ORGALUTRAN® (ganirelix injection) – Two syringe versions, on the Canadian market: one with latex and one without latex

Dear Healthcare professional,

Organon Canada would like to inform you of the following:

- Orgalutran is indicated for the prevention of premature luteinizing hormone surges in women undergoing controlled ovarian hyperstimulation for assisted reproduction techniques.
- In the Canadian market:
    - The **current version of Orgalutran affixed with a needle closed by a needle shield of dry natural rubber/latex** has an expiry date of February 28th, 2026 or earlier (depending on the lot).
    - In March 2025, Organon will be introducing **a new version of the pre-filled syringes of Orgalutran** in which the piston and needle shield are not made with natural rubber latex.
    - **As a result, for a certain period of time, two versions of the product will be available: one containing latex and one without latex**.
- The product monograph of Orgalutran reflects both sets of information (with latex and without latex).
- Products with latex have a latex warning on the box and in the package insert. Products without latex have a package insert containing information either about the two versions of syringes available or the latex-free version of syringes only.
- For patients with hypersensitivity to latex, please check the packaging to confirm whether it contains latex before use of the product.

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