

INSTRUCTIONS FOR USE
HADLIMA™ (HAD-lee-mah)
(adalimumab-bwwd)
40 mg/0.8 mL
Single Dose Prefilled Syringe

For subcutaneous (under the skin) use only

Do not try to inject HADLIMA yourself until you have been shown the right way to give an injection and have read and understand this Instructions for Use. If your doctor decides that you or a caregiver may be able to give your injection of HADLIMA at home, you should receive training on the right way to prepare and inject HADLIMA. It is important that you read, understand, and follow these instructions so that you inject HADLIMA the right way. Call your healthcare provider if you or your caregiver have any questions about the right way to inject HADLIMA.

To help you remember when to inject HADLIMA, you can mark your calendar ahead of time.

The following instructions are for preparing and giving 1 dose of HADLIMA using a single dose prefilled syringe. Read this Instructions for Use before you start using HADLIMA.

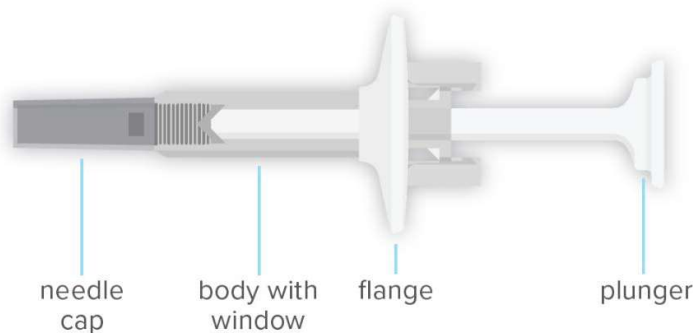
What is included in this Instructions for Use

- Your single dose prefilled syringe
- Caring for your syringe
- How to inject with your syringe
- Extra tips for injecting HADLIMA
- Frequently asked questions (FAQs)

Your single dose prefilled syringe:

After you push the plunger all the way down, the needle will be covered automatically (retract) to **help prevent needle stick injury**.

Figure A



Caring for your syringe

How should I store HADLIMA?



Store HADLIMA in the refrigerator between 36°F to 46°F (2°C to 8°C).

- **Do not freeze HADLIMA.** Do not use HADLIMA if frozen, even if it has been thawed.
- Refrigerated HADLIMA may be used until the expiration date printed on the HADLIMA carton, or prefilled syringe. **Do not** use HADLIMA after the expiration date.
- If needed, for example when you are traveling, you may also store HADLIMA at room

temperature up to 77°F (25°C) for up to 14 days. Throw away HADLIMA if it has been kept at room temperature and not been used within 14 days.



Store HADLIMA in the original carton until you use it to protect it from sunlight and indoor light.

- Record the date you first remove HADLIMA from the refrigerator in the spaces provided on the carton.
- **Do not** store HADLIMA in extreme heat or cold.
- **Do not** drop or crush HADLIMA. The prefilled syringe is glass.

Keep HADLIMA, injection supplies, and all other medicines out of the reach of children.



Use each syringe only 1 time. **Do not** reuse a syringe.



Throw away your used syringe in a sharps container.

If you have any questions, visit our website at www.HADLIMA.com or call the hotline at 1-844-674-3200.

How to inject with your syringe

Step 1: Remove your prefilled syringe from the refrigerator and wait 15 to 30 minutes

- For a more comfortable injection, you should wait 15 to 30 minutes for the medicine in your prefilled syringe to reach room temperature (see **Figure B**).
- **Do not** warm HADLIMA in any other way (for example, do not warm it in a microwave or in hot water).

Figure B



Step 2: Gather supplies

- You will need the following supplies for each injection of HADLIMA (see **Figure C**). Find a clean, flat surface to place the supplies on.
 - 1 HADLIMA prefilled syringe
 - 1 alcohol swab (not included in your HADLIMA carton)
 - cotton ball or gauze (not included in your HADLIMA carton)
 - puncture-resistant sharps disposal container for HADLIMA prefilled syringe disposal (not included in your HADLIMA carton). See **“How should I throw away (dispose of) the used prefilled syringes?”** section at the end of this Instructions for Use.

Figure C

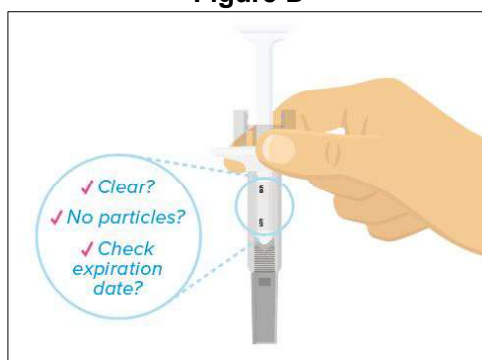


If you do not have all the supplies you need to give yourself an injection, go to a pharmacy or call your pharmacist.

Step 3: Inspect the medicine and check the expiration date

- You should always **check the expiration date** to make sure HADLIMA prefilled syringe has not expired. **Do not** use if the expiration date has passed.
- **Do not** use HADLIMA if:
 - the prefilled syringe is frozen or has been left in sunlight and indoor light.
 - it has been kept at room temperature for longer than **14** days or HADLIMA has been stored above 77°F (25°C).
 - See the “**Caring for your syringe**” and “**Frequently asked questions (FAQs)**” sections of this Instructions for Use.
- The solution should be clear and colorless to pale brown. **Do not** use the prefilled syringe if the liquid is cloudy, discolored, or has flakes or particles in it (see **Figure D**).
- You may see one or more air bubbles in the body with window, and that is okay. There is no reason to remove it.
- **Do not** remove the needle cap until Step 5.

Figure D



Step 4: Choose the injection site and clean the skin

- Wash and dry your hands.
- Choose an injection site on your body. The recommended injection site is the front of the thigh or lower abdomen (belly), but not the area 2 inches (5 cm) around your belly button (navel) (see **Figure E**).
- Choose a different site each time you give yourself an injection.
- **Do not** inject into areas where the skin is tender, bruised, red, scaly or hard. Avoid areas with scars or stretch marks. If you have psoriasis, you should not inject directly into areas with psoriasis plaques.
- Wipe your skin at the injection site with an alcohol swab in a circular motion. Let the

- skin dry before injecting.
- **Do not** touch this area again before giving the injection.

