
A member of Michele Peresso Group of Companies

20th February, 2017

Goserelin (Golexin[®]) Implants: Instructions for implant administration
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Dear Healthcare Professional,

Europharma Ltd, on behalf of the marketing authorization holder of Goserelin (Golexin[®]) Implants, AMW GmBH, in agreement with the European Medicine Agency and Malta Medicine Authority, would like to inform you of the following:

Summary

- **Importance of following implant administration procedure described in 'Instructions for use' to ensure correct, successful administration of implant.**
- **'Instructions for use' may be found attached to foil of each implant supplied, and reproduced with this letter for your convenience.**

Background

Inadequate adherence to 'instructions for use', as clearly described with each Golexin implant, when administering this implant may result in damage to implant device. This is particularly important when it comes to removing the protective cover, which as outlined in point 2 of 'instructions for use', should be carried out whilst [gripping on the syringe barrel](#).

For your convenience, we are reproducing the 'instructions for use' found on each Golexin Implant with this letter. We kindly ask you to read through these 'instructions for use' to ensure each Golexin Implant is injected in the way it was engineered to be injected.

Call for Reporting

May we kindly remind you to report any adverse reactions in line with local and European requirements.

Company Contact Point

Additional information is available from



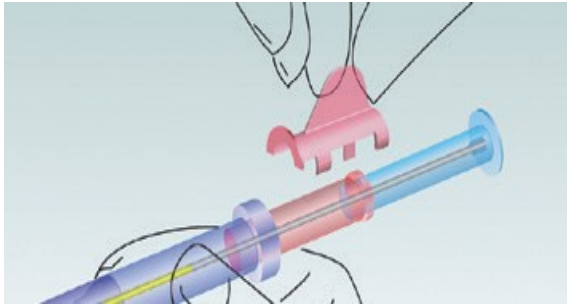
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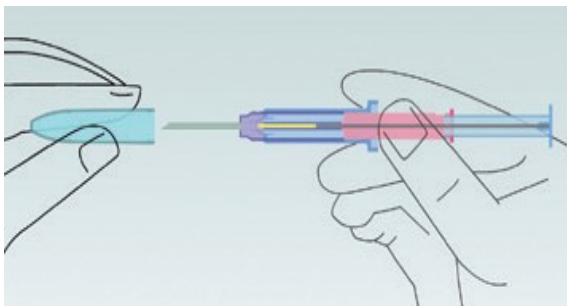
[Company Directors:](#) Emanuel Peresso (CEO), Michael Peresso Jnr, Maria Christina Peresso, Victoria Peresso

[Bankers:](#) HSBC Bank Malta plc [Company Registration Number:](#) C1822 [VAT Registration Number:](#) 1219-7413

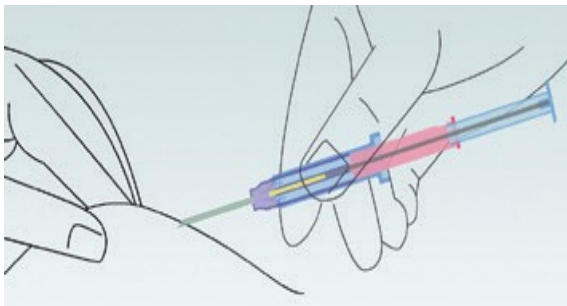
Instructions on use for administering Golexin Implants



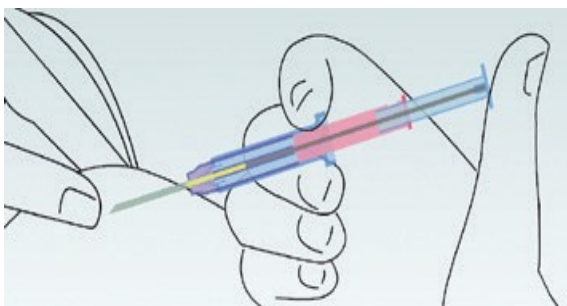
1. Remove the applicator from the sterile pack. Check whether the implant is in the intended position in the applicator. Remove the safety ring.



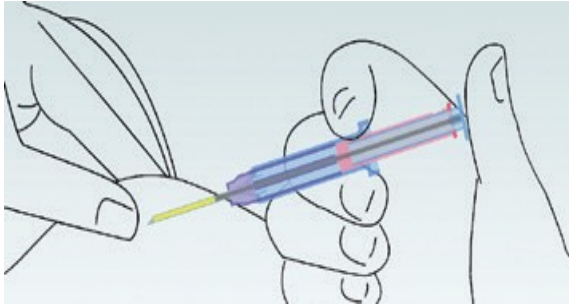
2. Grip the applicator on the syringe barrel and remove the protective cover.



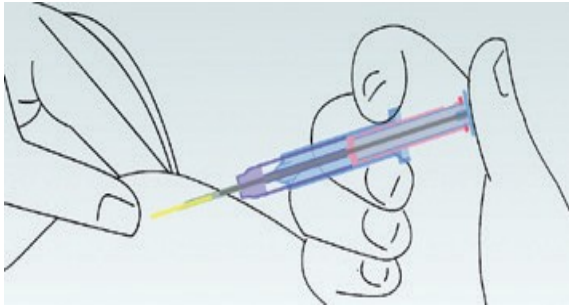
3. Press the skin of the patient together while you are comprising the syringe barrel and insert the needle obliquely (almost parallel to the skin). Insert the needle so far into the subcutaneous tissue (not in muscle or into the abdominal cavity) of the anterior abdominal wall under the umbilical line, until the syringe barrel touches the patient's skin. **This contact with the skin must remain during the entire application process!**



4. Press the syringe plunger down. The implant is transported to the needle tip. Do not pull the syringe back in any case. During the application the syringe barrel has to touch the skin of the patient!

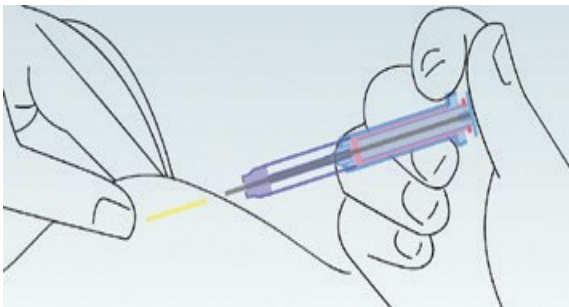


5. When the plunger is stopped, the needle retraction is unlocked automatically.

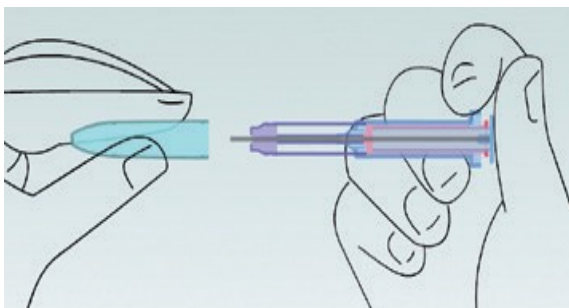


6. The needle is retracted from the tissue into the syringe barrel. **The syringe barrel must remain in contact with the patient's skin.**

Normally the plunger movement forward and needle retraction are carried out in one smooth motion.



7. The application process is completed. The needle has been fully retracted into the barrel of the syringe. The supernatant mandrel protects against injury at the needle tip.



8. Replace the protective cover again. Dispose the syringe in the container provided.