may return if you stop the treatment.

#### **70 mg/mL solution for injection**

If your healthcare professional prescribed the 70 mg dose, you must get one injection (subcutaneous) in your abdomen, thigh, or upper arm.

#### **140 mg/mL solution for injection**

If your healthcare professional prescribed the 140 mg dose, you must get one injection (subcutaneous) in your abdomen, thigh, or upper arm.

#### **Overdose:**

If you think you, or a person you are caring for, have taken too much Aimovig, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

#### **Missed Dose:**

If you forget to take your Aimovig dose, take it as soon as you can after the missed dose. Then, contact your healthcare professional who will tell you when you should schedule your next doses, and follow that schedule exactly as your healthcare professional has told you.

#### **What are possible side effects from using Aimovig?**

As with all medicines, patients treated with Aimovig may experience side effects, although not everybody gets them.

Possible side effects include the following listed below. Most of these side effects are mild to moderate. If these side effects become severe, please tell your healthcare professional.

- Signs and symptoms of pain, redness, swelling at the injection site (injection site reactions)
- Constipation
- Muscle spasm

- Itching
- Allergic reactions such as rash or swelling or sometimes, difficulty breathing. This can happen within hours to days after using Aimovig. Call your healthcare professional or get emergency medical help right away if you have a severe allergic reaction.
- Hair loss
- Mouth/lip sores

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

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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.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 healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### **Storage:**

Do not use this medicine after the expiry date, which is stated on the carton.

Store in a refrigerator at 2°C to 8°C, in the original carton.

After Aimovig is removed from the refrigerator, it should be kept at controlled room temperature (up to 25°C) in the original carton and must be used within 7 days. Do not put Aimovig back in the refrigerator once they have reached room temperature.

Protect from light. Do not freeze. Do not shake.

Keep out of reach and sight of children.

### **If you want more information about Aimovig:**

- 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/services/drugs-health-products/drug->

[products/drug-product-database.html](https://www.novartis.ca/products/drug-product-database.html); the manufacturer's website [www.novartis.ca](http://www.novartis.ca), or by calling 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

