

# *Whisper*JECT<sup>®</sup>

## INSTRUCTIONS FOR USE

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



## INSTRUCTIONS FOR USE FOR *WhisperJECT*<sup>®</sup> AUTOINJECTOR

**For single patient or individual use only.**

**For Rx only.**

**The *WhisperJECT*<sup>®</sup> Autoinjector is intended for use with FDA-approved drug products with non-viscous (aqueous) liquid formulations, which are presented in a 1.0 mL BD<sup>®</sup>, pre-filled, glass syringe with staked needle, containing a fixed needle of 27G to 29G.**

**The *WhisperJECT*<sup>®</sup> Autoinjector is a reusable injection device for the subcutaneous injection of FDA-approved drugs.**

**For instructions regarding the use of the drug, refer to the drug patient information booklet provided with the drug product.**

**If the device does not function, do not use.**

*Whisper***JECT**<sup>®</sup>



For more information, call  
Mylan Pharmaceuticals Inc.  
at 1-877-446-3679  
(1-877-4-INFO-RX).

Made in U.S.A.  
Manufactured for:  
**Mylan Pharmaceuticals Inc.**  
Morgantown, WV 26505 U.S.A.

## ABOUT THE *WhisperJECT*<sup>®</sup> AUTOINJECTOR AND CARRYING CASE

The *WhisperJECT*<sup>®</sup> Autoinjector is good for two years from first day of use and should then be replaced.

“Start use no later than” date presented in month and year on the outer carton indicates the date after which therapy should not be started with this *WhisperJECT*<sup>®</sup> Autoinjector.

Once set up and assembled, the *WhisperJECT*<sup>®</sup> Autoinjector will allow a user to administer a subcutaneous injection.

While not in use, store the *WhisperJECT*<sup>®</sup> Autoinjector in the Protective Case until required for your next dose.

## IMPORTANT WARNINGS

**CAUTION:** Keep out of reach of children.

Only use the 1.0 mL BD<sup>®</sup>, pre-filled, glass syringe with staked needle, containing a fixed needle of 27G to 29G with the *WhisperJECT*<sup>®</sup> Autoinjector.

**DO NOT** share your *WhisperJECT*<sup>®</sup> Autoinjector with other people.

**DO NOT** use the *WhisperJECT*<sup>®</sup> Autoinjector without a 1.0 mL BD<sup>®</sup>, pre-filled, glass syringe or with an empty or used 1.0 mL glass syringe. This could damage the *WhisperJECT*<sup>®</sup> Autoinjector.

**After inserting the 1.0 mL BD<sup>®</sup>, pre-filled, glass syringe, DO NOT** attempt to remove the Orange Needle Cap Remover unless the *WhisperJECT*<sup>®</sup> Autoinjector is fully assembled.

**DO NOT** insert anything other than the Orange Needle Cap Remover and Syringe Housing to reset the device.

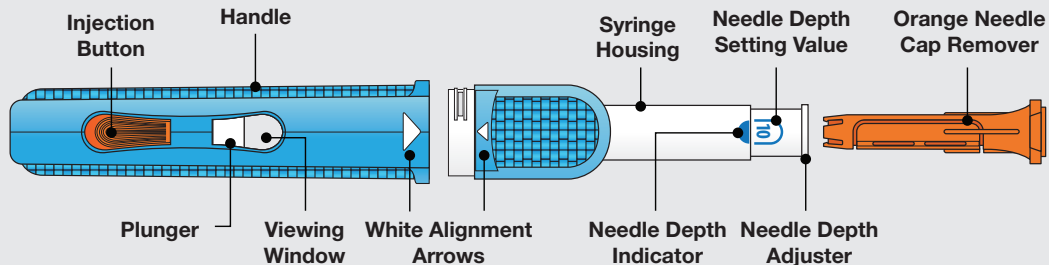
**DO NOT** twist or unscrew the Needle Depth past “10.”

**DO NOT** attempt to replace the Orange Needle Cap Remover after injection while a syringe is still in the device.

If the *WhisperJECT*<sup>®</sup> Autoinjector is dropped, it should be replaced.

**NOTE:** Refer to the Patient Information Leaflet for patient support information and to learn how to safely use the 1.0 mL BD<sup>®</sup>, pre-filled, glass syringe.

