

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

HRF 100 micrograms powder and solvent for solution for Injection

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains 100 micrograms of gonadorelin as Gonadorelin Hydrochloride.

After reconstitution with 1ml of the solvent for injection provided the resulting solution contains 100 micrograms/ml gonadorelin as gonadorelin hydrochloride.

Excipient: the solvent for injection contains 2.0% w/v benzyl alcohol (E1519)

For the full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Powder and solvent for solution for injection.

Powder: a white to off white lyophilised powder

Solvent: a clear, colourless solution.

The reconstituted solution has a pH of 4.0 to 8.0

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

HRF is indicated for the evaluation and assessment of the functional capacity and response of gonadotrophic pituitary reserve of luteinising hormone and follicle stimulating hormone in patients with possible impairment of pituitary function or hypothalamopituitary function.

### 4.2 Posology and method of administration

#### Route of administration

For subcutaneous and intravenous administration only.

#### Adults and Children

The test should be carried out in the early follicular phase of cycle (days 1-7).

100 micrograms as a single dose given by rapid injection. For more refined studies doses of 25 to 500 micrograms daily have been used. In females in whom the phase of the menstrual cycle can be established, the test should be done in the early follicular phase day 1-7.

### 4.3 Contraindications

HRF 100 micrograms Injection is contraindicated:

- During known or suspected pregnancy
- In children less than 1 year of age in view of presence of benzyl alcohol as a solvent.
- In patients who are hypersensitive to the product.

### 4.4 Special warnings and precautions for use

Administration of the releasing hormone during the follicular phase of the menstrual cycle may induce premature ovulation and appropriate measures are advised to avoid unwanted pregnancy.

Failure of response to a single injection requires retesting since one injection may give insufficient stimulus.

Tests using HRF should be carried out and interpreted under the direction of the appropriate specialist.

### 4.5 Interaction with other medicinal products and other forms of interaction

Certain drugs affect pituitary gonadotrophin production. These include: oestrogens, progestogens, androgens and glucocorticoids. Oral contraceptives and digoxin suppress gonadotrophin while phenothiazines may blunt the response to HRF. Levodopa and spironolactone increase gonadotrophin levels and dopamine antagonists give rise in serum prolactin.

### 4.6 Fertility, pregnancy and lactation

HRF 100 micrograms Injection should not be administered to pregnant women or nursing mothers.

### 4.7 Effects on ability to drive and use machines

None known.

### 4.8 Undesirable effects

Side effects have not yet been reported with diagnostic use but allergic reactions would be expected. Headache, light headedness, flushing and abdominal pain and hypersensitivity have been reported.

### 4.9 Overdose

HRF has been administered parenterally in doses up to 3 mg bd for 28 days without any signs or symptoms of overdosage. In cases of overdosage or idiosyncrasy, symptomatic treatment should be administered as required.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Gonadorelin stimulates the synthesis of follicle stimulating hormone and luteinising hormone in the anterior lobe of the pituitary as well as their release.

### 5.2 Pharmacokinetic properties

Gonadorelin is rapidly hydrolysed in plasma and excreted in urine with a half life of about 4 minutes.

### 5.3 Preclinical safety data

None applicable.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

*Powder*

Lactose monohydrate

*Solvent*

Benzyl alcohol (E1519)

Water for injections

### 6.2 Incompatibilities

This medicinal product must not be mixed with other medicinal products, except those mentioned in section 6.6

### 6.3 Shelf life

Unopened vial: 3 years if stored below 25°C

After reconstitution: 24 hours refrigerated at 2-8°C.

### 6.4 Special precautions for storage

Do not store above 25°C.

For storage of the reconstituted medicinal product, see section 6.3

### 6.5 Nature and contents of container

The powder is supplied in a clear Type 1 glass vial with a grey butyl rubber stopper and an aluminium collar. The sterile solvent is supplied in a clear 5ml Type 1 glass ampoule. Each pack comprises a carton containing one vial and one ampoule.

### 6.6 Special precautions for disposal and other handling

Preparation for single injection administration

Reconstitute the contents of one vial of HRF 100 micrograms powder for solution for injection with 1.0ml of the accompanying sterile solvent of 2% w/v benzyl alcohol. Discard remaining solvent. The reconstituted solution is a clear, colourless solution

Prepare the solution immediately before time of first injection.

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 H.R.F. 100 micrograms powder and solvent for solution for injection if the powder or solvent is discoloured, or if the reconstituted solution is discoloured.

**7 MARKETING AUTHORISATION HOLDER**

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**8 MARKETING AUTHORISATION NUMBER**

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**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 29 September 1978

Date of last renewal: 25 February 2008

**10 DATE OF REVISION OF THE TEXT**

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