Last Revised: October 27, 2022

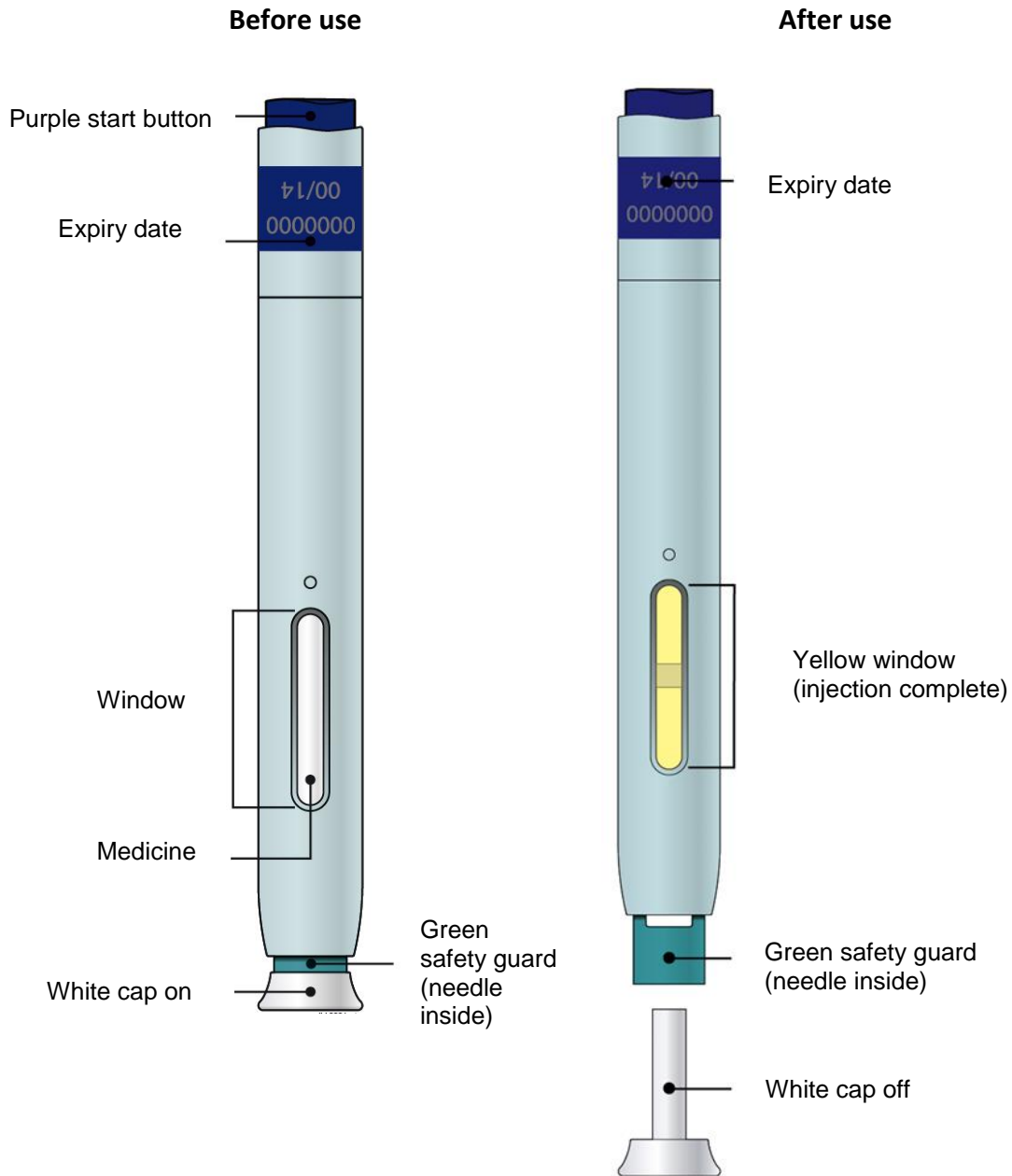
Novartis Version: April 04, 2023

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**Instructions for preparing and giving an injection of Aimovig 70 mg/mL:**

**Aimovig Single-Dose Pre-filled SureClick Autoinjector 70 mg/mL:**

**Guide to parts**



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

## Important

**Before you use an Aimovig SureClick autoinjector, read this important information:**

### Storing your Aimovig SureClick autoinjector

- Keep the autoinjector out of the sight and reach of children.
- Keep the autoinjector in the original carton to protect from light or physical damage.
- The autoinjector should be kept in the refrigerator at 2°C to 8°C.
- Throw away Aimovig that has been left at room temperature (up to 25°C) for more than 7 days.
- **Do not** store the autoinjector in extreme heat or cold. For example, avoid storing in your car.
- **Do not** freeze.

### Using your Aimovig SureClick autoinjector

- **Do not** try to inject Aimovig before receiving training from your healthcare professional.
- **Do not** use the autoinjector after the expiry date stated on the label.
- **Do not** shake the autoinjector.
- **Do not** remove the white cap from the autoinjector until you are ready to inject.
- **Do not** freeze or use the autoinjector if it has been frozen.
- **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 your healthcare professional.

This product contains natural rubber latex within the white cap. The product may cause allergic responses in individuals who are sensitized to latex. Tell your healthcare professional if you are allergic to latex.

For more information or help contact your healthcare professional.

### Step 1: Prepare

**Read this before you inject.**

**Check your prescription.**

Your healthcare professional has prescribed a 70 mg.

For a 70 mg dose, inject one autoinjector of 70 mg/mL.

To avoid discomfort at the site of injection, leave the autoinjector at room temperature for at least 30 minutes before injecting.

**A)** Remove the Aimovig autoinjector from the carton.

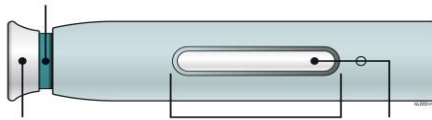
Carefully lift the autoinjector straight up out of the carton.

Leave the autoinjector at room temperature for at least **30** minutes before injecting.

