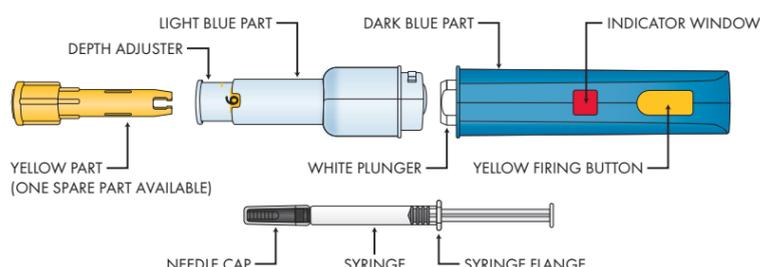


Glatopaject®

Instructions for Use



Precautions

- Only use the Glatopaject with Glatopa® pre-filled syringes manufactured by Sandoz.
- Do not operate the Glatopaject® without a syringe or with an empty syringe as this may damage the syringe or the device.
- Point the Glatopaject® away from yourself and others while loading the syringe.
- Do not use syringe if cracked or broken.
- Ensure that syringes have been adjusted to room temperature before injection. Failure to allow refrigerated drug to warm to room temperature may cause discomfort and injection times may be considerably increased.
- Do not expose the device to temperatures above 40°C/102°F, exposure to high temperatures may lead to a nonfunctional device.
- Confirm that the needle depth adjustment is correct prior to each injection.

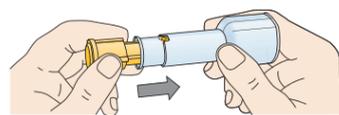
For single patient or individual use only.

The Glatopaject® is intended for use with a 1 mL glass syringe, containing a fixed needle of 27G to 29G gauge, and drug product solutions with a viscosity between 1 and 4 mPa*s. The Glatopaject® is a reusable injection device for the subcutaneous injection of FDA approved drugs. Glatopaject is intended to be used exclusively with Glatopa® (Glatiramer Acetate Injection) Pre-Filled Syringe manufactured by Sandoz.

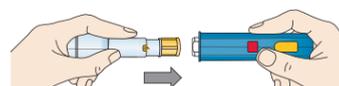
For instructions regarding the use of the drug, refer to the drug Patient Information Booklet provided with the drug product.

General instructions

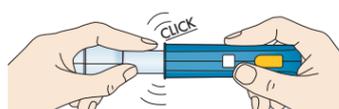
① Charging the Glatopaject®



Remove the Glatopaject® parts from the protective case. Insert the small end of the yellow part into the small end of the light blue part. Verify the correct depth setting is selected. (See Step 8 for instructions on setting the injection depth.)



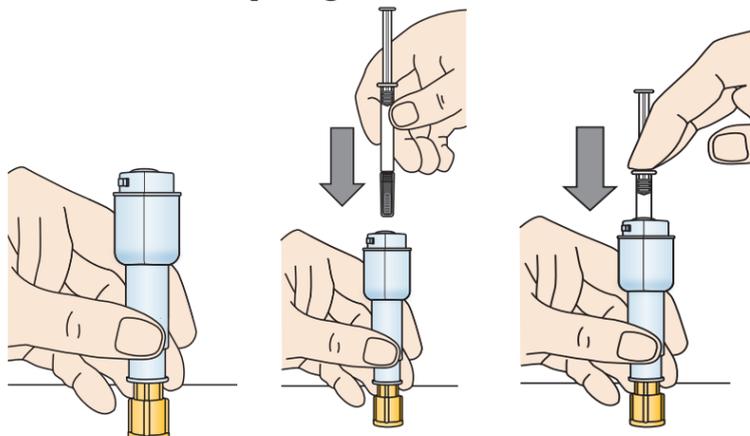
Hold the dark blue part with one hand, making sure you are not touching the Yellow Firing Button. With the other hand, push the yellow part squarely against the white plunger at the bottom of the dark blue part until a "click" is heard.



Make sure you complete this step and the Indicator Window turns white before progressing to the next step.

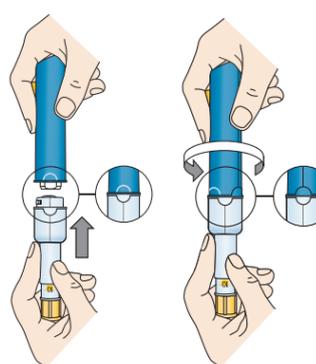
Note: To prevent drug leakage before injecting, be sure to press the parts together until you hear a click.

