# INSTRUCTIONS FOR USE DAWNZERA™ [dawn-ZAIR-ah] (donidalorsen) injection, for subcutaneous use

This Instructions for Use contains information on how to inject **DAWNZERA** using the autoinjector.

Read this Instructions for Use before you start using your DAWNZERA autoinjector and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or treatment. Your healthcare provider should show you or your caregiver how to use the DAWNZERA autoinjector the right way. If you or your caregiver have any questions, talk to your healthcare provider.



### Important information:

- DAWNZERA is injected under the skin (subcutaneous use) only.
- Each autoinjector contains 1 single-dose and can only be used 1 time.
- Do not remove the clear cap until you are ready to inject DAWNZERA (See Step 5).
- **Do not** share your autoinjector with anyone.
- **Do not** use if the autoinjector appears damaged.

### Storage information:

- Store the autoinjector in the refrigerator between 36°F to 46°F (2°C to 8°C) in the original carton.
- If needed, DAWNZERA can be stored at room temperature up to 86°F (30°C) in the original carton for up to 6 weeks.
- **Do not** store DAWNZERA at room temperatures above 86°F.
- Throw away the DAWNZERA if kept at room temperature longer than 6 weeks.
- Do not freeze.
- **Do not** expose the autoinjector to heat.
- Protect from direct light.
- Keep the autoinjector in the carton until ready to use.
- **Do not** store the autoinjector with the clear cap removed.

### Keep DAWNZERA and all medicine out of the reach of children.

# Plunger Viewing window Medicine Clear cap Orange needle shield (contains needle) Alcohol wipe Sharps container Cotton ball or gauze Small bandage

### Preparing to inject DAWNZERA

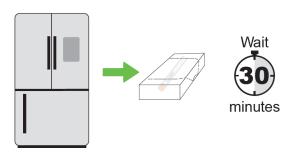
# Step 1 Remove from the refrigerator 30 minutes before you inject

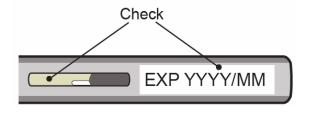
- a) Remove the autoinjector from the refrigerator.
- b) Keep the autoinjector in the original carton and let the autoinjector come to room temperature for 30 minutes before injecting.

**Do not** try to speed up the warming process using other heat sources, such as a microwave or hot water.

### Step 2 Check the medicine

- a) Check the expiration (EXP) date.
- **b)** Check the medicine through the viewing window. The DAWNZERA medicine should be clear and colorless to yellow. There should be no





particles. It is normal to see air bubbles in the solution.

### Do not use the autoinjector if the:

- · clear cap is missing or not attached.
- expiration (EXP) date has passed.
- medicine looks cloudy, discolored, or has particles.
- autoinjector appears damaged.

### Step 3 Choose the injection site

- **a)** Choose an injection site on the stomach or the front of the thigh.
- **b)** Only healthcare providers or caregivers may choose the back of the upper arm.

### Do not inject:

- within 2 inches of the belly button (navel).
- into skin that is bruised, tender, red, or hard.
- into scars or damaged skin.

## Step 4 Wash hands and clean the injection site

- a) Wash your hands with soap and water.
- **b)** Clean the injection site with an alcohol wipe in a circular motion. Let the skin air dry.

### Do not touch the cleaned skin before injecting.

### Injecting DAWNZERA

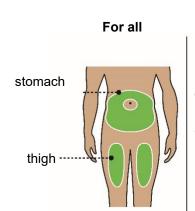
# Step 5 Remove and throw away the clear cap

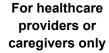
- **a)** Hold the autoinjector by the middle with the clear cap facing away from you.
- **b)** Remove the clear cap by pulling it straight off. **Do not** twist it off. The needle is inside the orange needle shield.
- **c)** Throw away the clear cap in the trash or sharps container.

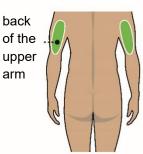
**Do not** remove the clear cap until right before you inject.

**Do not** recap the autoinjector.

**Do not** push the orange needle shield against the hand or finger.

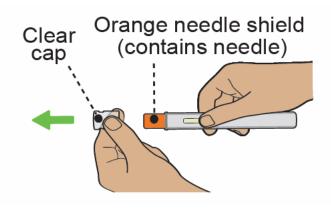












### Step 6 Begin injection

- **a)** Hold the autoinjector in 1 hand. Place the orange needle shield at a 90-degree angle against your skin. Make sure you can see the viewing window.
- **b)** Push firmly and hold the autoinjector straight against the skin. You will hear a click as the injection starts.

# You may hear a second click. This is normal. The procedure is not finished.

**c)** Hold the autoinjector against the skin for 10 seconds to make sure the full dose has been given.

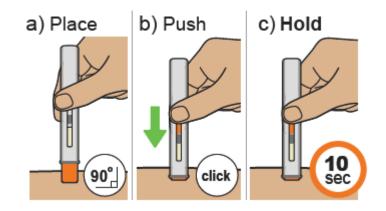
**Do not** move, turn, or change the angle of the autoinjector during the injection.

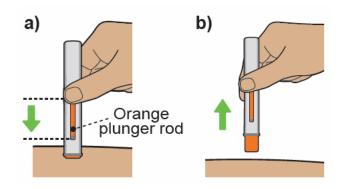
### Step 7 Finish injection

- **a)** Check that the orange plunger rod has moved down to fill the entire viewing window.
  - If the orange plunger rod does not fill the viewing window, you may not have received the full dose.
  - If this happens or if you have other concerns, contact your healthcare provider.
- **b)** Remove the autoinjector by lifting it straight up. After removal from the skin, the orange needle shield locks into place and covers the needle.
- **c)** There may be a small amount of blood or liquid where you injected. This is normal.

If needed, press a cotton ball or gauze on the area and apply a small bandage.

The autoinjector contains 1 dose. **Do not** reuse the autoinjector.





### Throwing away DAWNZERA

### Step 8 Throw away autoinjector

**a)** Put the used autoinjector in a sharps container right away after use.

**Do not** throw away the autoinjector in your household trash.

**Do not** recycle your used sharps disposal container.

Do not reuse the autoinjector or clear cap.



- 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 labelled 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 state or local laws about how you should throw away used autoinjectors.

For more information about safe sharps disposal, and 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** throw away your used sharps disposal container in your household trash unless your community guidelines permit this. **Do not** recycle your used sharps disposal container.

For more information, go to https://www.DAWNZERA.com or call 1-833-644-6647. If you still have questions, contact your healthcare provider.

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