- **Do not** put the autoinjector back in the refrigerator once they have 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 autoinjector.**

Green safety guard (needle inside)



White cap on    Window    Medicine

**Make sure the medicine in the window is clear and colorless to slightly yellow.**

- **Do not** use the autoinjector if the medicine is cloudy or discolored or contains flakes or 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 expiry date printed on the label has passed.

In all cases, use a new autoinjector, and in case of doubts contact your healthcare professional.

**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:

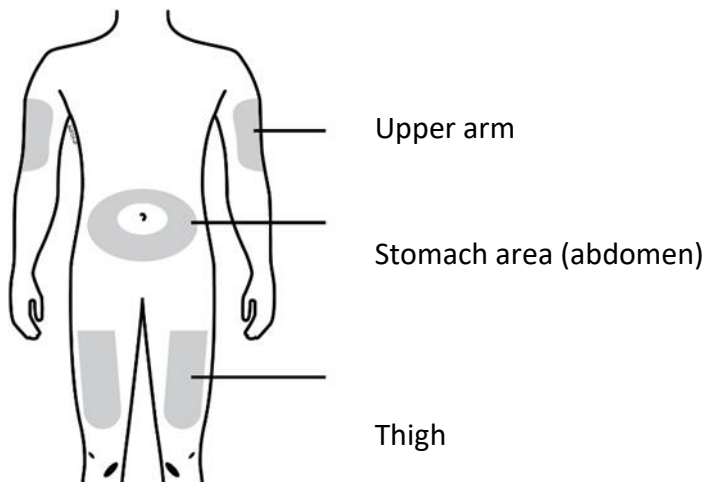
- Alcohol wipe
- One autoinjector
- Sharps disposal container
- Cotton ball(s) or gauze pad
- Adhesive bandage



D) Prepare and clean your injection site.

**Only use these injection sites:**

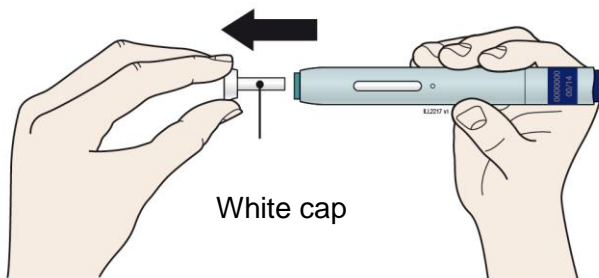
- The thigh
- Stomach area (abdomen), except for a **five** centimeter area right around your navel
- Outer area of upper arm (only if someone else is giving you the injection)



Clean your 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, make sure it is not the same spot on the injection site that you used for a previous injection.
- **Do not** inject into areas where the skin is tender, bruised, red, or hard.
- Avoid injecting directly into a raised, thick, red, or scaly skin patch or lesion, or areas with scars or stretch marks.

**Step 2: Get ready**

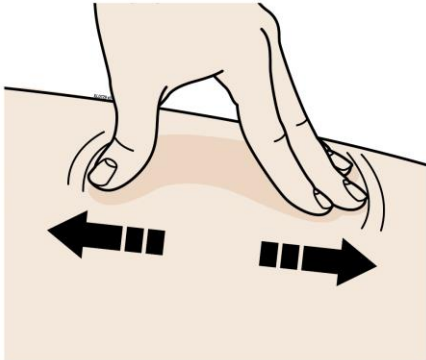


**E)** Pull the white cap straight off, only when you are ready to inject. **Do not** leave the white cap off for more than five minutes. This can dry out the medicine.

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

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

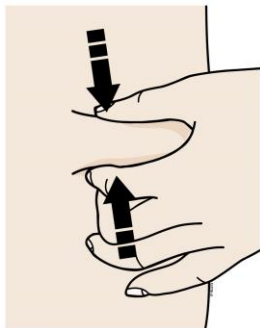
**F)** Create a firm surface at the selected injection site (thigh, stomach, or outer areas of the upper arm), by using **either** the Stretch method **or** the Pinch method.



