

6

REMOVE NEEDLE CAP

7

SELECT INJECTION SITE & DELIVER DOSE

8

LIFT & CONFIRM

9

REMOVE & DISPOSE

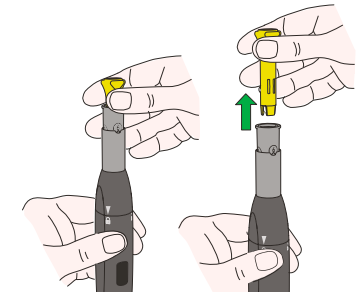
10

CLEAN & STORE

Remove the Yellow Needle Cap Remover

Pull the yellow needle cap remover straight away from the auto-injector to remove the syringe needle cap.

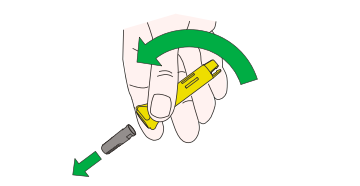
Keep the auto-injector in vertical position, with the yellow cap facing upwards.



Then tip the yellow needle cap remover upside down to allow the needle cap to fall out.

Dispose of the syringe needle cap.

IMPORTANT: Keep the yellow needle cap remover.



NOTE: If the needle cap is not removed, you must repeat Steps 4 – 6 with a new syringe.

TROUBLESHOOTING: Should the needle cap become stuck in the yellow needle cap remover, push on the needle cap until it falls out of the other end.

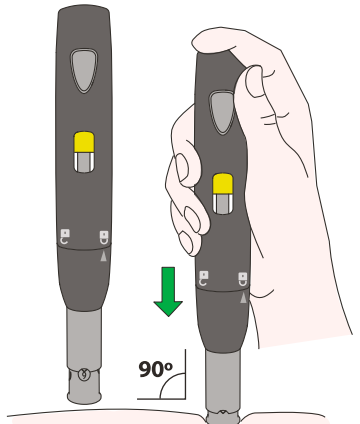
7A: Select and Clean Injection Site

For information about the allowable injection sites and injection site cleaning, refer to the patient information insert that comes with your medicine.

7B: Place Auto-injector Against Skin

Place the open white end of the autoinjector straight down against the injection site (**not at an angle**). **Firmly push the autoinjector down against your skin and hold in position.**

When **the needle depth adjuster is fully depressed**, the safety lock will be released and allows you to press the **white** injection button.

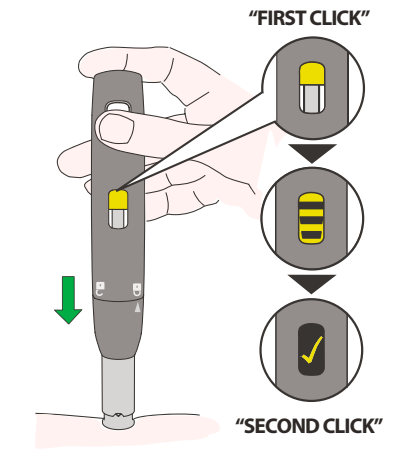


Push down & Hold to Unlock!

7C: Activate the Auto-injector to Deliver Dose

While holding the auto-injector down and steady, press the white injection button. You will hear the first “CLICK” as the injection starts.

Continue to hold the device down until you hear the second “CLICK” and see the yellow checkmark in the viewing window.

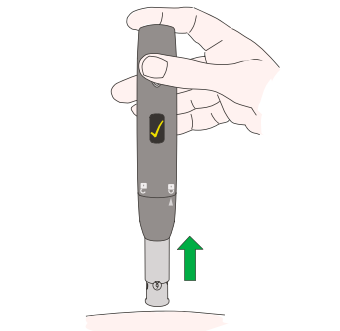


DO NOT lift up early!

NOTE: If you did not hear the second click or are unable to see the viewing window, wait at least 15 seconds after starting the injection before lifting the device away from the injection site.

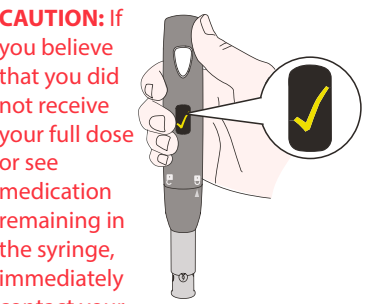


8A: Lift auto-injector from Injection Site



8B: Confirm that the Full Dose was Delivered

You will see a yellow check mark in the viewing window if the full dose was delivered.



CAUTION: If you believe that you did not receive your full dose or see medication remaining in the syringe, immediately contact your healthcare provider or medication supplier.

DO NOT attempt a second injection with the auto-injector.

Remove and Dispose of Syringe

Hold the auto-injector upright with the needle end pointing down.

Twist the syringe housing so the white alignment arrow points to the open lock symbol . Pull the syringe housing away from the injector body.

Next, tip the syringe housing so that the used syringe falls into the sharps container.

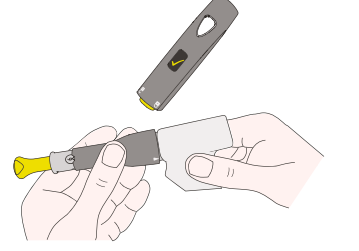
Put your used needles and syringes in a FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles and syringes in your household trash.