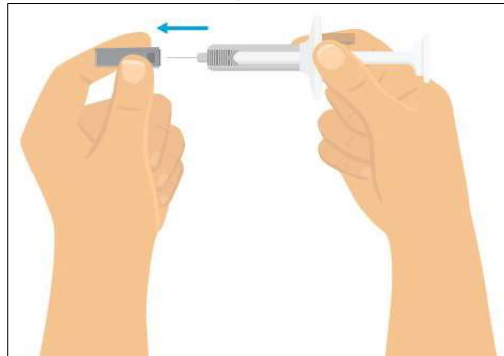
Figure E



Step 5: Pull off the needle cap

- Carefully pull off the needle cap straight off to remove it from the prefilled syringe (see **Figure F**).
- Throw away the needle cap.
- **Do not** touch the needle with your fingers or let the needle touch anything.

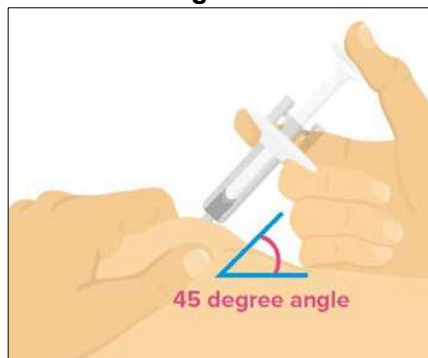
Figure F



Step 6: Pinch the skin and insert the needle

- Gently pinch your skin at the injection site and insert the needle all the way into your skin at about a **45 degree angle** (see **Figure G**).

Figure G



Step 7: Push the plunger all the way

- Hold the syringe and press the plunger all the way down until the syringe is empty (see **Figure H**).
- Then take your thumb off the plunger to let the needle retract into the body of the syringe.

Figure H**Step 8: Remove the syringe**

- Pull the syringe away from your skin at the same angle that you pushed it in.
- Make sure that the needle has retracted (see **Figure I**).
- ▶▶ Not sure if you received your dose? Call 1-844-674-3200.

Figure I**Step 9: How should I throw away (dispose of) the used prefilled syringes?**

- Put your used syringes in an FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) syringes in your household trash (see **Figure I**).
- If you do not have an FDA-cleared 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 sharps disposal containers. There may be state or local laws about how you should throw away used syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.

- 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.

Extra tips for injecting HADLIMA

Now that you understand the basics of giving yourself an injection, here are some extra tips to help you.

Choose a fatty area for injection

- Fatty areas, like your stomach, are generally the best injection sites. Fatty areas are easier to pinch and are good for inserting the needle correctly.

Use a different injection site every time

- When choosing an injection site, select an area that has not recently been used to avoid soreness and bruises.

Finalize your injection

- After the injection is complete, you can use a cotton ball or gauze to cover the injection site if there is a little bleeding.

Frequently asked questions (FAQs)

If you have questions, read through these FAQs to learn more. If you still have any questions, visit our website at www.HADLIMA.com or call 1-844-674-3200.

What should I do if:

My syringe is out of the refrigerator for more than 30 minutes

- It is okay to leave your syringe out for up to 14 days before injecting, as long as it is kept away from sunlight and indoor light. If your syringe has been at room temperature for more than 14 days, call 1-844-674-3200.

The medicine in my syringe is not clear, colorless to pale brown, free of particles, or is expired

- If the medicine in your syringe is not clear, colorless to pale brown, or free of particles, do not use it. If it is expired, do not use it. Get a new syringe. Call 1-844-674-3200.

I see air bubbles in my syringe

- It is normal to see small air bubbles in your syringe. There is no reason to remove them.

I took off my needle cap before I was ready to inject

- Do not put the needle cap back on. This could bend or damage the needle. You might accidentally stick yourself or waste the medicine. Call 1-844-674-3200.

I dropped my syringe

- If you dropped your syringe with the cap on, it is okay to use the syringe.
If you dropped your syringe with the cap off, do not use it. The needle might be dirty or damaged. Call 1-844-674-3200.

The syringe is damaged or broken

- Do not use a damaged syringe. Get a new syringe. Call 1-844-674-3200.

The needle never retracted

- If the needle never retracted into the body, the plunger was not pushed all the way down. Press the plunger harder to activate the shield. If you still have trouble, call 1-844-674-3200.

I am not sure I received my full dose

- You received your full dose if:
 - The plunger was pushed all the way down
 - The needle retracted into the shield
 - All of the medicine went into your skin and did not leak out. (If you see a drop, that is okay)
- If you are still not sure, call 1-844-674-3200.

My sharps container is full

- Call 1-844-674-3200 when your sharps container is full.
We will help you dispose of it.

I do not have a sharps container


- If you do not have a sharps container, call 1-844-674-3200 or visit our website at www.HADLIMA.com. We can give you a container.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

SAMSUNG BIOEPIS

Manufactured by: Samsung Bioepis Co., Ltd., 76, Songdogyoyuk-ro, Yeonsu-gu, Incheon, 21987, Republic of Korea

U.S. License No. 2046

Manufactured for:
Organon LLC, a subsidiary of
 **ORGANON & Co.**,
Jersey City, NJ 07302, USA

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Last Revised <12/2022>

INSTRUCTIONS FOR USE
HADLIMA™ PushTouch™ (HAD-lee-mah)
(adalimumab-bwwd)
40 mg/0.8 mL
Single Dose Autoinjector

For subcutaneous (under the skin) use only

Do not try to inject HADLIMA yourself until you have been shown the right way to give an injection and have read and understand this Instructions for Use. If your doctor decides that you or a caregiver may be able to give your injections of HADLIMA at home, you should receive training on the right way to prepare and inject HADLIMA. It is important that you read, understand, and follow these instructions so that you inject HADLIMA the right way. Call your healthcare provider if you or your caregiver have any questions about the right way to inject HADLIMA.

