ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS
1. **NAME OF THE MEDICINAL PRODUCT**

Ovidrelle 250 micrograms powder and solvent for solution for injection

2. **QUALITATIVE AND QUANTITATIVE COMPOSITION**

To ensure delivery of a 250 microgram dose, each vial contains 285 micrograms of choriogonadotropin alfa.

Choriogonadotropin alfa is produced by recombinant DNA technology in Chinese Hamster Ovary cells.

A dose of 250 micrograms is equivalent to approximately 6500 IU.

For excipients, see 6.1.

3. **PHARMACEUTICAL FORM**

Powder and solvent for solution for injection

4. **CLINICAL PARTICULARS**

4.1 **Therapeutic indications**

Ovidrelle is indicated in the treatment of
(i) Women undergoing superovulation prior to assisted reproductive techniques such as in vitro fertilisation (IVF): Ovidrelle is administered to trigger final follicular maturation and luteinisation after stimulation of follicular growth.

(ii) Anovulatory or oligo-ovulatory women: Ovidrelle is administered to trigger ovulation and luteinisation in anovulatory or oligo-ovulatory patients after stimulation of follicular growth.

4.2 Posology and method of administration

Ovidrelle is intended for subcutaneous administration. The powder should be reconstituted immediately prior to use with the solvent provided.

Treatment with Ovidrelle should be performed under the supervision of a physician experienced in the treatment of fertility problems.

The following dosing regimen should be applied:

(i) Women undergoing superovulation prior to assisted reproductive techniques such as in vitro fertilisation (IVF):

One vial of Ovidrelle (250 micrograms) is administered 24 to 48 hours after the last administration of an FSH- or hMG preparation, i.e. when optimal stimulation of follicular growth is achieved.

(ii) Anovulatory or oligo-ovulatory women:

One vial of Ovidrelle (250 micrograms) is administered 24 to 48 hours after optimal stimulation of follicular growth is achieved. The patient is recommended to have coitus on the day of, and the day after, Ovidrelle injection.

4.3 Contraindications
Ovidrelle is contraindicated for safety reasons in case of:

- Tumours of the hypothalamus and pituitary gland
- Hypersensitivity to the active substance or to any of the excipients
- Ovarian enlargement or cyst due to reasons other than polycystic ovarian disease
- Gynaecological haemorrhages of unknown aetiology
- Ovarian, uterine or mammary carcinoma
- Extrauterine pregnancy in the previous 3 months
- Active thrombo-embolic disorders?

Ovidrelle must not be used when an effective response cannot be obtained, for example:

- Primary ovarian failure
- Malformations of sexual organs incompatible with pregnancy
- Fibroid tumours of the uterus incompatible with pregnancy
- Postmenopausal women

4.4 Special warnings and special precautions for use

To date, there is no clinical experience with Ovidrelle in other indications commonly treated with urine derived human chorionic gonadotrophin.

Before starting treatment, the couple's infertility should be assessed as appropriate and putative contraindications for pregnancy evaluated. In particular, patients should be evaluated for hypothyroidism, adrenocortical deficiency, hyperprolactinemia and pituitary or hypothalamic tumours, and appropriate specific treatment given.

Special precautions should be taken before administering Ovidrelle to patients with clinically significant systemic disease where pregnancy could lead to a worsening of the condition.

Patients undergoing ovarian stimulation are at an increased risk of developing ovarian hyperstimulation syndrome (OHSS) due to multiple follicular development.
Ovarian hyperstimulation syndrome may become a serious medical event characterised by large ovarian cysts which are prone to rupture and the presence of ascites within a clinical picture of circulatory dysfunction. Ovarian hyperstimulation syndrome due to excessive ovarian response can be avoided by withholding hCG administration. Patients should be advised to refrain from coitus or use barrier methods for at least 4 days.

Careful monitoring of estradiol levels and ovarian response, based on ultrasound is recommended prior to and during stimulation therapy, for all patients.

The risk of multiple pregnancy following assisted reproductive technologies is related to the number of embryos replaced. In patients undergoing induction of ovulation, the incidence of multiple pregnancies and births (mostly twins) is increased compared with natural conception.

To minimise the risk of OHSS and of multiple pregnancy, ultrasound scans as well as estradiol measurements are recommended. In anovulation, the risk of OHSS is increased by a serum estradiol level > 1500 pg/ml (5400 pmol/l) and more than 3 follicles of 14 mm or more in diameter. In assisted reproductive techniques, there is an increased risk of OHSS with a serum estradiol > 3000 pg/ml (11000 pmol/l) and 20 or more follicles of 12 mm or more in diameter. When the estradiol level is > 5500 pg/ml (20000 pmol/l) and when there are 40 or more follicles in total, it may be necessary to withhold hCG administration.

