



Model 1



VIDEO MANUAL

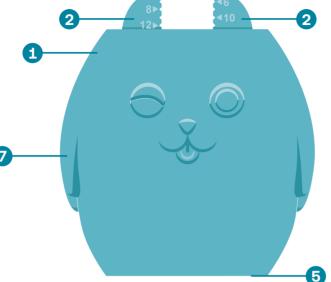
Name and type:

## **Applicator TUGI model 1**

A medical device to facilitate the injection of medicine Copaxone / Orgalutran / Ovitrelle.

The applicator is only suitable for pre-filled syringes with a diameter of 8 mm, a total construction length of 64 mm, and a needle length of 12 mm.

- The applicator is made of a silicone compound.
- Injection depth: 4 to 12 mm is adjustable on the fixing brackets to control the injection depth.
- The recommended rate of the medicine's application, i.e., pushing the plunger down, is 10 to 15 seconds.
- To maintain hygienic safety, we recommend disinfecting TUGI with an aerosol non-alcoholic disinfectant before each use. TUGI can also be cleaned with warm running water. In case of heavy soiling, the applicator can be cleaned by immersion in boiling water.
- The applicator is intended for adults. The applicator is not intended for children.
- Store at (T: +4 ° C to +35 ° C)

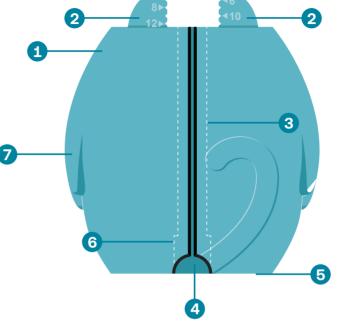


1 applicator's body

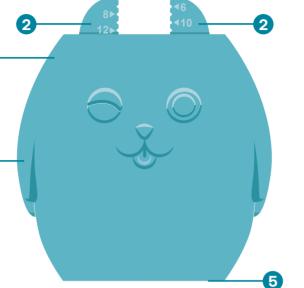
3 central syringe canal

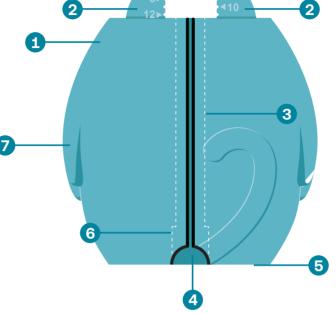
4 air duct

2 brackets for injection depth control



- 5 applicator's flat surface for stable injection
- 6 central canal extension
- 7 applicator's side





#### Intended use

TUGI is a medical device intended exclusively for the subcutaneous administration of pre-filled syringes. It facilitates and promotes the safe handling of the syringe during the medicine's administration.

The TUGI applicator is a class I medical device without a measuring function intended for repeated use.

#### Warning

The TUGI model 1 applicator is only suitable for pre-filled syringes with a diameter of 8 mm and a total construction length of 64 mm.

The use of the injection depth control function is only possible for pre-filled glass syringes with a 12 mm needle. Your doctor will recommend a specific injection depth.

For medicines where it is not necessary to control the depth of the injection (e.g., Orgalutran or Ovitrelle) and where the entire length of the needle is used for administration, the pre-filled syringe must be inserted into the applicator along its entire length so that the depth of the fixation brackets is set at 12 mm.



When used with a different syringe or needle size, incorrect dosing or administration may occur.

The service life of the TUGI model 1 applicator is 5 years from the date of manufacture stated on the applicator packaging.

## Warning / Safety Precautions

- Read these instructions and this manual carefully before use.
- Prior to use, the package and applicator must be inspected for damage.
- If the applicator is damaged, do not use it.
- The applicator is intended for repeated use.
- Always insert the syringe into the central canal of the applicator with the protective cap facing downwards; see instructions for the use of the TUGI applicator.
- Before administering a particular medicine, carefully read the package leaflet of the medicine's manufacturer and apply the recommendations for safe administration of the given medicine (e.g., disinfection of the injection site or disposal of the used material after the injection).

## Disposal

The used syringe must be disposed of as hazardous waste in a disposal container specifically designed for hazardous waste. See the TUGI applicator's instructions for use.