To help you remember when to inject HADLIMA, you can mark your calendar ahead of time.

The following instructions are for preparing and giving 1 dose of HADLIMA PushTouch. Read this Instructions for Use before you start using HADLIMA PushTouch.

What is included in this Instructions for Use

- Your HADLIMA PushTouch
- Caring for your autoinjector
- How to inject with your autoinjector
- Extra tips for injecting HADLIMA
- Frequently asked questions (FAQs)

Your HADLIMA PushTouch:

The needle is hidden below the green base. When you push the HADLIMA PushTouch onto your skin, the injection will start automatically.

Important: There is no button on your HADLIMA PushTouch.

Figure A



Caring for your autoinjector

How should I store HADLIMA PushTouch?



Store HADLIMA in the refrigerator between 36°F to 46°F (2°C to 8°C).

- **Do not freeze HADLIMA.** Do not use HADLIMA if frozen, even if it has been thawed.
- Refrigerated HADLIMA may be used until the expiration date printed on the HADLIMA carton, or autoinjector. **Do not** use HADLIMA after the expiration date.
- If needed, for example when you are traveling, you may also store HADLIMA at room

temperature up to 77°F (25°C) for up to 14 days. Throw away HADLIMA if it has been kept at room temperature and not been used within 14 days.



Store HADLIMA in the original carton until you use it to protect it from sunlight and indoor light.

- Record the date you first remove HADLIMA from the refrigerator in the spaces provided on the carton.
- **Do not** store HADLIMA in extreme heat or cold.
- **Do not** drop or crush HADLIMA. The prefilled syringe is glass.

Keep HADLIMA, injection supplies, and all other medicines out of the reach of children.



Use each HADLIMA PushTouch only 1 time. **Do not** reuse HADLIMA PushTouch.



Throw away your used HADLIMA PushTouch in a sharps container.

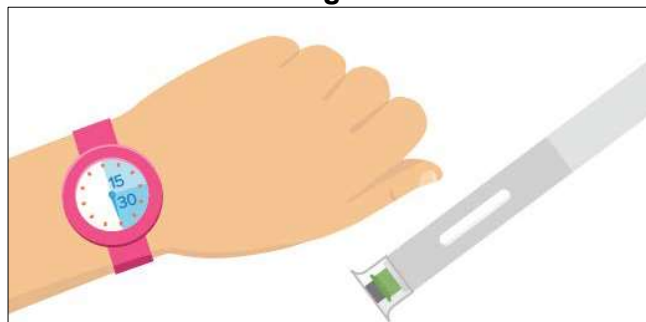
If you have any questions, visit our website at www.HADLIMA.com or call the hotline at 1-844-674-3200.

How to inject with your autoinjector

Step 1: Remove your HADLIMA PushTouch from the refrigerator and wait 15 to 30 minutes

- For a more comfortable injection, you should wait 15 to 30 minutes for the medicine in PushTouch to reach room temperature (see **Figure B**).
- **Do not** warm HADLIMA in any other way (for example, do not warm it in a microwave or in hot water).

Figure B



Step 2: Gather supplies

- You will need the following supplies for each injection of HADLIMA (see **Figure C**). Find a clean, flat surface to place the supplies on.
 - 1 HADLIMA PushTouch
 - 1 alcohol swab (not included in your HADLIMA carton)
 - cotton ball or gauze (not included in your HADLIMA carton)
 - puncture-resistant sharps disposal container for HADLIMA PushTouch disposal (not included in your HADLIMA carton). See “**How should I throw away (dispose of) the used autoinjectors?**” section at the end of this Instructions for Use.

Figure C

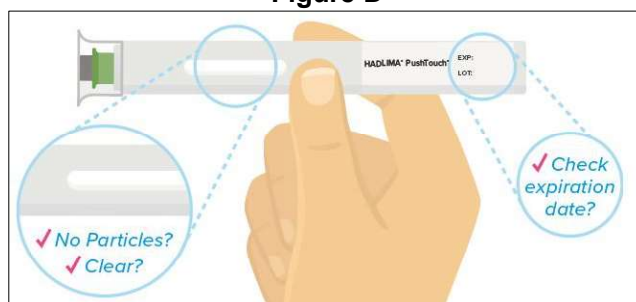


If you do not have all the supplies you need to give yourself an injection, go to a pharmacy or call your pharmacist.

Step 3: Inspect the medicine and expiration date

- You should always **check the expiration date** to make sure your PushTouch has not expired. **Do not** use if the expiration date has passed.
- **Do not** use HADLIMA if:
 - the PushTouch is frozen or has been left in sunlight and indoor light.
 - it has been kept at room temperature for longer than **14** days or HADLIMA has been stored above 77°F (25 °C).
 - see the “**Caring for your autoinjector**” and “**Frequently asked questions (FAQs)**” sections of this Instructions for Use.
- The solution should be clear and colorless to pale brown. **Do not** use the PushTouch if the liquid is cloudy, discolored, or has flakes or particles in it (see **Figure D**).
- You may see one or more air bubbles in the medicine window, and that is okay. There is no reason to remove it.
- **Do not** remove the needle cap until Step 5.

Figure D



Step 4: Choose the injection site and clean the skin

- Wash and dry your hands.
- Choose an injection site on your body. The recommended injection site is the front of the thigh or lower abdomen (belly), but not the area 2 inches (5 cm) around your belly button (navel) (see **Figure E**).
- Choose a different site each time you give yourself an injection.
- **Do not** inject into areas where the skin is tender, bruised, red, scaly or hard. Avoid areas with scars or stretch marks. If you have psoriasis, you should not inject directly

into areas with psoriasis plaques.

- Wipe your skin at the injection site with an alcohol swab in a circular motion. Let the skin dry before injecting.
- **Do not** touch this area again before giving the injection.