Adherence to recommended Ovidrelle dosage, regimen of administration and careful monitoring of therapy will minimise the incidence of ovarian hyperstimulation and multiple pregnancy.

The rate of miscarriage, in both anovulatory patients and women undergoing assisted reproductive techniques, is higher than that found in the normal population but comparable with the rates observed in women with other fertility problems.

Self-administration of Ovidrelle should only be performed by patients who are adequately trained and have access to expert advice.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically significant drug interactions have been reported during hCG therapy.
Following administration, Ovidrelle may interfere for up to ten days with the immunological determination of serum / urinary hCG, leading to a false positive pregnancy test.

During Ovidrelle therapy, a minor thyroid stimulation is possible, of which the clinical relevance is unknown.

4.6 Pregnancy and lactation

Considering the indication, Ovidrelle should not be used during pregnancy and lactation. For Ovidrelle no clinical data on exposed pregnancies are available. No reproduction studies with choriogonadotropin alfa in animals were performed (see 5.3). The potential risk for humans is unknown.

There are no data on the excretion of choriogonadotropin alfa in milk.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Ovidrelle is used to trigger final follicular maturation and early luteinisation after use of medicinal products for the stimulation of follicular growth. In this context, it is difficult to attribute undesirable effects to any one of the products used.

In comparative trials with different doses of Ovidrelle, the following undesirable effects were found to be associated with Ovidrelle in a dose-related fashion: ovarian hyperstimulation syndrome, and vomiting and nausea. Ovarian hyperstimulation syndrome was observed in approximately 4% of patients treated with Ovidrelle. Severe ovarian hyperstimulation syndrome was reported in less than 0.5% patients (section 4.4 Special warnings and special precautions for use).

In rare instances, thromboembolisms have been associated with menotrophin/hCG therapy. Although this adverse event was not observed, there is the possibility that this may also occur with Ovidrelle.
Ectopic pregnancy, ovarian torsion and other complications have been reported in patients after hCG administration. These are considered concomitant effects related to Assisted Reproductive Technologies (ART).

After best evidence assessment, the following undesirable effects may be observed after administration of Ovidrelle.

(i) Common (>1/100, < 1/10)
- **Application site disorders**: Local reaction/pain at injection site
- **General disorders**: Headache, tiredness
- **Gastro-intestinal system disorders**: Vomiting/nausea, abdominal pain
- **Reproductive disorders**: Mild or moderate ovarian hyperstimulation syndrome

(ii) Uncommon (>1/1000, <1/100)
- **Psychiatric disorders**: Depression, irritability, restlessness
- **Gastro-intestinal system disorders**: Diarrhoea
- **Reproductive disorders**: Severe ovarian hyperstimulation syndrome, Breast pain

### 4.9 Overdose

No case of overdosage has been reported.

Nevertheless, there is a possibility that ovarian hyperstimulation syndrome (OHSS) may result from an overdosage of Ovidrelle (see “4.4 Special warnings and special precautions for use”).

### 5. PHARMACOLOGICAL PROPERTIES

#### 5.1 Pharmacodynamic properties
Pharmacotherapeutic group: gonadotropins, ATC code: G03G A01

Ovidrelle is a medicinal product of chorionic gonadotropin produced by recombinant DNA techniques. It shares the amino acid sequence with urinary hCG. Chorionic gonadotropin binds on the ovarian theca (and granulosa) cells to a transmembrane receptor shared with the luteinising hormone, the LH/CGR receptor.

The principal pharmacodynamic activity in women is oocyte meiosis resumption, follicular rupture (ovulation), corpus luteum formation and production of progesterone and estradiol by the corpus luteum.

In women, Chorionic gonadotropin acts as a surrogate LH-surge that triggers ovulation.

Ovidrelle is used to trigger final follicular maturation and early luteinisation after use of medicinal products for stimulation of follicular growth.

In comparative clinical trials, administration of a dose of 250 micrograms of Ovidrelle was as effective as 5000 IU and 10000 IU of urinary hCG in inducing final follicular maturation and early luteinisation in assisted reproductive techniques, and as effective as 5000 IU of urinary hCG in ovulation induction.

So far, there are no signs of antibody development in humans to Ovidrelle. Repeated exposure to Ovidrelle was investigated in male patients only. Clinical investigation in women for the indication of ART and anovulation was limited to one treatment cycle.