- If you do not have a 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
 - 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 state or local laws about how you should throw away used needles and 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>

10A: Clean Auto-injector with a Damp Cloth

After **each** injection, use a clean, damp cloth to **thoroughly** clean the auto-injector external parts and inside the syringe housing.



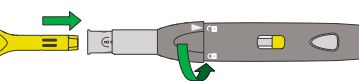
DO NOT immerse in water or clean the auto-injector with detergents, solvents, or alcohol, as this can damage the auto-injector.

Perform a visual inspection for residual soil and, if needed, repeat cleaning in the event that residual soil is visible on the device or safely dispose of the device.

10B: Storage

Assemble the auto-injector and store:

- At room temperature
- In a clean, dry place
- Out of direct sunlight



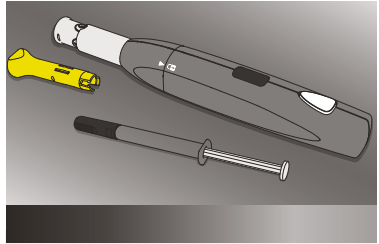
DO NOT store the auto-injector in the refrigerator.

DO NOT store syringes inside the auto-injector.

Latest revision date: February 2024

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GripMate™



Instructions for Use

IMPORTANT: Please read these instructions prior to administering your first injection, even if you have used similar auto-injector devices.

Indications For Use

The GripMate™ autoinjector is intended for use with Sun Pharma’s glatiramer acetate 20 mg/mL and 40 mg/mL prefilled syringes (a 1 mL BD Hypak Biotech glass syringe, containing a ½” fixed needle of 29G, and drug product solutions with a viscosity between 1.7 and 2.3 mPas). The GripMate™ autoinjector is a reusable injection device for patients with multiple sclerosis age 18 and older for the subcutaneous injection of Sun Pharma’s glatiramer acetate 20 mg/mL and 40 mg/mL prefilled syringes.

Each time it is setup and assembled, the auto-injector will allow a user to administer a single subcutaneous injection.

Replace the auto-injector two years after first use.

NOTE: If at any point during the use of this device, it fails to deliver the full dose, please contact your healthcare provider and/or refer to the Patient Information for instructions on how to perform a manual injection.

IMPORTANT WARNINGS

AUTO-INJECTOR PARTS

CAUTION:
Use only with 1 mL BD Hypak Biotech glass syringe, containing a ½" 29 G fixed needle and needle cap. Replace the auto-injector two years after first use.

The needle cover does not protect against accidental needle sticks. Use caution after activation and follow disposal instructions provided.

Exposure of the auto-injector to temperatures above 40°C/102°F should be avoided. Store and Use your auto-injector at a temperature between 18-28°C (65-82°F).

The auto-injector was tested with glatiramer 20 and 40 mg/mL:

Please use only with glatiramer acetate 20 and 40 mg/mL pre-filled syringes manufactured for Sun Pharmaceutical Industries Inc.

DO NOT use the auto-injector without a syringe, or with an empty or used syringe. This could damage the auto-injector.

DO NOT use if the auto-injector does not function.

DO NOT use if the auto-injector is dropped. It should be replaced.

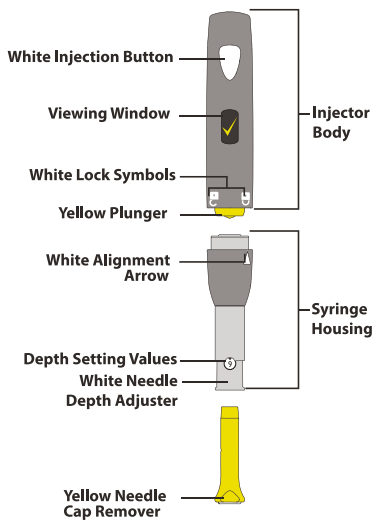
DO NOT use if the syringe is cracked or broken.

If you need help, or have any questions, please call 1-800-818-4555.

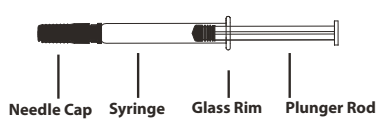
Note: For instructions regarding use refer to your Health Care Provider.

Caution: Federal law restricts this device to sale by or on the order of a physician.

WARNING !
Keep out of reach of children. **DO NOT** share your auto-injector with other people. For single patient use only. This device has not been tested for use with biologics.



PREFILLED SYRINGE PARTS



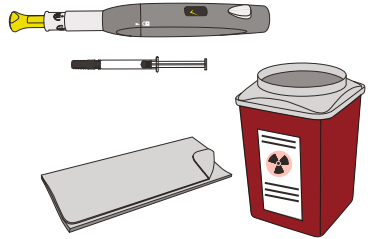
NOTE: A 1.0 mL BD prefilled glass syringe is not included with the GripMate™

Manufactured for and Distributed by:
Sun Pharmaceutical Industries, Inc.
Cranbury, NJ 08512

1 GET STARTED

1A: Remove from Package and Gather Supplies

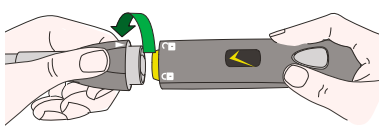
- Collect the following supplies:
- GripMate™
- Additional supplies not included with auto-injector:
- 1.0mL Prefilled Syringe
 - FDA cleared sharps container
 - Clean Damp Cloth



1B: Disassemble the Auto-injector

Twist the syringe housing so the white alignment arrow points to the open lock symbol.

