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| Product name: <b>Esteve<br/>Gonadorelin 100mcg Carton</b><br>Reference: XXXXXXX<br>Artwork origination: 29/06/22<br>Last Modified: 23/08/22<br>Dimensions (mm): 148.5 x 210 | Printed Colours:<br> | Non Printed<br> |
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## PATIENT INFORMATION LEAFLET

# Gonadorelin 100 micrograms powder for solution for injection

**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### **In this leaflet:**

1. What Gonadorelin injection is and what it is used for
2. Before you take Gonadorelin injection
3. How to take Gonadorelin injection
4. Possible side effects
5. How to store Gonadorelin 100 micrograms powder for solution for injection
6. Further information

## **1. WHAT GONADORELIN INJECTION IS AND WHAT IT IS USED FOR**

This product's full name is Gonadorelin 100 micrograms powder for solution for injection. In this leaflet it is referred to as Gonadorelin or Gonadorelin injection.

The powder in the vial contains 100 micrograms of the active ingredient gonadorelin as gonadorelin hydrochloride and lactose monohydrate. The powder is dissolved in 1 ml of sterile water for injections before use.

Gonadorelin is a synthetically produced hormone which is the same as a naturally occurring hormone (LH/FSH-RH).

Gonadorelin injection is used to help check whether the hormones called luteinising hormone (LH) and follicle-stimulating hormone (FSH), which occur naturally within the human body, are being produced and released at the correct levels.

LH stimulates egg production (ovulation) from the ovary in the female, and the hormone testosterone from the testicle in the male. FSH stimulates the ovaries to release eggs, and the testicles to produce sperm.

## 2. BEFORE YOU TAKE GONADORELIN INJECTION

### Do not take Gonadorelin injection if you:

- are **allergic** (hypersensitive) to Gonadorelin, similar medicines, or to lactose.
- are, or suspect you may be, **pregnant**
- are **breast-feeding**

### Take special care with Gonadorelin injection

If you are in the early part of your menstrual cycle, adequate contraceptive measures should be taken.

Gonadorelin injection may provoke **early ovulation** in women. If you rely on the timing of your menstrual cycle to avoid pregnancy, then you need to be aware of this risk.

Gonadorelin injection is not recommended if you have a brain tumour called a pituitary adenoma.

### Taking other medicines

You should tell your doctor if you are taking or have taken any of the following medicines:

- spironolactone (diuretic)
- steroids (such as glucocorticoids)
- oestrogens, progestogens, androgens or oral contraceptives (hormones)
- phenothiazines (psychiatric medicine)
- levodopa (Parkinson's medicine)
- dopamine antagonist (schizophrenia medicine)
- digoxin (heart medicine)

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

### Pregnancy and breast-feeding

If you are pregnant, likely to become pregnant or are breast-feeding, you should not receive Gonadorelin injection. Ask your doctor or pharmacist for advice before taking any medicine.

### Driving and using machines

Gonadorelin injection should not affect your ability to drive or operate machinery.

## 3. HOW TO TAKE GONADORELIN INJECTION

Gonadorelin injection should be given in a hospital under the supervision of an appropriate healthcare professional.

### Dosage

The powder is dissolved in 1 ml of sterile water for injections before use.

Gonadorelin is given by means of a small injection under the surface of the skin or into a vein.

The doctor or nurse will take several blood samples before and after you receive the Gonadorelin injection to monitor hormone levels.

In women, Gonadorelin injection should be given in the first week of the menstrual cycle.

### If you take more Gonadorelin than you should

This is unlikely, since you will be given Gonadorelin injection by a healthcare professional. Large doses do not seem to produce any unwanted effects which are not seen at normal doses.

### If you forget to take Gonadorelin injection

This is unlikely, since you will be given Gonadorelin injection by a healthcare professional. If you suspect that you have not been given Gonadorelin injection correctly then contact your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, Gonadorelin injection can cause side effects, although not everybody gets them.

### Allergic reaction

Allergic reactions have occurred on rare occasions after several doses. These may produce a wheezing cough, a rapid heartbeat, flushing, rash, swelling, itching, redness of face, eyelids and lips, or a hard lump at the injection site.

### Menstrual cycle changes

Gonadorelin injection may interfere with women's menstrual cycles, causing early ovulation. If you are practising the rhythm method of contraception you should employ a barrier method of contraception for the period of treatment, or take other steps to avoid unwanted pregnancy.

Gonadorelin may cause heavy and/or prolonged menstrual periods (menorrhagia).

### Rare side effects

Headaches, nausea, lightheadedness, stomach discomfort or hot flushes.

### Local side effects

Occasionally, swelling, with or without pain and a rash, may occur at the point where the injection was given.

A skin rash at the point where the injection was given, or covering a wider area of skin, has sometimes been seen in situations where the injection has been given repeatedly over a long period of time.

Very rarely, pain underneath and inflammation around the site of injection with accompanying feverishness has been reported.

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at Website: <http://www.mhra.gov.uk/yellowcard> or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. HOW TO STORE GONADORELIN 100 MICROGRAMS POWDER FOR SOLUTION FOR INJECTION**

Keep out of the sight and reach of children.

Do not use Gonadorelin 100 micrograms powder for solution for injection after the expiry date, which is stated on the label and carton.

Store the unopened pack below 25° C.

Store the reconstituted solution in a refrigerator (2 - 8°C). If unused after 24 hours it must be discarded.

Do not use Gonadorelin 100 micrograms powder for solution for injection if you notice that the reconstituted solution is discoloured.

## **6. FURTHER INFORMATION**

### **Marketing authorisation holder and manufacturer**

Esteve Pharmaceuticals Ltd, The Courtyard Barns, Choke Lane, Cookham Dean, Maidenhead, Berkshire SL6 6PT, United Kingdom

This leaflet was last revised in August 2022.