

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

This leaflet was last revised in June 2019.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: <http://www.ema.europa.eu>.

THIS MEDICINE

Is a product, which affects your health, and its consumption contrary to instructions is dangerous for you. Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicine.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers,
 Union of Arab Pharmacists.

Instructions for use:
 AMGEVITA single-use SureClick pre-filled pen
 For subcutaneous use

Guide to parts

Before use	After use

Important: Needle is inside

Important

Before you use an AMGEVITA pre-filled pen, read this important information:

Using your AMGEVITA pre-filled pen

- It is important that you do not try to give the injection unless you or your caregiver has received training.
- **Do not use** an AMGEVITA pre-filled pen if it has been dropped on a hard surface. Part of the AMGEVITA pre-filled pen may be broken even if you cannot see the break. Use a new AMGEVITA pre-filled pen.
- The needle cover of the AMGEVITA pre-filled pen is made from dry natural rubber, which contains latex. Tell your healthcare provider if you are allergic to latex.

Step 1: Prepare

A. Remove one AMGEVITA pre-filled pen from the package.

Carefully lift the pre-filled pen straight up out of the box.

Put the original package with any unused pre-filled pens back in the refrigerator.

For a more comfortable injection, leave the pre-filled pen at room temperature for 15 to 30 minutes before injecting.

- **Do not** put the pre-filled pen back in the refrigerator once it has reached room temperature.
- **Do not** try to warm the pre-filled pen by using a heat source such as hot water or microwave.
- **Do not** shake the pre-filled pen.
- **Do not** remove the yellow cap from the pre-filled pen yet.

B. Inspect the AMGEVITA pre-filled pen.

Make sure the medicine in the window is clear and colourless to slightly yellow.

- **Do not** use the pre-filled pen if:
 - The medicine is cloudy or discoloured, or contains flakes or particles.
 - Any part appears cracked or broken.
 - The pre-filled pen has been dropped on a hard surface.
 - The yellow cap is missing or not securely attached.
 - The expiration date printed on the label has passed.

In all cases, use a new pre-filled pen.

C. Gather all materials needed for your injection.

Wash your hands thoroughly with soap and water.
 On a clean, well-lit work surface, place a new, pre-filled pen.

You will also need these additional items, as they are not included in the carton:

- Alcohol wipes
- Cotton ball or gauze pad
- Plaster
- Sharps disposal container

D. Prepare and clean your injection site.

You can use:

- Your thigh
- Belly, except for a 2-inch (5 centimetre) area right around your belly button

Clean your injection site with an alcohol wipe. Let your skin dry.

Step 2: Get ready

E. Pull the yellow cap straight off when you are ready to inject.

It is normal to see a drop of liquid at the end of the needle or yellow safety guard.

- **Do not** twist or bend the yellow cap.
- **Do not** put the yellow cap back onto the pre-filled pen.
- **Do not** remove the yellow cap from the pre-filled pen until you are ready to inject.

F. Stretch or pinch your injection site to create a firm surface.

Stretch method

Stretch the skin firmly by moving your thumb and fingers in opposite directions, creating an area about 2 inches (5 centimetres) wide.

OR

Pinch method

Pinch the skin firmly between your thumb and fingers, creating an area about 2 inches (5 centimetres) wide.

Important: Keep the skin stretched or pinched while injecting.

Step 3: Inject

G. Hold the stretch or pinch. With the yellow cap off, place the pre-filled pen on your skin at 90 degrees.

Important: Do not touch the blue start button yet.

H. Firmly push the pre-filled pen down onto the skin until it stops moving.

Important: You must push all the way down but do not touch the blue start button until you are ready to inject.

I. When you are ready to inject, press the blue start button.

"Click"

J. Keep pushing down on your skin. Your injection could take about 10 seconds.

"Click"

The window turns yellow
 When the injection is done

Note: After you remove the pre-filled pen from your skin, the needle will be automatically covered.

Important: When you remove the pre-filled pen, if the window has not turned yellow, or if it looks like the medicine is still injecting, this means you have not received a full dose. Call your doctor immediately.

Step 4: Finish

K. Discard the used pre-filled pen and the yellow cap.

- Put the used pre-filled pen in a sharps disposal container immediately after use. **Do not** throw away (dispose of) the pre-filled pen in your household waste.
- Talk with your doctor or pharmacist about proper disposal. There may be local guidelines for disposal.
- **Do not** reuse the pre-filled pen.
- **Do not** recycle the pre-filled pen or sharps disposal container or throw them into the household waste.

Important: Always keep the sharps disposal container out of the sight and reach of children.

L. Examine the injection site.

If there is blood, press a cotton ball or gauze pad on your injection site. **Do not** rub the injection site. Apply a plaster if needed.