Pull the syringe housing away from the injector body.

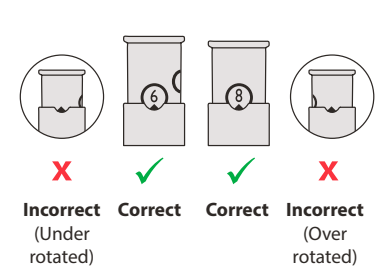
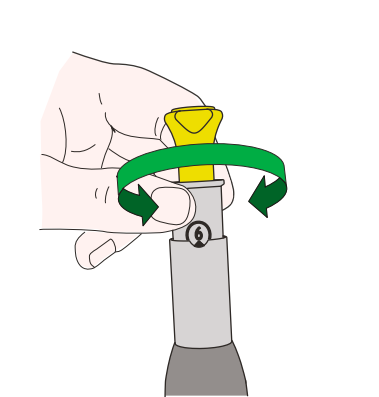


2 SET DEPTH

Set the Needle Depth

Confirm that the yellow needle cap remover is fully inserted.

Then turn the white needle depth adjuster so that the gray arrow points to your desired depth setting (6 or 8).



DO NOT twist the needle depth below 6 or beyond 8

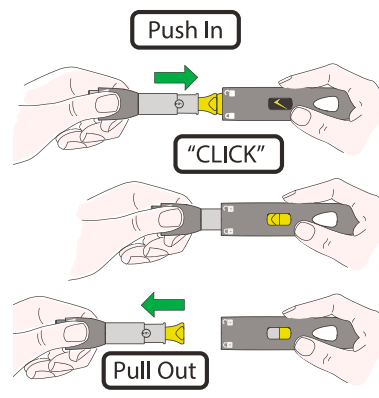
NOTE: Please check with your doctor to determine your correct needle depth setting. Smaller needle depth number (6) results in a more shallow injection and higher number (8) result in a deeper injection.

3 RESET

Reset the Auto-injector

Position the yellow needle cap remover end of the syringe housing toward the yellow plunger end of the injector body.

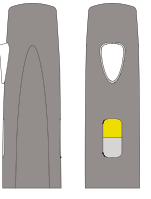
Push the syringe housing into the injector body until you hear a "CLICK". Then pull the syringe housing back out.



The auto-injector has been correctly reset when:

- The white injection button pops out
- AND
- The viewing window is half filled with a yellow color.

When Reset



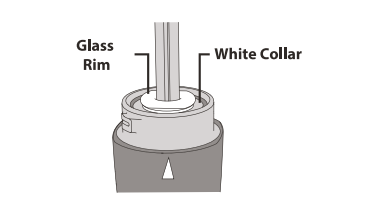
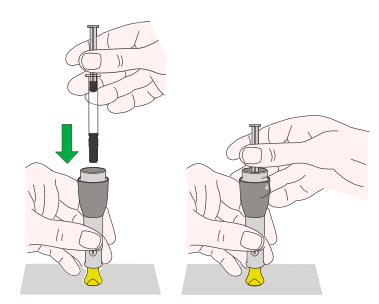
4 LOAD SYRINGE

Insert the Syringe

Hold the syringe housing down firmly against a table or flat surface with the yellow needle cap remover side down.

Insert the needle cap end of the prefilled syringe into the syringe housing until it is fully seated.

Firmly push the syringe down into the syringe housing by grasping the plunger rod just above the glass rim and pressing down until the glass rim of the syringe is touching the white plastic collar of the syringe housing.



DO NOT remove the syringe needle cap.

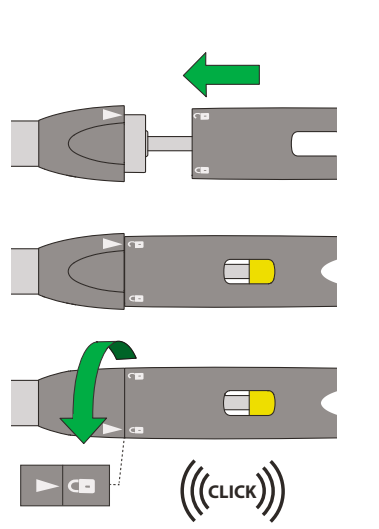
DO NOT use if the syringe is cracked or broken.

5 REASSEMBLE

Reassemble the Auto-injector

To connect the syringe housing and injector body: hold the syringe housing so the white alignment arrow points to the open lock symbol.

Then press the two parts together and turn until the white alignment arrow points to the closed lock symbol and you hear a "CLICK".



See Reverse Side of Document for Remainder of Steps