ORGALUTRAN® (ganirelix injection) – Clarification regarding the Product Monograph and Latex Component

Dear Healthcare professional,

Organon Canada would like to inform you of the following:

Summary

- **Orgalutran is indicated for the prevention of premature luteinizing hormone surges in women undergoing controlled ovarian hyperstimulation for assisted reproduction techniques.**
- **Orgalutran is currently packaged as a disposable prefilled syringe that is affixed with a needle closed by a needle shield of dry natural rubber/latex. Orgalutran is contraindicated in patients who are hypersensitive to this drug or to any ingredient in the formulation including dry natural rubber/latex or to any similar peptides.**
- **The product currently available on the Canadian market is the version containing latex. The product on the market contains a latex warning on the box and in the package insert. However, the online product monograph approved by Health Canada on January 11th, 2024 does not include a latex warning since the online product monograph reflects the features of the updated latex-free product that will be available on the market in 2025.**
- **As mentioned above, Organon Canada is planning to introduce new pre-filled syringes to the Canadian market in 2025 in which the piston and needle shield are not made with natural rubber latex.**
- **Organon Canada estimates that depletion of current stock (with latex) on the market will take until February 2025. The expiry date of the last lot of latex-containing product is February 28th, 2026. Organon Canada will update the online product monograph to reflect both sets of information (with latex and without latex).**
- **Please check the packaging and package insert to confirm whether it contains latex before administration of the product until the expiry of the last lot containing latex.**

Hypersensitivity Warnings and Precautions

Very rare cases of hypersensitivity reactions (both generalized and local) including various symptoms such as rash, facial swelling and dyspnea, have been reported with Orgalutran, as early as with the first dose, during post-marketing surveillance. These events have included anaphylaxis (including anaphylactic shock), angioedema, and urticaria. If a hypersensitivity reaction is suspected, Orgalutran should be discontinued, and appropriate treatment administered. In the absence of clinical experience, Orgalutran treatment is not advised in women with severe allergic conditions.

Report an Adverse Event

Please report any suspected adverse events associated with the use of Orgalutran by contacting Organon Canada Medical Information Centre:

1-844-820-5468/ 1-450-366-1750

medinfocanada@organon.com