#### **Stretch method**

Stretch the skin firmly by moving your thumb and fingers in opposite directions, creating an area about **five** centimeters wide.

**OR**

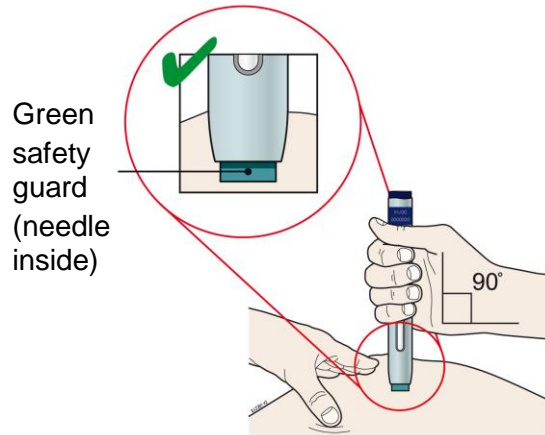


#### **Pinch method**

Pinch the skin firmly between your thumb and fingers, creating an area about **five** centimeters wide.

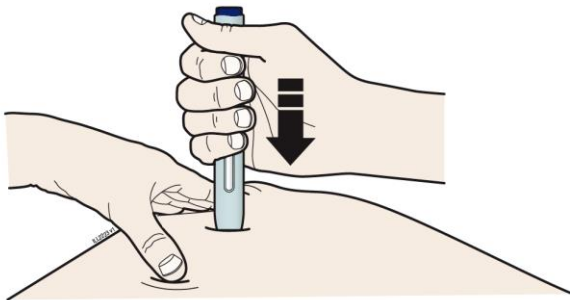
**Important:** Keep skin stretched or pinched while injecting.

### Step 3: Inject



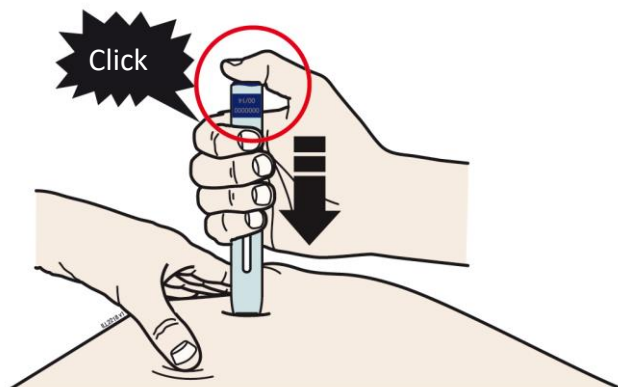
**G)** Keep holding the stretched or pinched skin. With the white cap off, **put** the green safety guard on the skin at an angle of 90 degrees. The needle is inside the green safety guard. Do not touch the purple start button yet.

### Push down



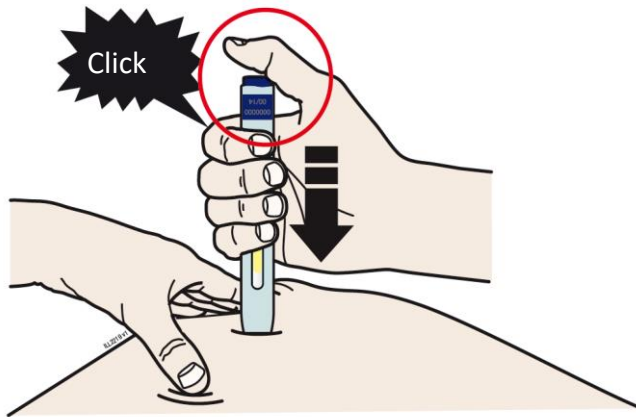
**H)** Firmly **push** the autoinjector down onto skin until it stops moving.

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

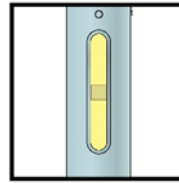


**I)** When you are ready to inject, **press** the purple start button.

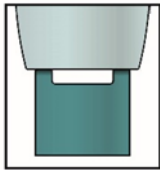
You will hear a click.



