

## **Patient Information Leaflet**

### **HRF\* 100 micrograms powder and solvent for solution for injection**

#### **Gonadorelin**

Please read this leaflet before you receive this injection. It is essential to follow your doctor's advice. If there is anything you do not understand please ask your doctor or pharmacist.

*Keep this leaflet until you have finished your test, as you may want to read it again.*

#### **What is HRF 100 micrograms powder and solvent for solution for injection?**

Each pack of HRF 100 micrograms powder and solvent for injection contains a vial and an ampoule. The powder in the vial contains 100 micrograms of the active ingredient gonadorelin as gonadorelin hydrochloride and lactose monohydrate. The ampoule contains 5 ml of a solution of benzyl alcohol in water for injections, which is used as a solvent. The powder is dissolved in 1 ml of the solvent before use. Discard excess.

#### **What type of medicine is this?**

HRF is a synthetically produced hormone which is the same as a naturally occurring hormone (LH/FSH-RH). HRF is given by means of a small injection under the surface of the skin or into a vein.

#### **Who makes the injection?**

The manufacturer and product authorisation holder is:

Intrapharm Laboratories Ltd, The Courtyard Barns, Choke Lane, Cookham Dean, Maidenhead, Berkshire SL6 6PT, United Kingdom.

#### **What is the injection for?**

HRF 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 produce eggs, and the testicles to produce sperm.

#### **When should you not receive HRF injection?**

You should not receive this medicine if you:

- are allergic to gonadorelin or certain other similar medicines; your doctor can advise on these.
- are, or suspect you may be, pregnant.
- are breastfeeding.

HRF injection contains the preservative benzyl alcohol which is generally well tolerated in adults (it is not, however, suitable for injections given to children under one year old).

#### **Before receiving HRF injection**

If the answer to any of the following questions is yes, talk to your doctor before your test with HRF injection starts.

- Are you taking any of the following medicines, which may interfere with the way HRF works: a diuretic called spironolactone, steroids such as glucocorticoids, hormones such as oestrogens, progestogens, androgens or oral contraceptives? Your doctor can advise on these.
- Are you taking any of the phenothiazine class of drugs for psychiatric conditions, or levodopa for Parkinson's disease?
- Are you taking a type of drug called a dopamine antagonist, which may be used to treat schizophrenia?
- Are you taking a drug called digoxin used to treat heart disease?

- Are you in the first part of your menstrual cycle? If so, adequate contraceptive measures should be taken.

HRF injection should be given in hospital under the supervision of an appropriate healthcare professional. Very rarely people find that they react to some of the other ingredients in products. Of these other ingredients, HRF injection contains benzyl alcohol and lactose monohydrate.

### **What dose of HRF injection should you be given?**

100 micrograms of HRF injection can be given as one single dose under the skin or into the vein. In women, it should be given during the first 7 days of their menstrual cycle.

It will be given by a healthcare professional according to the following procedure:

Reconstitute the 100 microgram vial with **1 ml only** of the accompanying solvent and discard unused solvent. Prepare solution immediately before use. After reconstitution, refrigerate at 2-8°C and use within 24 hours. If unused after 24 hours the remaining solution and solvent must be discarded. Do not use HRF injection if the powder, solvent or resulting solution is discoloured: the powder should be white to off-white and the solvent and solution should be clear and colourless.

Procedure:

- Blood samples are drawn at 15 minutes and immediately before HRF is given. The LH baseline is obtained by averaging the LH values of the two samples.
- A dose of HRF is given.
- Blood samples are drawn at 15, 30, 45, 60 and 120 minutes after administration.
- Blood samples should be handled as recommended by the laboratory that will determine the LH content.

### **What if I have been given too much?**

This is not likely, because of the type of situation in which HRF injection is used. Large doses do not seem to produce any unwanted effects which are not seen at normal doses.

### **What should I do if a dose is missed?**

This is unlikely because of the type of situation in which HRF Injection is used. As the medicine is given by a healthcare professional, should you suspect that a dose has been missed, contact them and they will tell you what you should do.

### **What unwanted effects might it have?**

HRF 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.

Rarely, HRF injection can cause headaches, nausea, lightheadedness, stomach discomfort or hot flushes. 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. 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.

### **How can I obtain more information about HRF Injection?**

In this short leaflet we can only give you the most important patient information about **HRF** Injection. If you would like to know more ask your doctor or pharmacist.

### **How to store HRF powder and solvent for solution for injection**

Keep out of reach and sight of children.

Do not use HRF powder and solvent for solution for injection after the expiry date, which is stated on the labels and carton.

Store the unopened pack below 25 C

Store the reconstituted solution in a refrigerator (2°C – 8°C). If unused after 24 hours the remaining solution or solvent must be discarded.

Do not use HRF powder and solvent for solution for injection if you notice that the reconstituted solution or solvent is discoloured.

\* Trade Mark

This leaflet was last revised in November 2014.