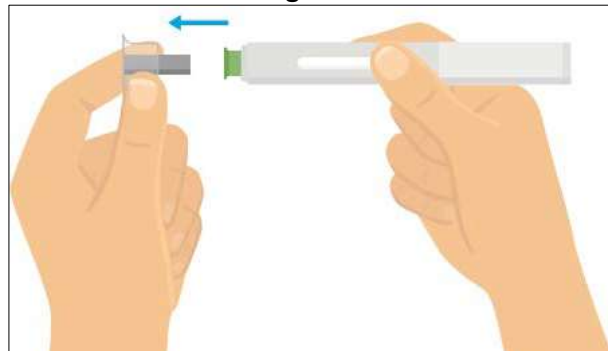
Figure E



Step 5: Pull off the clear needle cap

- Carefully pull off the clear needle cap with a metal center straight off to remove it from the PushTouch (see **Figure F**).
- Throw away the needle cap.

Figure F



Step 6: Place the green base of the PushTouch on your skin, 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 will start (see **Figure G**).
- You may hear the **first click** which means the injection has started.

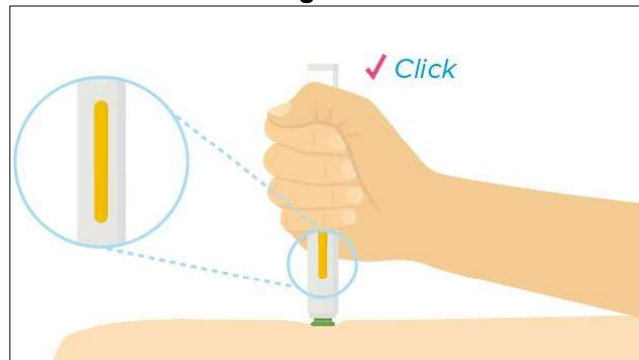
Figure G



Step 7: Keep holding the PushTouch

- Keep holding the PushTouch against your skin until the yellow indicator fills the medicine window and the yellow indicator stops moving (see **Figure H**).
- After a few seconds you may hear a **second click**. This means the injection is complete.

Figure H



Step 8: Make sure the entire dose is given

- If the medicine window is all yellow, this means your dose is complete (see **Figure I**).
 - Remove the PushTouch away from your skin. The needle should be covered by the green base.
- ▶▶ Not sure if you received your dose? Call 1-844-674-3200.

Figure I



Step 9: How should I throw away (dispose of) the used autoinjectors?

- Put your used autoinjectors in an FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) autoinjectors in your household trash. (see **Figure I**)
- If you do not have an FDA-cleared 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 sharps disposal containers. There may be state or local laws about how you should throw away used autoinjectors. For more information

about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.

- 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.

Extra tips for injecting HADLIMA

Now that you understand the basics of giving yourself an injection, here are some extra tips to help you.

Use a different injection site every time

- When choosing an injection site, select an area that has not recently been used to avoid soreness and bruises.

Finalize your injection

- After the injection is complete, you can use a cotton ball or gauze to cover the injection site if there is a little bleeding.

Frequently asked questions (FAQs)

If you have questions, read through these FAQs to learn more. If you still have any questions, visit our website at www.HADLIMA.com or call 1-844-674-3200.

What should I do if:

My autoinjector is out of the refrigerator for more than 30 minutes

- It is okay to leave your autoinjector out for up to 14 days before injecting, as long as it is kept away from sunlight and indoor light. If your HADLIMA PushTouch has been at room temperature for more than 14 days, call 1-844-674-3200.

The medicine in my HADLIMA PushTouch is not clear, colorless to pale brown, free of particles, or is expired

- If your medicine in your HADLIMA PushTouch is not clear, colorless to pale brown, or free of particles, do not use it. If it is expired, do not use it. Get a new autoinjector. Call 1-844-674-3200.

I see air bubbles in my autoinjector

- It is normal to see small air bubbles in your autoinjector. There is no reason to remove them.

I took off my autoinjector cap before I was ready to inject

- Do not put the autoinjector cap back on. This could bend or damage the needle. You might accidentally stick yourself or waste the medicine. Call 1-844-674-3200.

I dropped my autoinjector

- If you dropped your autoinjector with the cap on, it is okay to use the autoinjector. If you dropped your autoinjector with the cap off, do not use it. The needle might be dirty or damaged. Call 1-844-674-3200.

The autoinjector is damaged or broken

- Do not use a damaged autoinjector. Get a new autoinjector. Call 1-844-674-3200.

The entire medicine window is not yellow after injection

- If your medicine window is not entirely yellow after injection, you may not have received your full dose. Call 1-844-674-3200.

I am not sure I received my full dose

- You received your full dose if:
 - The entire medicine window is yellow at the end of injection
 - All of the medicine went into your skin and did not leak out. (If you see a drop, that is okay)
- If you are still not sure, call 1-844-674-3200.

My sharps container is full

- Call 1-844-674-3200 when your sharps container is full. We will help you dispose of it.

I do not have a sharps container

- If you do not have a sharps container, call 1-844-674-3200 or visit our website at www.HADLIMA.com. We can give you a container.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

SAMSUNG BIOEPIS

Manufactured by: Samsung Bioepis Co., Ltd., 76, Songdogyoyuk-ro, Yeonsu-gu, Incheon, 21987, Republic of Korea

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Manufactured for:
Organon LLC, a subsidiary of
 **ORGANON & Co.,**
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Last Revised <12/2022>

INSTRUCTIONS FOR USE
HADLIMA™ (HAD-lee-mah)
(adalimumab-bwwd)
40 mg/0.4 mL
Single Dose Prefilled Syringe

For subcutaneous (under the skin) use only

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To help you remember when to inject HADLIMA, you can mark your calendar ahead of time.