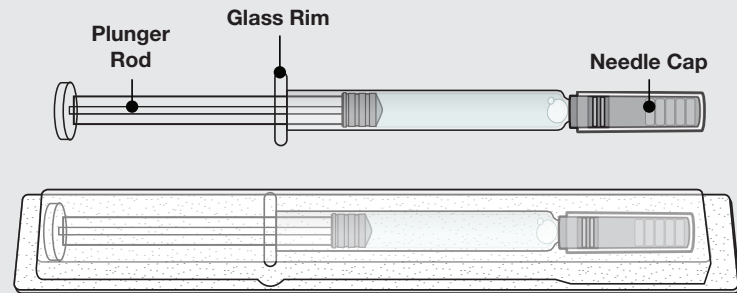
## AUTOINJECTOR PARTS



If you need help, or have any questions, please call  
1-877-446-3679 (1-877-4-INFO-RX).

## 1.0 mL BD<sup>®</sup>, PRE-FILLED, GLASS SYRINGE

*(Not Included with WhisperJECT<sup>®</sup> Autoinjector Kit)*



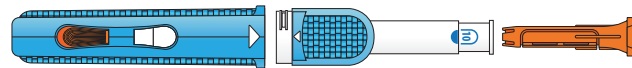
**1.0 mL BD<sup>®</sup>, pre-filled, glass syringe in Protective Blister Packaging**

## Wash Hands and Gather Supplies

Wash hands with soap and water prior to handling supplies.

Gather the following supplies:

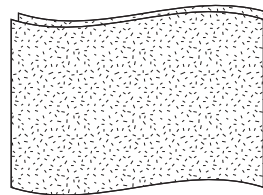
- *WhisperJECT*<sup>®</sup> Autoinjector in Protective Case
- 1.0 mL BD<sup>®</sup>, pre-filled, Glass Syringe *(not included with device)*
- Sharps Container *(not included with device)*
- Clean damp cloth for device cleaning post-injection *(not included with device)*
- Alcohol swab for skin *(not included with device)*



**WhisperJECT<sup>®</sup> Autoinjector**



**1.0 mL BD<sup>®</sup>, pre-filled, Glass Syringe**



**Clean Damp Cloth  
(for Device Cleaning)**



**Alcohol Swab**

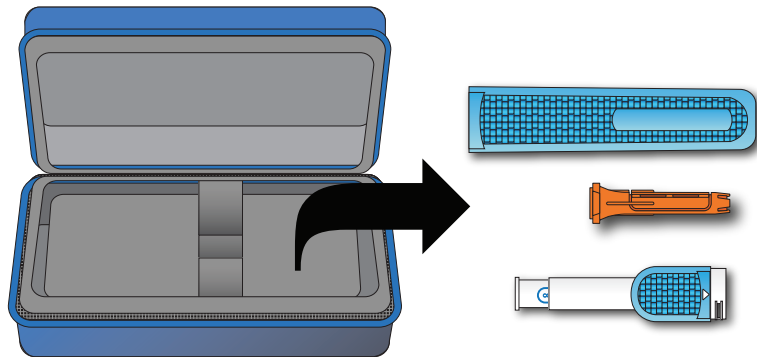


**Sharps Container**

## Step 1 – Attach the Orange Needle Cap Remover

1A

Remove the Handle, Orange Needle Cap Remover and Syringe Housing from the Protective Case.

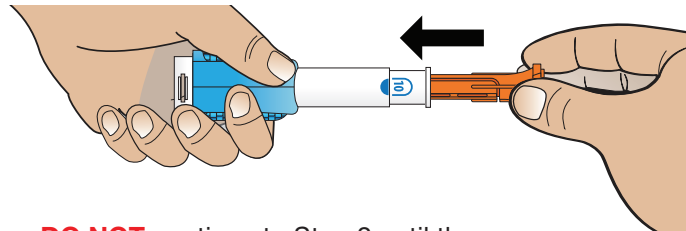


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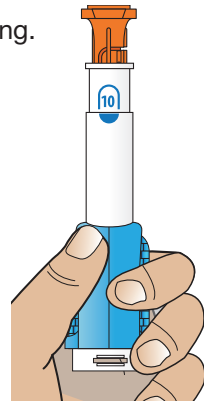
1B

Insert the Orange Needle Cap Remover into the Syringe Housing.

