Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

GEREF® 50

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ampoule of powder contains sermorelin acetate equivalent to 50 micrograms of sermorelin.

Each ampoule of Geref is accompanied by a solvent ampoule containing 0.9 % Sodium Chloride Injection BP.

3 PHARMACEUTICAL FORM

Powder and solvent for solution for injection
A white, sterile, pyrogen-free, crystalline powder for solution for injection in a clear, Type I glass ampoule accompanied by a clear, Type 1 glass ampoule containing a clear colourless, sterile solution for reconstitution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the evaluation of the functional capacity and response of the somatotrophs of the anterior pituitary.

4.2 Posology and method of administration

Recommended procedure: A single intravenous injection of 1.0 microgram/kg body weight in the morning following an overnight fast.

Geref should be reconstituted immediately before use with a minimum of 0.5ml of the accompanying sterile solvent.

Venous blood samples should be drawn 15 minutes before and immediately prior to Geref administration. Venous blood samples are then drawn at 15, 30, 45 and 60 minutes following Geref injection. Samples at 90 and 120 minutes are optional, since in the majority of patients they do not give additional information.

4.3 Contraindications

Use in patients known to be hypersensitive to sermorelin acetate or any of the excipients of Geref.

Use during pregnancy or lactation.

4.4 Special warnings and precautions for use

The test should only be carried out and interpreted under specialist supervision.

Patients already on growth hormone therapy should have therapy discontinued one to two weeks pre-test.

The test should be carried out with particular caution in patients with diabetes mellitus or epilepsy.

Untreated hypothyroidism or use of anti-thyroid medications such as propylthiouracil or high levels of somatostatin at the time of injection may affect the response to Geref.

Obesity, hyperglycaemia and elevated plasma fatty acids are generally associated with poor GH responses to Geref.

4.5 Interaction with other medicinal products and other forms of interaction

The Geref test should be conducted in the absence of drugs which affect directly the pituitary secretion of somatotrophin. These would include preparations which contain or induce the release of somatostatin, insulin, or glucocorticoids, and cyclo-oxygenase inhibitors such as aspirin and indomethacin.

The somatotrophin levels may be transiently elevated by clonidine, levodopa or insulin-induced hypoglycaemia. The response to Geref may also be reduced by anti-muscarinic agents such as atropine.

It is possible that beta adrenoceptor agonists and blockers may affect responses to Geref.

4.6 Pregnancy and lactation

The product should not be used during pregnancy or lactation.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Facial heat, facial flush and injection site pain occasionally occur and usually disappear within a few minutes.

4.9 Overdose

No data relating to acute overdosage are available.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Sermorelin is a synthetic peptide consisting of the 1-29 amino acid sequence of natural GHRF(Growth Hormone Releasing Factor).

5.2 Pharmacokinetic properties

Sermorelin has a plasma half life of 6-7 minutes after intravenous administration. Peak response is reached approximately 30 minutes (15-60) post dose and lasts 2-3 hours.

5.3 Preclinical safety data

Toxicity studies demonstrate the good tolerance of the product, no clinically relevant affects were found at doses up to 100 times the recommended human dose.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol
Sodium hydrogen phosphate dihydrate
Sodium dihydrogen phosphate monohydrate

6.2 Incompatibilities

No known chemical incompatibilities.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Store at 2°C to 8°C.
Protect from light.

6.5 Nature and contents of container

The 3 ml ampoule of Geref 50 and the 2 ml ampoule containing 1 ml of the solvent are of colourless neutral glass.

Geref 50 is available in the following pack sizes: 1 ampoule of Geref 50 and 1 ampoule of solvent.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

The injection should be reconstituted immediately prior to use with the solvent provided. Discard any product remaining after use.

7 MARKETING AUTHORISATION HOLDER

Serono Limited
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8 MARKETING AUTHORISATION NUMBER

PA 285/6/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26 July 1991

Date of last renewal: 26 July 2001

10 DATE OF REVISION OF THE TEXT

May 2004