J) Remove your thumb from the button, but keep **pushing** down on the skin. Your injection could take about 15 seconds.



**Important:** Window turns from clear to yellow when injection is done and you may hear a second click.



**Note:** After you remove the 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 being released, this means you have not received a full dose. Call your healthcare professional immediately.

#### Step 4: Finish



#### K) Discard the used autoinjector and the white cap.

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

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

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

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.
- 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 provincial or local laws about how you should throw away used needles and syringes.

**L)** Examine the injection site.

If there is blood, press a cotton ball or gauze pad on your injection site. **Do not** rub the injection site. Apply an adhesive bandage if needed.

## **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.

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

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.

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

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

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

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.

### ***What do I do if I didn't hear a click after pushing the device down on my skin for 15 seconds?***

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

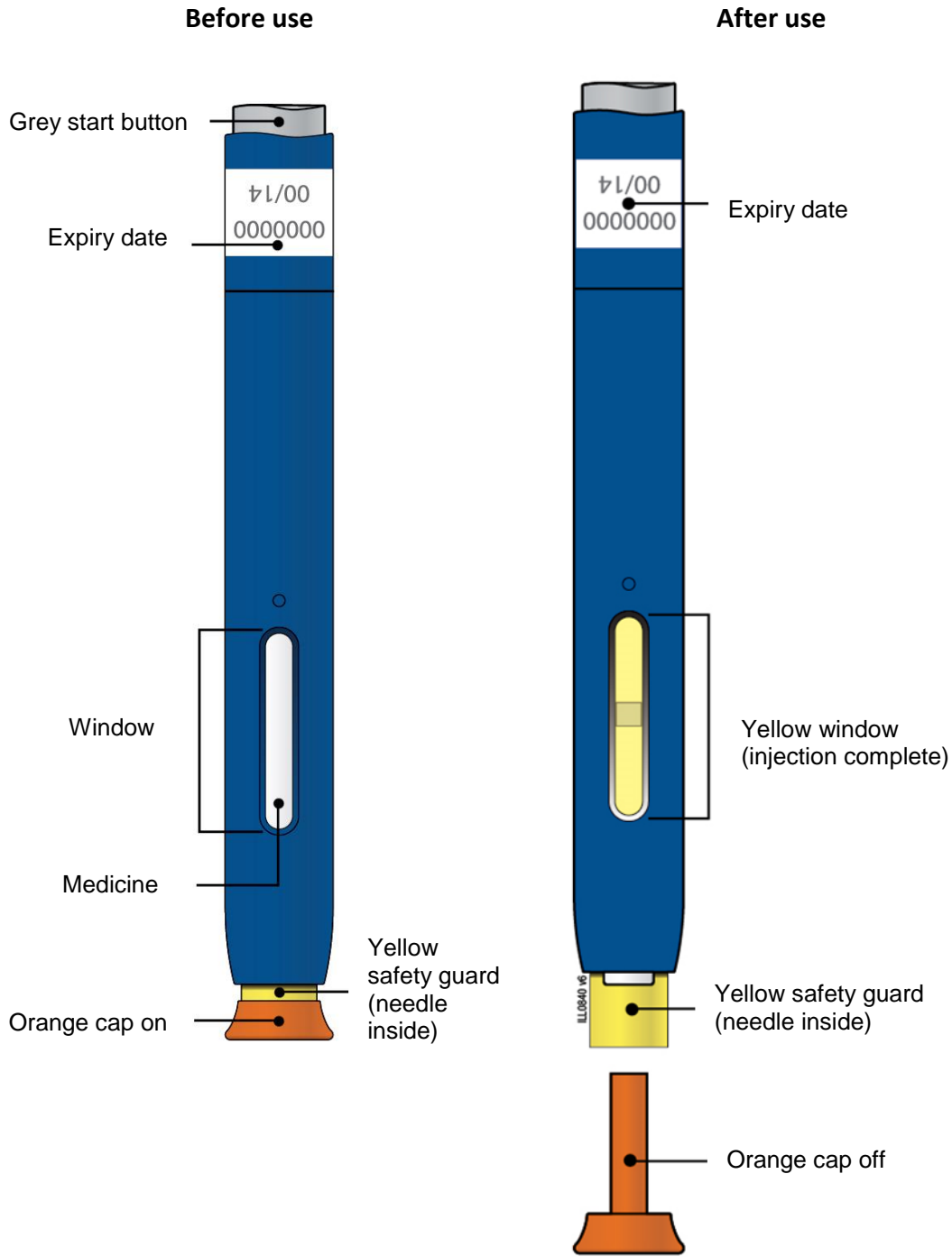
### ***Whom do I contact if I need help with the autoinjector or my injection?***

