Pregnyl® 1500 I.U.

4.3 Protecting and method of administration
In the male

Hypogonadotrophic hypogonadism: 1,500 Units twice weekly for at least 6 months.

Delayed puberty associated with insufficient gonadotrophin pituitary function

1,500 Units twice weekly for at least 6 months.

In females

Sterility due to the absence of follicle formation or ovulation

• In the pregnancies occurring after induction of ovulation with gonadotrophin preparations, there is an increased risk of abortion and multiple pregnancy.

Multiple pregnancy, especially high order, occurs in a small number of cases. Intrauterine growth retardation and prematurity may occur. If complications arise during the pregnancy, the continuation of therapy should be discussed with your doctor. If the benefits of IVF treatment need to be weighed against the risks, it should be noted however, that pregnancy itself carries an increased risk of thromboembolic complications.

• There have been reports of ovarian and other reproductive system abnormalities of female patients after IVF treatment. In these women the risks associated with pregnancy are considered against the benefits of IVF treatment need to be weighed against the risks. It should be noted however, that pregnancy itself carries an increased risk of thromboembolic complications.

Method of administration

After all the ovulations and the oocyte retrieval, the solution should be administered immediately. For information on how to use a delayed stimulation protocol, consult the prescribing information for the respective GnRH agonist or antagonist.

What other medicines are you taking?

In patients undergoing ovulation induction:

• Breast, uterine, ovarian, testicular cancers of the sex organs.

Should you become pregnant?

• Recent or prolonged use of HMG may result in final adult height not being reached.

Mothers of children with congenital malformations after Assisted Reproduction Technology (ART) may be excluded by the determination of

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Information on the patient

Women

Pregnyl® 1500 I.U

What you should know about your medicine

This leaflet has been written to help you understand your medicine. If you have any questions or worries, ask your doctor, pharmacist or practice nurse. At the end of this leaflet, you will find a list of terms you may have read about during your visit, or an earlier visit?

There have been reports of ovarian and other reproductive system abnormalities of female patients after IVF treatment. In these women the risks associated with pregnancy are considered.

• The incidence of congenital malformations after a single cycle of HMG or HMG/HCG is not known. However, the background incidence of congenital malformations is estimated to be approximately 2–3%.

Pregnyl® is a powder to be administered subcutaneously. If you give this medicine to a woman who is pregnant or breast feeding, it may result in final adult height not being reached. (For information on how to use a delayed stimulation protocol, consult the prescribing information for the respective GnRH agonist or antagonist.)

In the female

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3. Tell your doctor treating you what medicines you are taking. It is especially important to tell your doctor if you are taking any of the following medicines:

- angiotensin-converting enzyme (ACE) inhibitors
- angiotensin receptor blockers (ARBs)
- diuretics
- other drugs that lower blood pressure
- any over-the-counter (OTC) or prescription medicine
- any herbal or dietary supplement

4. Return any medicines you have not used to your pharmacist.

5. Things to remember about medicines

- Follow the instructions on the label or in the information leaflet. Do not change the way you use your medicine without checking with your doctor or pharmacist.
- Do not allow other people to use your medicines.
- Do not give medicines to children.
- Do not use medicines that are past their expiry date.
- Keep the medicines out of the reach of children.
- Make sure you know before taking your medicine. It is especially important to tell your doctor if you are pregnant or lactating.

6. Instructions for using/handling

- Keep the ampoules in the outer container to protect from light. Do not open the ampoules before use. Keep the ampoules in the original package until they are needed and the expiry date has not been reached.

7. Marketing authorization holder

Cambridge, CB4 0FL, U.K.

8. Date of first authorisation/renewal of authorization

January 2005.