5.2 Pharmacokinetic properties

Following intravenous administration, choriogonadotropin alfa is distributed to the extracellular fluid space with a distribution half-life of around 4.5 hours. The steady-state volume of distribution and the total clearance are 6 l and 0.2 l/h, respectively. There are no indications that choriogonadotropin alfa is metabolised and excreted differently than endogenous hCG.
Following subcutaneous administration, choriogonadotropin alfa is eliminated from the body with a terminal half-life of about 30 hours, and the absolute bioavailability is about 40%.

5.3 Preclinical safety data

Preclinical safety data reveal no intrinsic toxicity of choriogonadotropin alfa. Studies on carcinogenic potential were not performed. This is justified, given the proteinous nature of the active substance and the negative outcome of the genotoxicity testing.

Studies on reproduction were not performed in animals.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Powder for solution for injection:

- Sucrose
- Phosphoric acid, concentrated
- Sodium hydroxide

Solvent:

- Water for injections

6.2 Incompatibilities

In the absence of incompatibility studies, this medicinal product must not be mixed with other medicinal products.
6.3 Shelf life

2 years. For immediate and single use following first opening and reconstitution.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package.

6.5 Nature and contents of container

The powder container is a neutral colourless (type 1) glass vial with a bromobutyl rubber stopper.

The solvent container is a neutral, colourless glass type 1 vial with a bromobutyl rubber stopper or a neutral, colourless glass type 1 ampoule.

The product is supplied in packs of 1, 2, 10 vials with the corresponding number of solvent containers.

6.6 Instructions for use, handling and disposal

Ovidrelle is for single use only. One vial of Ovidrelle can be reconstituted with 1 ml of the solvent before use. The reconstituted solution should not be administered if it contains particles or is not clear. Any unused product or waste material should be disposed of in accordance with local requirements.
7. MARKETING AUTHORISATION HOLDER

ARES-SERONO (EUROPE) Ltd.

24 Gilbert Street

London W1Y 1RJ

United Kingdom

8. NUMBER(S) IN THE COMMUNITY REGISTER OF MEDICINAL PRODUCTS

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

10. DATE OF REVISION OF THE TEXT
ANNEX II

A. MANUFACTURING AUTHORIZATION HOLDER RESPONSIBLE FOR BATCH RELEASE AND MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE
B. CONDITIONS OF THE MARKETING AUTHORIZATION
A MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE AND MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCE

Name and address of the manufacturer of the biological active substance

Laboratoires Serono S.A.
1170 Aubonne
Switzerland

Manufacturing Authorisation issued on 22 February 1999 by the Département de la Santé et de l’action sociale (Department of Interior and of Public Health), Canton de Vaud, Switzerland.

Name and address of the manufacturer responsible for batch release

Industria Farmaceutica Serono S.p.A
70123 Bari
Italy

Manufacturing Authorisation issued on 7 October 1999 by the Ministero della Sanita (Italian Ministry of Health), Rome, Italy.

B CONDITIONS OF THE MARKETING AUTHORISATION

• CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IMPOSED ON THE MARKETING AUTHORISATION HOLDER

Medicinal product subject to restricted medical prescription (See Annex I: Summary of Product Characteristics, 4.2).
ANNEX III

LABELLING AND PACKAGE LEAFLET
[N.B.: shaded headings are provided to help applicants when completing the template; they should remain in the annexes during evaluation. However, they are not to appear in the final printed packaging materials (mock-ups/specimens).]
A. LABELLING
1. **NAME OF THE MEDICINAL PRODUCT**

OVIDRELLE 250 micrograms powder and solvent for solution for injection.
Choriogonadotropin alfa.

2. **STATEMENT OF ACTIVE SUBSTANCE(S)**

Composition: one vial delivers: Choriogonadotropin alfa 250 micrograms (6500 IU).

3. **LIST OF EXCIPIENTS**

Other ingredients: Sucrose, phosphoric acid, sodium hydroxide.
One ampoule of solvent contains: 1 ml water for injections.

4. **PHARMACEUTICAL FORM AND CONTENTS**

1 vial of powder for solution for injection.
1 ampoule of solvent.
5. METHOD AND, IF NECESSARY, ROUTE(S) OF ADMINISTRATION

For subcutaneous use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use.

8. EXPIRY DATE

Expiry date:

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Store in the original package.
10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Discard any unused solution.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder: Ares-Serono (Europe) Ltd.
24 Gilbert Street
London W1Y 1RJ

United Kingdom

12. NUMBER(S) IN THE COMMUNITY REGISTER OF MEDICINAL PRODUCTS

EU/0/00/000/000

13. MANUFACTURER’S BATCH NUMBER

Batch No:

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE
PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OVIDRELLE 250 MICROGRAMS, POWDER AND SOLVENT FOR SOLUTION FOR INJECTION, SOLVENT IN AMPOULES

1. NAME OF THE MEDICINAL PRODUCT

OVIDRELLE 250 micrograms powder and solvent for solution for injection.
Choriogonadotropin alfa.