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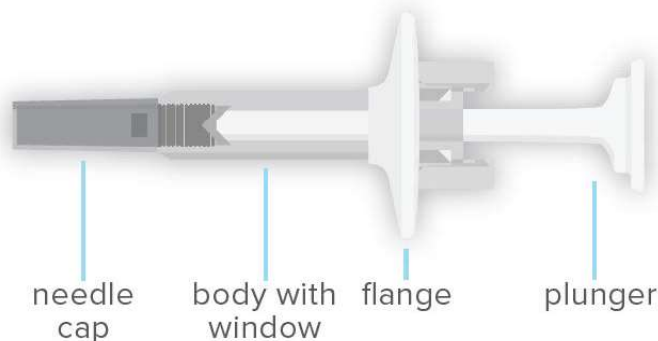
What is included in this Instructions for Use

- Your single dose prefilled syringe
- Caring for your syringe
- How to inject with your syringe
- How should I throw away (dispose of) the used prefilled syringes?
- Extra tips for injecting HADLIMA
- Frequently asked questions (FAQs)

Your single dose prefilled syringe:

After you push the plunger all the way down, the needle will be covered automatically (retract) to **help prevent needle stick injury**.

Figure A



Caring for your syringe

How should I store HADLIMA?



Store HADLIMA in the refrigerator between 36°F to 46°F (2°C to 8°C).

- **Do not freeze HADLIMA.** Do not use HADLIMA if frozen, even if it has been thawed.
- Refrigerated HADLIMA may be used until the expiration date printed on the HADLIMA carton or prefilled syringe. **Do not** use HADLIMA after the expiration date.

- If needed, for example when you are traveling, you may also store HADLIMA at room temperature up to 77°F (25°C) for up to 14 days. Throw away HADLIMA if it has been kept at room temperature and not been used within 14 days.



Store HADLIMA in the original carton until you use it to protect it from sunlight and indoor light.

- Record the date you first remove HADLIMA from the refrigerator in the spaces provided on the carton.
- **Do not** store HADLIMA in extreme heat or cold.
- **Do not** drop or crush HADLIMA. The prefilled syringe is glass.

Keep HADLIMA, injection supplies, and all other medicines out of the reach of children.



Use each syringe only 1 time. **Do not** reuse a syringe.



Throw away your used syringe in a sharps container.

If you have any questions, visit our website at www.HADLIMA.com or call the hotline at 1-844-674-3200.

How to inject with your syringe

Step 1: Remove your prefilled syringe from the refrigerator and wait 15 to 30 minutes

- For a more comfortable injection, you should wait 15 to 30 minutes for the medicine in your prefilled syringe to reach room temperature (see **Figure B**).
- **Do not** warm HADLIMA in any other way (for example, do not warm it in a microwave or in hot water).

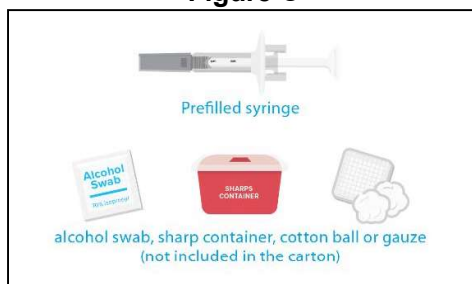
Figure B



Step 2: Gather supplies

- You will need the following supplies for each injection of HADLIMA (see **Figure C**). Find a clean, flat surface to place the supplies on.
 - 1 HADLIMA prefilled syringe
 - 1 alcohol swab (not included in your HADLIMA carton)
 - cotton ball or gauze (not included in your HADLIMA carton)
 - puncture-resistant sharps disposal container for HADLIMA prefilled syringe disposal (not included in your HADLIMA carton). See **“How should I throw away (dispose of) the used prefilled syringes?”** section at the end of this Instructions for Use.

Figure C

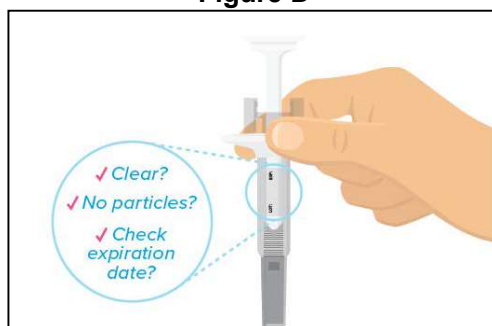


If you do not have all the supplies you need to give yourself an injection, go to a pharmacy or call your pharmacist.

Step 3: Inspect the medicine and check the expiration date

- You should always **check the expiration date** to make sure HADLIMA prefilled syringe has not expired. **Do not** use if the expiration date has passed.
- **Do not** use HADLIMA if:
 - the prefilled syringe is frozen or has been left in sunlight and indoor light.
 - it has been kept at room temperature for longer than **14** days or HADLIMA has been stored above 77°F (25 °C).
 - See the “**Caring for your syringe**” and “**Frequently asked questions (FAQs)**” sections of this Instructions for Use.
- The solution should be clear and colorless to pale brown. **Do not** use the prefilled syringe if the liquid is cloudy, discolored, or has flakes or particles in it (see **Figure D**).
- You may see one or more air bubbles in the body with window, and that is okay. There is no reason to remove it.
- **Do not** remove the needle cap until Step 5.

Figure D



Step 4: Choose the injection site and clean the skin

- Wash and dry your hands.
- Choose an injection site on your body. The recommended injection site is the front of the thigh or lower abdomen (belly), but not the area 2 inches (5 cm) around your belly button (navel) (see **Figure E**).
- Choose a different site each time you give yourself an injection.
- **Do not** inject into areas where the skin is tender, bruised, red, scaly or hard. Avoid areas with scars or stretch marks. If you have psoriasis, you should not inject directly into areas with psoriasis plaques.
- Wipe your skin at the injection site with an alcohol swab in a circular motion. Let the

skin dry before injecting.

- **Do not** touch this area again before giving the injection.

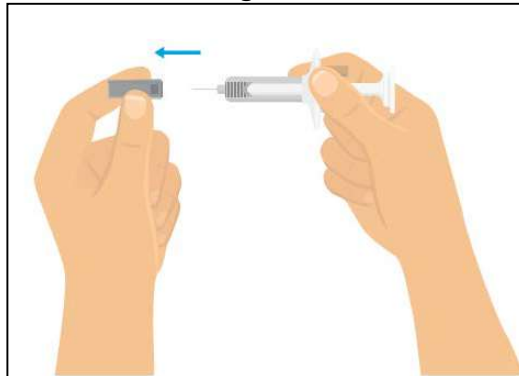
Figure E



Step 5: Pull off the needle cap

- Carefully pull off the needle cap straight off to remove it from the prefilled syringe (see **Figure F**).
- Throw away the needle cap.
- **Do not** touch the needle with your fingers or let the needle touch anything.