If you have any questions about the autoinjector, its storage, or about your injection contact your healthcare professional.

**Instructions for preparing and giving an injection of Aimovig 140 mg/mL:**

Aimovig Single-Dose Pre-filled SureClick Autoinjector 140 mg/mL:

**Guide to parts**



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



## Important

**Before you use an Aimovig SureClick autoinjector, read this important information:**

### Storing your Aimovig SureClick autoinjector

- Keep the autoinjector out of the sight and reach of children.
- Keep the autoinjector in the original carton to protect from light or physical damage.
- The autoinjector should be kept in the refrigerator at 2°C to 8°C.
- Throw away Aimovig that has been left at room temperature (up to 25°C) for more than 7 days.
- **Do not** store the autoinjector in extreme heat or cold. For example, avoid storing in your car.
- **Do not** freeze.

### Using your Aimovig SureClick autoinjector

- **Do not** try to inject Aimovig before receiving training from your healthcare professional.
- **Do not** use the autoinjector after the expiry date stated on the label.
- **Do not** shake the autoinjector.
- **Do not** remove the orange cap from the autoinjector until you are ready to inject.
- **Do not** freeze or use the autoinjector if it has been frozen.
- **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 your healthcare professional.

This product contains natural rubber latex within the orange cap. The product may cause allergic responses in individuals who are sensitized to latex. Tell your healthcare professional if you are allergic to latex.

For more information or help contact your healthcare professional.

### Step 1: Prepare

**Read this before you inject.**

**Check your prescription.**

Your healthcare professional has prescribed a 140 mg dose.

For a 140 mg dose, inject one autoinjector of 140 mg/mL.

To avoid discomfort at the site of injection, leave the autoinjector at room temperature for at least 30 minutes before injecting.

**A)** Remove the Aimovig autoinjector from the carton.

Carefully lift the autoinjector straight up out of the carton.

Leave the autoinjector at room temperature for at least **30** minutes before injecting.

- **Do not** put the autoinjector back in the refrigerator once they have 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 orange cap from the autoinjector yet.

**B) Inspect the autoinjector.**

Yellow safety guard (needle inside)



Orange cap on    Window    Medicine

**Make sure the medicine in the window is clear and colorless to slightly yellow.**

- **Do not** use the autoinjector if the medicine is cloudy or discolored or contains flakes or 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 orange cap is missing or not securely attached.
- **Do not** use the autoinjector if the expiry date printed on the label has passed.

In all cases, use a new autoinjector, and in case of doubts contact your healthcare professional.

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



Wash your hands thoroughly with soap and water.

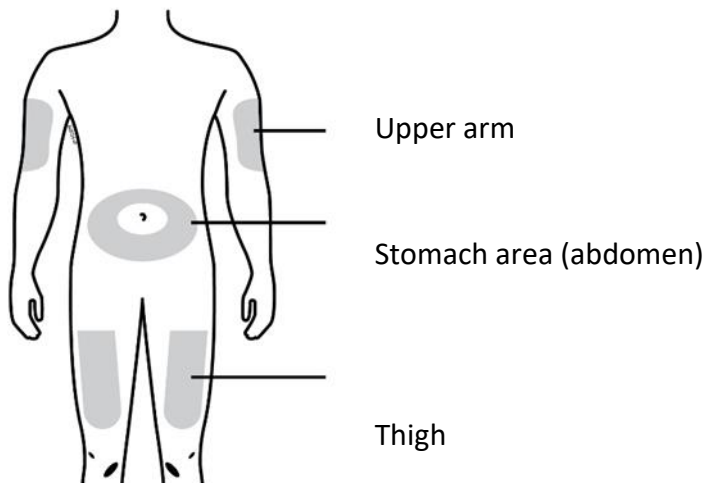
On a clean, well-lit work surface, place the:

- Alcohol wipe
- One new autoinjector
- Sharps disposal container
- Cotton ball(s) or gauze pad(s)
- Adhesive bandage

D) Prepare and clean your injection site.

