



Edition: BP 2025 (Ph. Eur. 11.6 update)

## Menotrophin Injection

### [General Notices](#)

#### Action and use

Gonadotrophins for the treatment of infertility.

### DEFINITION

Menotrophin Injection is a sterile solution of Menotrophin in Water for Injections. It is prepared by dissolving Menotrophin for Injection in the requisite amount of Water for Injections immediately before use.

*The injection complies with the requirements stated under Parenteral Preparations.*

### STORAGE

Menotrophin Injection should be used immediately after preparation.

## MENOTROPHIN FOR INJECTION

### DEFINITION

Menotrophin for Injection is a sterile material consisting of Menotrophin with or without [excipients](#). It is supplied in a sealed container.

*The contents of the sealed container comply with the requirements for Powders for Injections or Infusions stated under Parenteral Preparations and with the following requirements.*

#### Potency

The estimated potency for each component is not less than 80% and not more than 125% of the stated potency.

### IDENTIFICATION

Cause enlargement of the ovaries of immature female rats and increase the weight of the seminal vesicles and prostate gland of immature male rats when administered as directed in the Assay.

### TESTS

#### Acidity or alkalinity

Dissolve the contents of the sealed container in 3 mL of [water](#) (solution A). The pH is 6.0 to 8.0, [Appendix V L](#).

#### Clarity and colour of solution

Solution A is *clear*, [Appendix IV A](#), and *colourless*, [Appendix IV B](#), Method I.

#### [Water](#)

Not more than 5% w/w, [Appendix IX C](#), Method III. Use 75 IU of follicle stimulating hormone.

#### [Bacterial endotoxins](#)

Carry out the [test for bacterial endotoxins](#), [Appendix XIV C](#). The endotoxin limit is not more than 0.78 IU per IU of follicle stimulating hormone.

### ASSAY

Carry out the *biological assay of menotrophin* described under Menotrophin. The fiducial limits of error are not less than 64% and not more than 156% of the stated potency.

### STORAGE

The sealed container should be protected from light.

### LABELLING

The label of the sealed container states the number of IU (Units) of follicle-stimulating hormone activity, the number of IU (Units) of luteinising hormone activity and, where applicable, the number of IU (Units) of chorionic gonadotrophin activity contained in it.