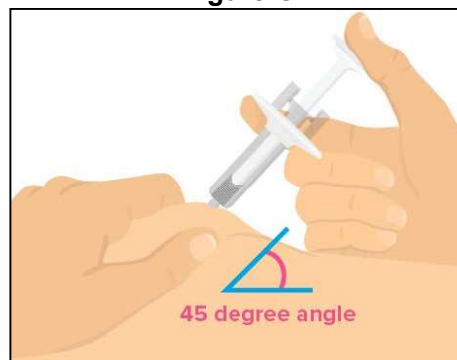
Figure F



Step 6: Pinch the skin and insert the needle

- Gently pinch your skin at the injection site and insert the needle all the way into your skin at about a **45 degree angle** (see **Figure G**).

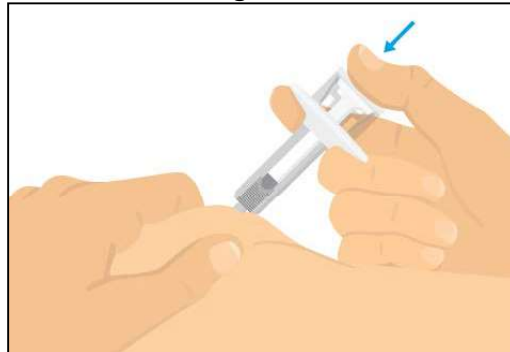
Figure G



Step 7: Push the plunger all the way

- Hold the syringe and press the plunger all the way down until the syringe is empty (see **Figure H**).
- Then take your thumb off the plunger to let the needle retract into the body of the syringe.

Figure H



Step 8: Remove the syringe

- Pull the syringe away from your skin at the same angle that you pushed it in.
 - Make sure that the needle has retracted (see **Figure I**).
- ▶▶ Not sure if you received your dose? Call 1-844-674-3200.

Figure I



Step 9: How should I throw away (dispose of) the used prefilled syringes?

- Put your used syringes in an FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) syringes in your household trash (see **Figure I**).
- If you do not have an FDA-cleared 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 sharps disposal containers. There may be state or local laws about how you should throw away used syringes. For more information about

safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.

- 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.

Extra tips for injecting HADLIMA

Now that you understand the basics of giving yourself an injection, here are some extra tips to help you.

Choose a fatty area for injection

- Fatty areas, like your stomach, are generally the best injection sites. Fatty areas are easier to pinch and are good for inserting the needle correctly.

Use a different injection site every time

- When choosing an injection site, select an area that has not recently been used to avoid soreness and bruises.

Finalize your injection

- After the injection is complete, you can use a cotton ball or gauze to cover the injection site if there is a little bleeding.

Frequently asked questions (FAQs)

If you have questions, read through these FAQs to learn more. If you still have any questions, visit our website at www.HADLIMA.com or call 1-844-674-3200.

What should I do if:

My syringe is out of the refrigerator for more than 30 minutes

- It is okay to leave your syringe out for up to 14 days before injecting, as long as it is kept away from sunlight and indoor light. If your syringe has been at room temperature for more than 14 days, call 1-844-674-3200.

The medicine in my syringe is not clear, colorless to pale brown, free of particles, or is expired

- If the medicine in your syringe is not clear, colorless to pale brown, or free of particles, do not use it. If it is expired, do not use it. Get a new syringe. Call 1-844-674-3200.

I see air bubbles in my syringe

- It is normal to see small air bubbles in your syringe. There is no reason to remove them.

I took off my needle cap before I was ready to inject

- Do not put the needle cap back on. This could bend or damage the needle. You might accidentally stick yourself or waste the medicine. Call 1-844-674-3200.

I dropped my syringe

- If you dropped your syringe with the cap on, it is okay to use the syringe.
If you dropped your syringe with the cap off, do not use it. The needle might be dirty or damaged. Call 1-844-674-3200.

The syringe is damaged or broken

- Do not use a damaged syringe. Get a new syringe. Call 1-844-674-3200.

The needle never retracted

- If the needle never retracted into the body, the plunger was not pushed all the way down. Press the plunger harder to activate the shield. If you still have trouble, call 1-844-674-3200.

I am not sure I received my full dose

- You received your full dose if:
 - The plunger was pushed all the way down
 - The needle retracted into the shield
 - All of the medicine went into your skin and did not leak out. (If you see a drop, that is okay)
- If you are still not sure, call 1-844-674-3200.

My sharps container is full

- Call 1-844-674-3200 when your sharps container is full.
We will help you dispose of it.


I do not have a sharps container

- If you do not have a sharps container, call 1-844-674-3200 or visit our website at www.HADLIMA.com. We can give you a container.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

SAMSUNG BIOEPIS

Manufactured by: Samsung Bioepis Co., Ltd., 76, Songdogoyuk-ro, Yeonsu-gu, Incheon, 21987, Republic of Korea
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Last Revised <12/2022>

INSTRUCTIONS FOR USE
HADLIMA™ PushTouch™ (HAD-lee-mah)
(adalimumab-bwwd)
40 mg/0.4 mL
Single Dose Autoinjector

For subcutaneous (under the skin) use only

Do not try to inject HADLIMA yourself until you have been shown the right way to give an injection and have read and understand this Instructions for Use. If your doctor decides that you or a caregiver may be able to give your injections of HADLIMA at home, you should receive training on the right way to prepare and inject HADLIMA. It is important that you read, understand, and follow these instructions so that you inject HADLIMA the right way. Call your healthcare provider if you or your caregiver have any questions about the right way to inject HADLIMA.

To help you remember when to inject HADLIMA, you can mark your calendar ahead of time.