**Note:** The Orange Needle Cap Remover does not click into place.



**DO NOT** continue to Step 2 until the Orange Needle Cap Remover is inserted.

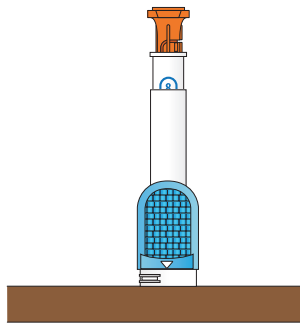


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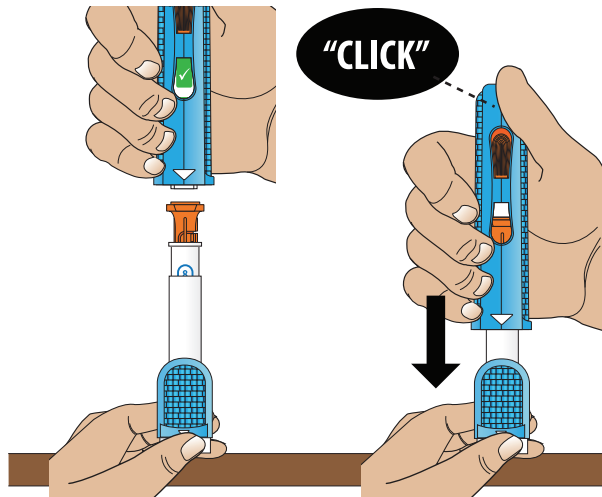
## Step 2 – Reset the Autoinjector

2A

Place the Syringe Housing on a clean flat surface with the Orange Needle Cap Remover end up.



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2B

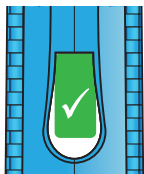
Position the Handle above the Syringe Housing with the open end of the Handle against the Orange Needle Cap Remover.

While maintaining one hand on the Syringe Housing for stability, push the Handle down onto the Syringe Housing until you feel and hear a "CLICK." This signals that the device has locked into position.

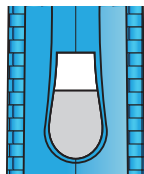
The Viewing Window should be blank (no green hash mark or check mark visible).

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## BEFORE



## AFTER



2C

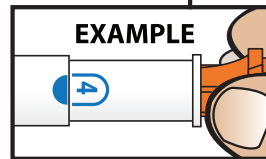
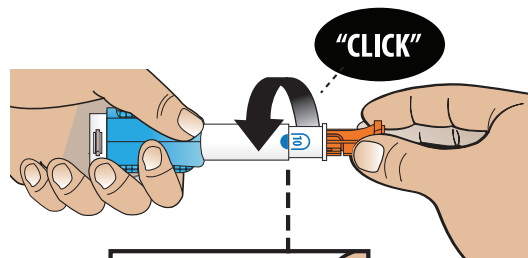
Confirm the Autoinjector is reset.

### When the Autoinjector is reset:

- The white check mark inside a green box will no longer be visible and the white Plunger will occupy about half of the Viewing Window.
- The Orange Injection Button will pop up.

**DO NOT** proceed to Step 3 until you have confirmed the Autoinjector has been fully reset.

## Step 3 – Set the Needle Depth



Needle Depth Setting of 4mm

Rotate the Orange Needle Cap Remover until the desired depth value (4, 6, 8 or 10) is aligned with the blue semi-circle (see image left). You will hear a slight “CLICK” sound when a Needle Depth Setting Value correctly lines up with the Needle Depth Indicator.

**Note:** Smaller values (4 and 6) will result in a shallow injection. Higher numbers (8 and 10) will result in a deeper injection. Check with your healthcare provider to determine your correct needle depth setting.

**DO NOT** unscrew the white Needle Depth Adjuster from device.



## Step 4 – Insert 1.0 mL BD<sup>®</sup>, pre-filled, Glass Syringe into Syringe Housing

4A

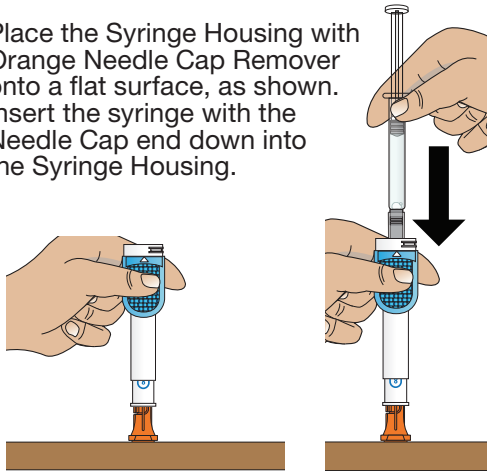
Remove the 1.0 mL BD<sup>®</sup>, pre-filled, Glass Syringe from the protective blister packaging. (1.0 mL BD<sup>®</sup>, pre-filled, Glass Syringe is not included with the *WhisperJECT<sup>®</sup>* Kit.)