**Only use these injection sites:**

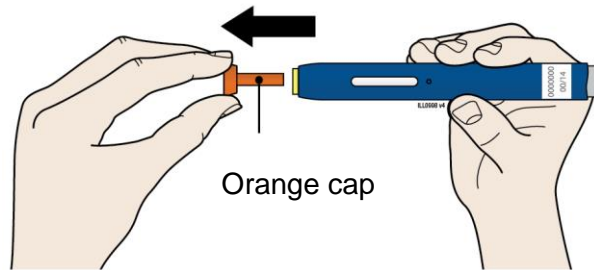
- The thigh
- Stomach area (abdomen), except for a **five** centimeter area right around your navel
- Outer area of upper arm (only if someone else is giving you the injection)



Clean your 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, make sure it is not the same spot on the injection site that you used for a previous injection.
- **Do not** inject into areas where the skin is tender, bruised, red, or hard.
- Avoid injecting directly into a raised, thick, red, or scaly skin patch or lesion, or areas with scars or stretch marks.

## Step 2: Get ready

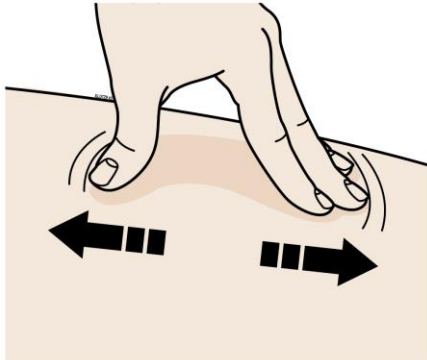


**E)** Pull the orange cap straight off, only when you are ready to inject. **Do not** leave the orange cap off for more than five minutes. This can dry out the medicine.

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

- **Do not** twist or bend the orange cap.
- **Do not** put the orange cap back onto the autoinjector.
- **Do not** put your fingers into the yellow safety guard.
- **Do not** remove the orange cap from the autoinjector until you are ready to inject.

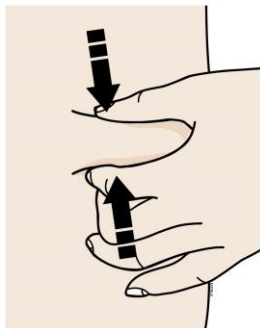
**F)** Create a firm surface at the selected injection site (thigh, stomach, or outer areas of the upper arm), by using **either** the Stretch method **or** the Pinch method.



#### **Stretch method**

Stretch the skin firmly by moving your thumb and fingers in opposite directions, creating an area about **five** centimeters wide.

**OR**

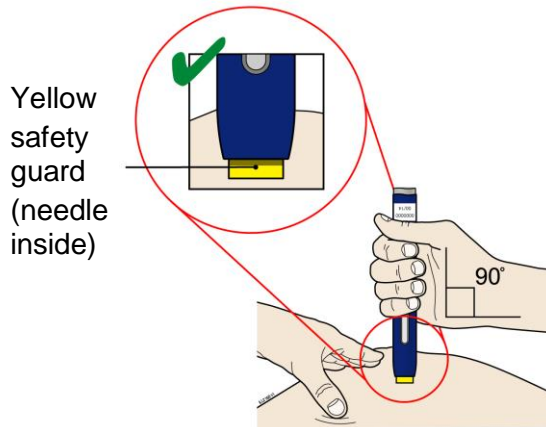


#### **Pinch method**

Pinch the skin firmly between your thumb and fingers, creating an area about **five** centimeters wide.