The following instructions are for preparing and giving 1 dose of HADLIMA PushTouch. Read this Instructions for Use before you start using HADLIMA PushTouch.

What is included in this Instructions for Use

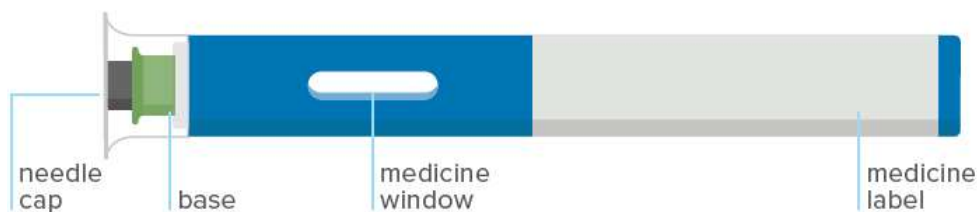
- Your HADLIMA PushTouch
- Caring for your autoinjector
- How to inject with your autoinjector
- How should I throw away (dispose of) the used autoinjectors?
- Extra tips for injecting HADLIMA
- Frequently asked questions (FAQs)

Your HADLIMA PushTouch:

The needle is hidden below the green base. When you push the HADLIMA PushTouch onto your skin, the injection will start automatically.

Important: There is no button on your HADLIMA PushTouch.

Figure A



Caring for your autoinjector

How should I store HADLIMA PushTouch?



Store HADLIMA in the refrigerator between 36°F to 46°F (2°C to 8°C).

- **Do not freeze HADLIMA.** Do not use HADLIMA if frozen, even if it has been thawed.
- Refrigerated HADLIMA may be used until the expiration date printed on the HADLIMA carton or autoinjector. **Do not** use HADLIMA after the expiration date.

- If needed, for example when you are traveling, you may also store HADLIMA at room temperature up to 77°F (25°C) for up to 14 days. Throw away HADLIMA if it has been kept at room temperature and not been used within 14 days.



Store HADLIMA in the original carton until you use it to protect it from sunlight and indoor light.

- Record the date you first remove HADLIMA from the refrigerator in the spaces provided on the carton.
- **Do not** store HADLIMA in extreme heat or cold.
- **Do not** drop or crush HADLIMA. The prefilled syringe is glass.

Keep HADLIMA, injection supplies, and all other medicines out of the reach of children.



Use each HADLIMA PushTouch only 1 time. **Do not** reuse HADLIMA PushTouch.



Throw away your used HADLIMA PushTouch in a sharps container.

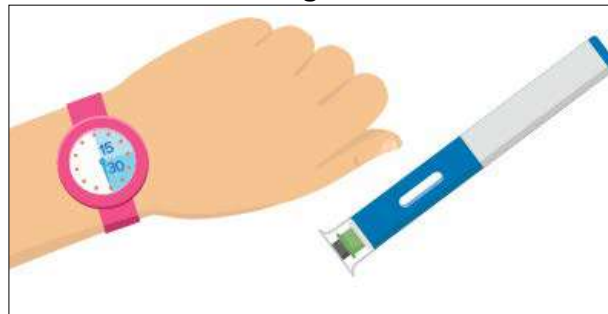
If you have any questions, visit our website at www.HADLIMA.com or call the hotline at 1-844-674-3200.

How to inject with your autoinjector

Step 1: Remove your HADLIMA PushTouch from the refrigerator and wait 15 to 30 minutes

- For a more comfortable injection, you should wait 15 to 30 minutes for the medicine in PushTouch to reach room temperature (see **Figure B**).
- **Do not** warm HADLIMA in any other way (for example, do not warm it in a microwave or in hot water).

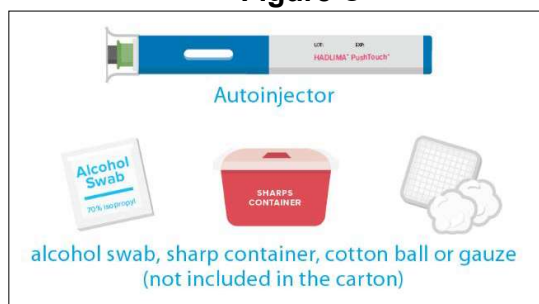
Figure B



Step 2: Gather supplies

- You will need the following supplies for each injection of HADLIMA (see **Figure C**). Find a clean, flat surface to place the supplies on.
 - 1 HADLIMA PushTouch
 - 1 alcohol swab (not included in your HADLIMA carton)
 - cotton ball or gauze (not included in your HADLIMA carton)
 - puncture-resistant sharps disposal container for HADLIMA PushTouch disposal (not included in your HADLIMA carton). See **“How should I throw away (dispose of) the used autoinjectors?”** section at the end of this Instructions for Use.

Figure C

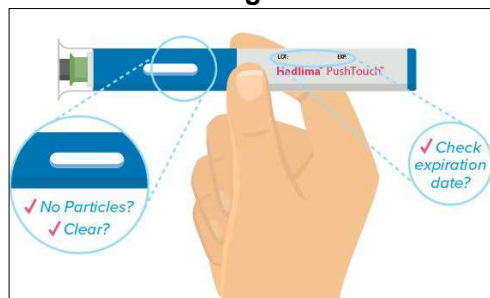


If you do not have all the supplies you need to give yourself an injection, go to a pharmacy or call your pharmacist.

Step 3: Inspect the medicine and check the expiration date

- You should always **check the expiration date** to make sure your PushTouch has not expired. **Do not** use if the expiration date has passed.
- **Do not** use HADLIMA if:
 - the PushTouch is frozen or has been left in sunlight and indoor light.
 - it has been kept at room temperature for longer than **14** days or HADLIMA has been stored above 77°F (25 °C).
 - see the “**Caring for your autoinjector**” and “**Frequently asked questions (FAQs)**” sections of this Instructions for Use.
- The solution should be clear and colorless to pale brown. **Do not** use the PushTouch if the liquid is cloudy, discolored, or has flakes or particles in it (see **Figure D**).
- You may see one or more air bubbles in the medicine window, and that is okay. There is no reason to remove it.
- **Do not** remove the needle cap until Step 5.