#### Package contents

1 TUGI applicator - a medical device for subcutaneous injection.

2 Leaflet with instructions for use.



temperature limitation (T: +4 ° C to +35 ° C)



protect from sunlight



read instructions for use

#### Manufacturer:

PROMOTON s.r.o. | Tleskačova 17 | 323 00 Plzeň | CZ www.tugi.eu/en

# Instructions for use

of the TUGI model 1 applicator for administering

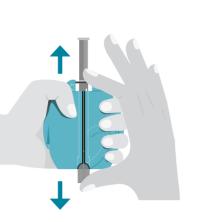
Copaxone Orgalutran Ovitrelle





The syringe with the drug is inserted into the applicator from above **between the TUGI ears.** 





While loosely holding the TUGI, set the desired injection depth. The depth of the injection (in millimeters) corresponds to the number on the fixing brackets (TUGI's ears).

IMPORTANT! For Orgalutran and Ovitrelle, the injection depth is always set to 12 mm.

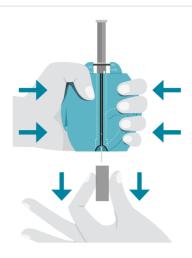
Example: by fixing the syringe at number 6, the depth of the injection is set to 6 millimeters.

about the appropriate depth of injection.

MPORTANT! For Orgalutran and

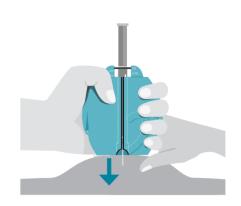
Consult your doctor in advance

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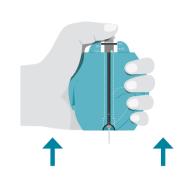


Still holding the TUGI applicator in the palm of your hand, carefully remove the needle cover with your other hand and place it in a pre-prepared hazardous waste container.

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Make a controlled injection perpendicular to the skin. When injecting, the support surface of the TUGI applicator must rest on the formed skin fold.



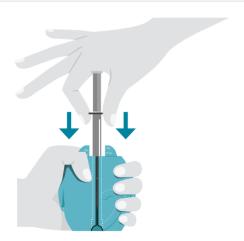
After administering the full dose, carefully and vertically lift the applicator from the injection site. Then loosen the skin fold.





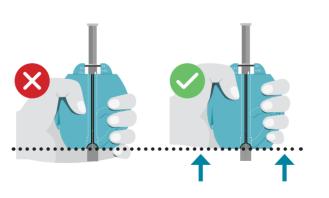
VIDEO MANUAL





Loosely hold the TUGI applicator in the palm of your hand and, with your other hand, lower the syringe into the central channel of the TUGI applicator with the needle cover facing down.

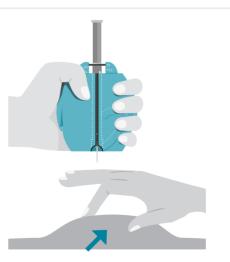




**IMPORTANT! Check the grip.** Press TUGI lightly. This will securely fix the syringe and the entire TUGI applicator in your palm. The hand must not restrict the full use of the support surface when gripping the TUGI applicator. This support surface must be completely free. Only then can you proceed to perform the following steps and administer the medicine safely.

Hold the TUGI applicator firmly; however, there is no need to press TUGI hard.

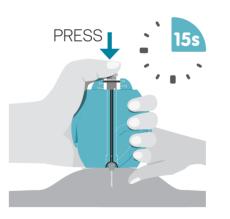




Use your free hand's index finger and thumb to gently pinch the skin to create a skin fold at a pre-selected location on your body.

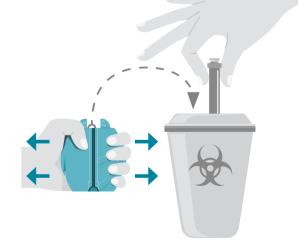
Avoid painful squeezing of the skin.





Inject the medicine. Slowly push the plunger of the syringe all the way down with your thumb. The recommended rate of administration of the full dose is 10 to 15 seconds.





Loosen the grip on the TUGI applicator and the syringe. With your other hand, carefully remove the syringe and dispose of it in a pre-prepared hazardous waste container.