② Insert the Syringe



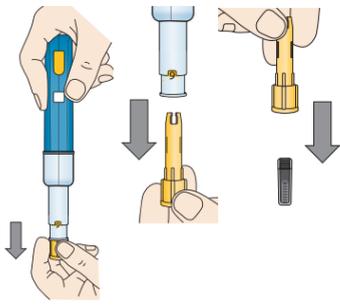
Hold the combined yellow and light blue parts upright onto a flat surface (yellow side touching the flat surface). Insert the syringe cap first into the light blue housing and use the syringe flanges to push the syringe down firmly until it cannot go any further.

③ Assemble the Glatopaject®



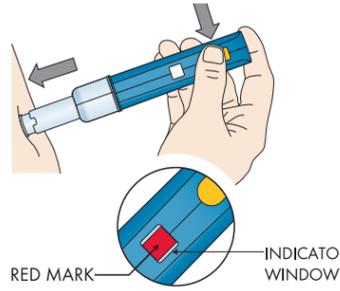
Insert the end of the light blue part into the open end of the dark blue part. Twist the light and dark blue parts together until the two semicircle marks line up to form a complete circle. Take care not to touch the Yellow Firing Button during this assembly.

4 Remove the Needle Cap



Remove the needle cap from the syringe by firmly pulling the yellow part away from the light blue part. The yellow part will come out of the light blue part with the needle cap inside. Save the yellow part for future use.

5 Perform the Injection



Note: If the end of the Glatopaject[®] is not fully depressed, the Yellow Firing Button will not be activated.

Confirm that the needle depth adjustment is correct prior to each injection. (Refer to Step 8 for how to modify the depth setting.)

Ensure that you can see the Indicator Window. Place the light blue end at a 90° angle to the injection site and firmly push the Glatopaject[®] against the injection site all the way down. Press the Yellow Firing Button keeping the device in position until the red mark appears fully in the Indicator Window. This could take up to 12 seconds. Failure to warm the drug to room temperature can lead to longer injection times. Continue to hold the Glatopaject[®] against the skin for an additional 5 seconds after the Indicator Window turns red.

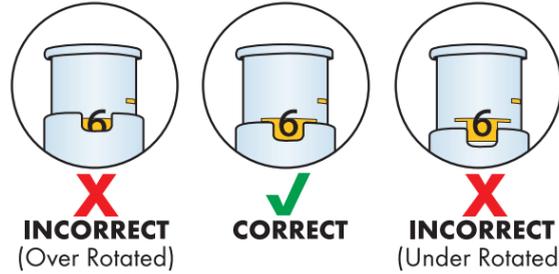
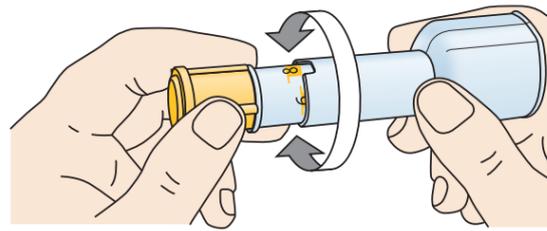
6 Removing and Disposing of the Syringe after Use

Holding the Glatopaject[®] with the dark blue part facing upwards, untwist the light blue from the dark blue part and separate the two parts slowly. Invert the light blue part above the opening of a hard-walled container, allowing the syringe to fall into the disposal container.

7 Cleaning the Glatopaject[®]

After every use, the surface of the Glatopaject[®] should be gently cleaned by wiping with a clean damp cloth. Please make sure to separate the light blue part from the dark blue part and clean all accessible surfaces. Do not immerse in water and do not use solvents.

8 Optional: Modify the Injection Depth



Typically the Glatopaject[®] is set to “6”, a setting suggested for subcutaneous injections. Your doctor or nurse may recommend a different setting. To do this, rotate the Depth Adjuster until the recommended scale mark is positioned within the notch. The yellow dashes on either side of the scale mark should be aligned with the top of the light blue part. It is possible that the needle depth adjustment setting inadvertently changes from device handling and manipulation. Confirm that the needle depth adjustment is correct prior to each injection.

9 Storing the Glatopaject[®]

After use, insert the parts of the Glatopaject[®] into their cavities inside the protective case provided. Close the zipper completely by pulling the zipper all around the case. Store the Glatopaject[®] at room temperature and avoid exposure to moisture.

The “Start use by no later than” date presented in year, month and day on the outer carton, indicates the date after which therapy should not be initiated with this Glatopaject[®].

The Glatopaject[®] is guaranteed against manufacturing defects for 2 years from date of first use. Replace the Glatopaject[®] after 2 years of use. In the unlikely event of a failure or for customer service/reorder, please contact: 1-855-Glatopa (1-855-452-8672).

Manufactured by Sandoz GmbH, Kundl, Austria
Distributed by Sandoz Inc., Princeton, NJ 08540

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