Figure D



Step 4: Choose the injection site and clean the skin

- Wash and dry your hands.
- Choose an injection site on your body. The recommended injection site is the front of the thigh or lower abdomen (belly), but not the area 2 inches (5 cm) around your belly button (navel) (see **Figure E**).
- Choose a different site each time you give yourself an injection.
- **Do not** inject into areas where the skin is tender, bruised, red, scaly or hard. Avoid areas with scars or stretch marks. If you have psoriasis, you should not inject directly into areas with psoriasis plaques.
- Wipe your skin at the injection site with an alcohol swab in a circular motion. Let

the skin dry before injecting.

- **Do not** touch this area again before giving the injection.

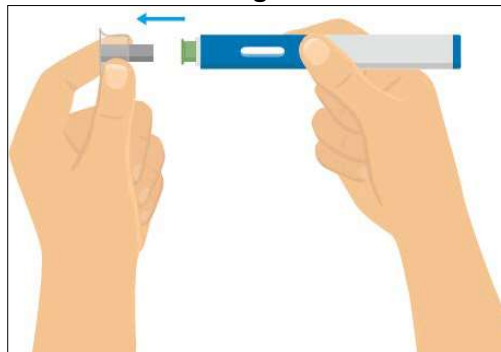
Figure E



Step 5: Pull off the clear needle cap

- Carefully pull off the clear needle cap with a metal center straight off to remove it from the PushTouch (see **Figure F**).
- Throw away the needle cap.

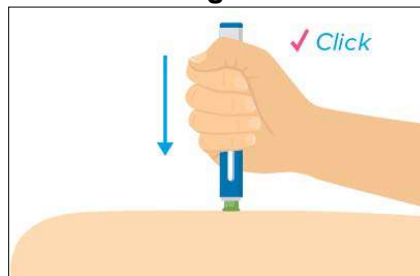
Figure F



Step 6: Place the green base of the PushTouch on your skin, 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 will start (see **Figure G**).
- You may hear the **first click** which means the injection has started.

Figure G

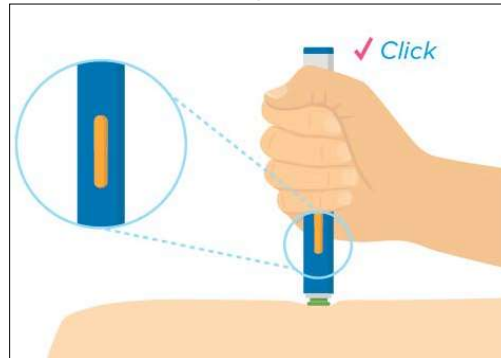


Step 7: Keep holding the PushTouch

- Keep holding the PushTouch against your skin until the yellow indicator fills the medicine window and the yellow indicator stops moving (see **Figure H**).

- After a few seconds you may hear a **second click**. This means the injection is complete.

Figure H



Step 8: Make sure the entire dose is given

- If the medicine window is all yellow, this means your dose is complete (see **Figure I**).
 - Remove the PushTouch away from your skin. The needle should be covered by the green base.
- ▶▶ Not sure if you received your dose? Call 1-844-674-3200.

Figure I



Step 9: How should I throw away (dispose of) the used autoinjectors?

- Put your used autoinjectors in an FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) autoinjectors in your household trash (see **Figure I**).
- If you do not have an FDA-cleared 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 sharps disposal containers. There may be state or local laws about how you should throw away used autoinjectors. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.
- 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.

Extra tips for injecting HADLIMA

Now that you understand the basics of giving yourself an injection, here are some extra tips to help you.

Use a different injection site every time

- When choosing an injection site, select an area that has not recently been used to avoid soreness and bruises.

Finalize your injection

- After the injection is complete, you can use a cotton ball or gauze to cover the injection site if there is a little bleeding.

Frequently asked questions (FAQs)

If you have questions, read through these FAQs to learn more. If you still have any questions, visit our website at www.HADLIMA.com or call 1-844-674-3200.

What should I do if:

My autoinjector is out of the refrigerator for more than 30 minutes

- It is okay to leave your autoinjector out for up to 14 days before injecting, as long as it is kept away from sunlight and indoor light. If your HADLIMA PushTouch has been at room temperature for more than 14 days, call 1-844-674-3200.

The medicine in my HADLIMA PushTouch is not clear, colorless to pale brown, free of particles, or is expired

- If your medicine in your HADLIMA PushTouch is not clear, colorless to pale brown, or free of particles, do not use it. If it is expired, do not use it. Get a new autoinjector. Call 1-844-674-3200.

I see air bubbles in my autoinjector

- It is normal to see small air bubbles in your autoinjector. There is no reason to remove them.

I took off my autoinjector cap before I was ready to inject

- Do not put the autoinjector cap back on. This could bend or damage the needle. You might accidentally stick yourself or waste the medicine. Call 1-844-674-3200.

I dropped my autoinjector

- If you dropped your autoinjector with the cap on, it is okay to use the autoinjector. If you dropped your autoinjector with the cap off, do not use it. The needle might be dirty or damaged. Call 1-844-674-3200.

The autoinjector is damaged or broken

- Do not use a damaged autoinjector. Get a new autoinjector. Call 1-844-674-3200.

The entire medicine window is not yellow after injection

- If your medicine window is not entirely yellow after injection, you may not have received your full dose. Call 1-844-674-3200.

I am not sure I received my full dose

- You received your full dose if:
 - The entire medicine window is yellow at the end of injection
 - All of the medicine went into your skin and did not leak out. (If you see a drop, that is okay)
- If you are still not sure, call 1-844-674-3200.

My sharps container is full

- Call 1-844-674-3200 when your sharps container is full. We will help you dispose of it.


I do not have a sharps container

- If you do not have a sharps container, call 1-844-674-3200 or visit our website at www.HADLIMA.com. We can give you a container.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

SAMSUNG BIOEPIS

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Last Revised <12/2022>