**DO NOT** remove the 1.0 mL BD<sup>®</sup>, pre-filled, Glass Syringe Needle Cap.

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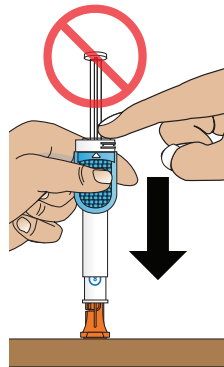
4B

Place the Syringe Housing with Orange Needle Cap Remover onto a flat surface, as shown. Insert the syringe with the Needle Cap end down into the Syringe Housing.



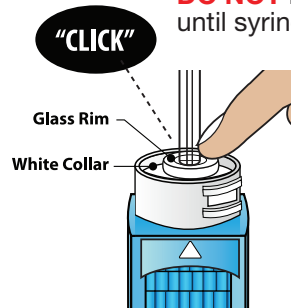
4C

Firmly push down on the Glass Rim of the 1.0 mL BD<sup>®</sup>, pre-filled, Glass Syringe so it is firmly set into the Syringe Housing. You may feel the syringe “CLICK” into place. The Glass Rim should be touching the white collar.



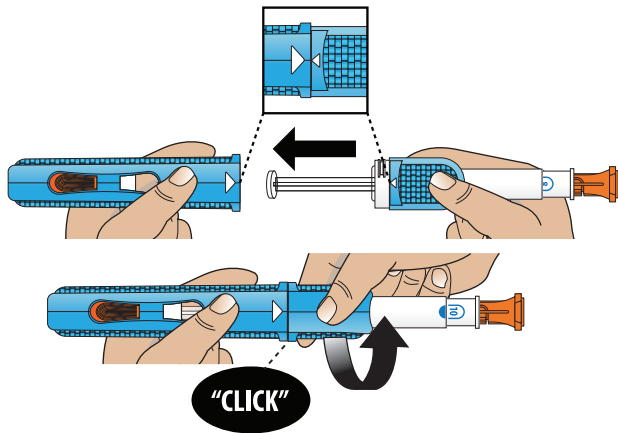
**WARNING: DO NOT** press on the Plunger Rod when inserting syringe into Syringe Housing. This may result in sterile seal being broken and loss of drug.

**DO NOT** remove the Orange Needle Cap Remover until syringe is inserted and device reassembled.



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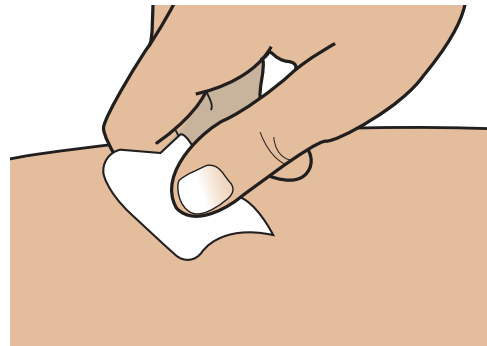
## Step 5 – Reassemble the Autoinjector



Reassemble the device by aligning the white arrows and turning the Syringe Housing until it locks into the Handle. You will hear a “CLICK” as the two parts lock together.

Once the Autoinjector is fully assembled, you are ready to start the injection process.

## Step 6 – Select and Clean Injection Site

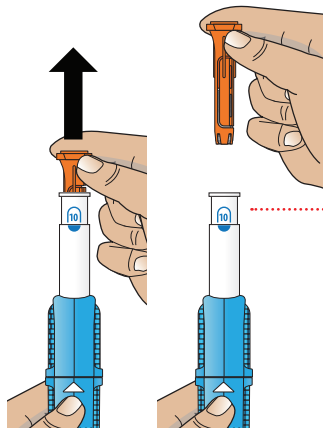


Place the Autoinjector on a clean surface before preparing your injection site.