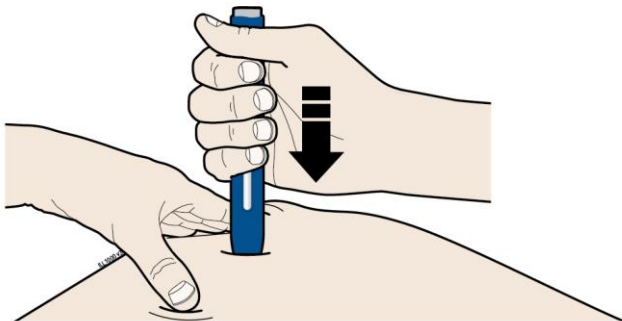
**Important:** Keep skin stretched or pinched while injecting.

### Step 3: Inject



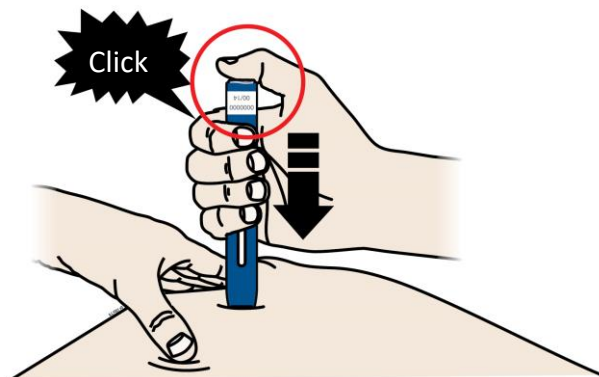
**G)** Keep holding the stretched or pinched skin. With the orange cap off, **put** the yellow safety guard on the skin at an angle of 90 degrees. The needle is inside the yellow safety guard. Do not touch the grey start button yet.

### Push down



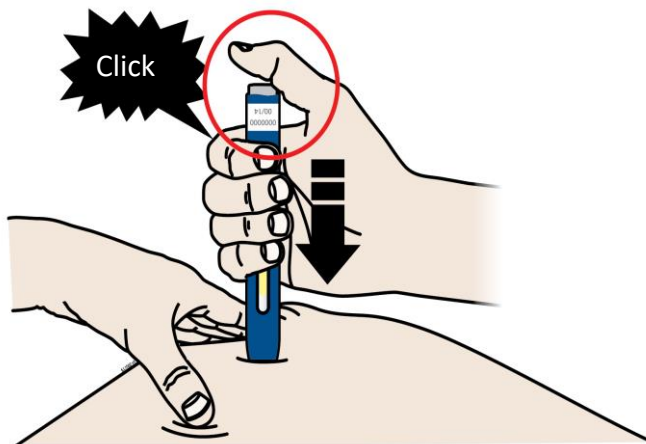
**H)** Firmly **push** the autoinjector down onto skin until it stops moving.

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



**I)** When you are ready to inject, **press** the grey start button.

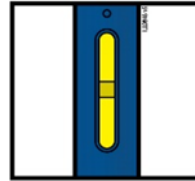
You will hear a click.



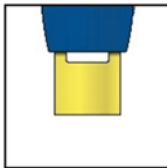
J) Remove your thumb from the button, but keep **pushing** down on the skin. Your injection could take about 15 seconds.



15 seconds



**Important:** Window turns from clear to yellow when injection is done and you may hear a second click.



**Note:** After you remove the 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 being released, this means you have not received a full dose. Call your healthcare professional immediately.

#### Step 4: Finish



#### K) Discard the used autoinjector and the orange cap.

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

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

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

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.
- 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 provincial or local laws about how you should throw away used needles and syringes.

**L)** Examine the injection site.

If there is blood, press a cotton ball or gauze pad on your injection site. **Do not** rub the injection site. Apply an adhesive bandage if needed.



## **Commonly asked questions**

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

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

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

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

### ***Can I release the grey start button after I start my injection?***

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

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

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

### ***What do I do if I didn't hear a click after pushing the device down on my skin for 15 seconds?***

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

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

If you have any questions about the autoinjector, its storage, or about your injection contact your healthcare professional.