Select the injection site. See the Patient Information Leaflet/Brochure for the allowable injection sites.

Clean injection site with alcohol swab.

## Step 7 – Remove the Syringe Needle Cap



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7A

Hold the Handle with one hand and the Orange Needle Cap Remover in your other hand, and then pull the Orange Needle Cap Remover out of the Syringe Housing. The grey pre-filled Syringe Needle Cap will be removed.

**DO NOT** replace the Orange Needle Cap Remover onto the Syringe Housing. This may damage the needle.

**DO NOT** remove the Orange Needle Cap Remover until syringe is inserted and device reassembled.

**IMPORTANT:** DO NOT press down on Needle Depth Adjuster as the needle will be exposed and you could accidentally stick and/or inject yourself.

7B

Turn the Orange Needle Cap Remover upside down over a table to allow the pre-filled Syringe Needle Cap to fall out.

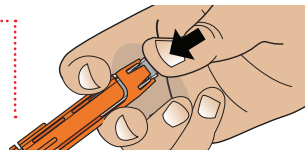
Make sure that both the rubber inner part and the transparent plastic outer part of the Needle Cap fall out.



**DO NOT** recap the syringe.

### **TROUBLESHOOTING:**

If the needle cap becomes stuck at the end of the Orange Needle Cap remover, press on the needle cap until it dislodges.



7C

Save the Orange Needle Cap Remover for future use.

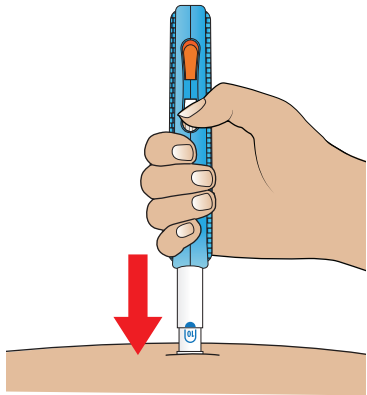
**DO NOT** dispose of the Orange Needle Cap Remover in the trash.



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## Step 8 – Inject the Dose

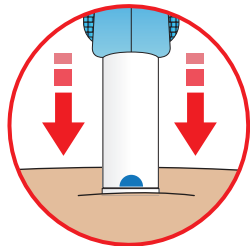
- 8A** Place the Autoinjector straight on the injection site (not at an angle).



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- 8B** Firmly push the Autoinjector down against your skin and hold in position.

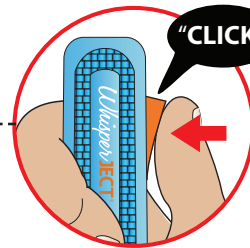
When the needle depth adjuster is fully depressed your device will be unlocked so that the orange injection button can be pressed.



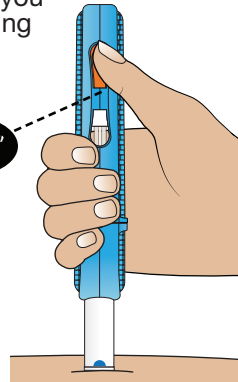
Push down & Hold to unlock

- 8C** Press the orange Injection Button to start the injection. You will hear a “CLICK” when the injection has started.

Note: Make sure you can see the viewing window.



Push to start



Continue to hold the Autoinjector down against the injection site. You will see green hash marks in the Viewing Window as the medication is injected



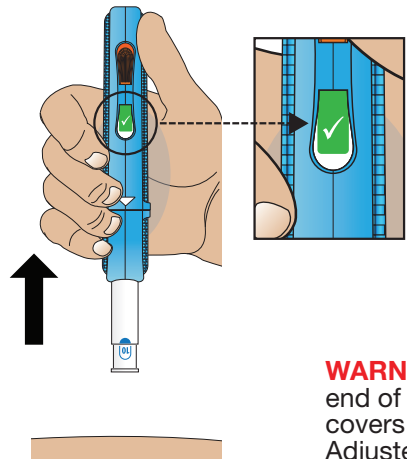
When the injection is complete, a check mark will be fully visible in the window.

If you cannot see the Viewing Window slowly count to 10 seconds after pressing the Injection Button and hearing the first “CLICK”.

**DO NOT** lift up early

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## Step 9 – Confirm Full Dose Received



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When your injection is complete, remove the Autoinjector straight up from the injection site.

Always confirm that the full dose was delivered by checking the Viewing Window. If the full dose was delivered, you will see a white check mark in a green box inside the window.

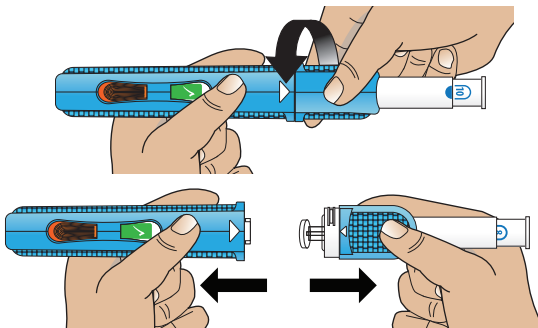
If you believe you did not receive a full dose, immediately contact your healthcare provider.

**WARNING: DO NOT** put your fingers near the needle end of the Autoinjector. The Needle Depth Adjuster which covers the needle does not lock. If the Needle Depth Adjuster is pushed, you may accidentally stick yourself.

## Step 10 – Remove and Dispose of the Used Syringe

10A

Carefully and slowly unscrew the Syringe Housing from the Handle. Hold onto the Syringe Housing that contains the used syringe.



10B

Carefully hold and tip the Syringe Housing to allow the used 1.0 mL BD<sup>®</sup>, pre-filled, Glass Syringe to fall into the Sharps Container.

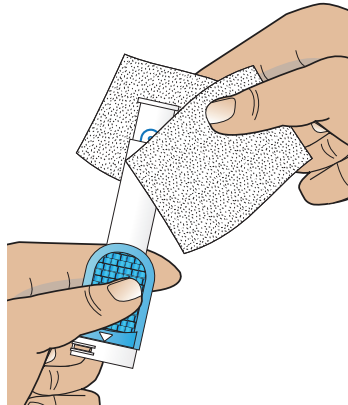
**DO NOT** dispose in regular trash or a recycling bin.

Check with your healthcare provider for the correct way to dispose of used syringes in your area.



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## Step 11 – Clean the Autoinjector



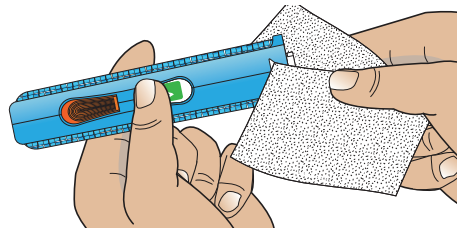
Wipe the external parts and the accessible areas of the Syringe Holder and Handle with a clean, damp cloth after each use.

**IMPORTANT:**

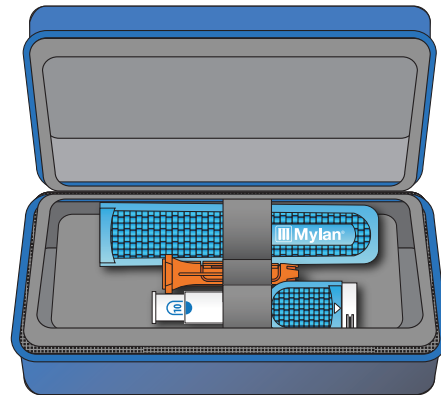
DO NOT clean the Autoinjector using any other methods (e.g., DO NOT immerse in water as this can damage the Autoinjector).

**DO NOT**

clean with detergents, solvents or alcohol.



## Step 12 – Place the Autoinjector in Protective Case for Storing



Store the Autoinjector in the Protective Case as shown until required for your next dose.

**WARNING:**

Keep in a clean dry place at room temperature and out of direct sunlight.

**DO NOT** store the Autoinjector in the refrigerator.

**DO NOT** store 1.0 mL BD<sup>®</sup>, pre-filled, glass syringe inside the device.

Manufactured for: Mylan Pharmaceuticals Inc.

\**WhisperJECT*<sup>®</sup> is available by prescription only  
WHISPERJECT is a registered trademark of Mylan Pharmaceuticals Inc.,  
a Viatris Company.

BD<sup>®</sup> is a registered trademark of Becton, Dickinson and Company.

For more information call 1-877-446-3679 (1-877-4-INFO-RX)  
or visit [Mylan.com](http://Mylan.com)

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