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Composition: one vial delivers: Choriogonadotropin alfa 250 micrograms (6500 IU).

3. LIST OF EXCIPIENTS

Other ingredients: Sucrose, phosphoric acid, sodium hydroxide.
One ampoule of solvent contains: 1 ml water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

2 vials of powder for solution for injection.
2 ampoules of solvent.
5. METHOD AND, IF NECESSARY, ROUTE(S) OF ADMINISTRATION

For subcutaneous use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use.

8. EXPIRY DATE

Expiry date:

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Store in the original package.
10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Discard any unused solution.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder: Ares-Serono (Europe) Ltd.
24 Gilbert Street
London W1Y 1RJ
U.K.

12. NUMBER(S) IN THE COMMUNITY REGISTER OF MEDICINAL PRODUCTS

EU/0/00/000/000

13. MANUFACTURER’S BATCH NUMBER

Batch No:

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE
PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OVIDRELLE 250 MICROGRAMS, POWDER AND SOLVENT FOR SOLUTION FOR INJECTION, SOLVENT IN AMPOULES

1. NAME OF THE MEDICINAL PRODUCT

OVIDRELLE 250 micrograms powder and solvent for solution for injection.
Choriogonadotropin alfa.

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Composition: one vial delivers: Choriogonadotropin alfa 250 micrograms (6500 IU).

3. LIST OF EXCIPIENTS

Other ingredients: Sucrose, phosphoric acid, sodium hydroxide.
One ampoule of solvent contains: 1 ml water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

10 vials of powder for solution for injection.
10 ampoules of solvent.
5. METHOD AND, IF NECESSARY, ROUTE(S) OF ADMINISTRATION

For subcutaneous use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use.

8. EXPIRY DATE

Expiry date:

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Store in the original package.
10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Discard any unused solution.

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing authorisation holder: Ares-Serono (Europe) Ltd.
24 Gilbert Street
London W1Y 1RJ
U.K.

12. NUMBER(S) IN THE COMMUNITY REGISTER OF MEDICINAL PRODUCTS

EU/0/00/000/000

13. MANUFACTURER’S BATCH NUMBER

Batch No:

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE
PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OVIDRELLE 250 MICROGRAMS, POWDER AND SOLVENT FOR SOLUTION FOR INJECTION, SOLVENT IN VIALS

1. NAME OF THE MEDICINAL PRODUCT

OVIDRELLE 250 micrograms powder and solvent for solution for injection.
Choriogonadotropin alfa.

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Composition: one vial delivers: Choriogonadotropin alfa 250 micrograms (6500 IU).

3. LIST OF EXCIPIENTS

Other ingredients: Sucrose, phosphoric acid, sodium hydroxide.
One vial of solvent contains: 1 ml water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

1 vial of powder for solution for injection.
1 vial of solvent.
5. **METHOD AND, IF NECESSARY, ROUTE(S) OF ADMINISTRATION**

For subcutaneous use.

6. **SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN**

Keep out of the reach and sight of children.

7. **OTHER SPECIAL WARNING(S), IF NECESSARY**

Read package leaflet before use.

8. **EXPIRY DATE**

Expiry date:

9. **SPECIAL STORAGE CONDITIONS**

Do not store above 25°C. Store in the original package.
10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

Discard any unused solution.

11. NAME AND ADDRESS OF THE MARKETING AUTHORIZATION HOLDER

Marketing authorization holder: Ares-Serono (Europe) Ltd.
24 Gilbert Street
London W1Y 1RJ
U.K.

12. NUMBER(S) IN THE COMMUNITY REGISTER OF MEDICINAL PRODUCTS

EU/0/00/000/000

13. MANUFACTURER’S BATCH NUMBER

Batch No:

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE
PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OVIDRELLE 250 MICROGRAMS, POWDER AND SOLVENT FOR SOLUTION FOR INJECTION, SOLVENT IN VIALS

1. NAME OF THE MEDICINAL PRODUCT

OVIDRELLE 250 micrograms powder and solvent for solution for injection.
Choriogonadotropin alfa.

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Composition: one vial delivers: Choriogonadotropin alfa 250 micrograms (6500 IU).

3. LIST OF EXCIPIENTS

Other ingredients: Sucrose, phosphoric acid, sodium hydroxide.
One vial of solvent contains: 1 ml water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

2 vials of powder for solution for injection.
2 vials of solvent.
5. METHOD AND, IF NECESSARY, ROUTE(S) OF ADMINISTRATION

For subcutaneous use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use.

8. EXPIRY DATE

Expiry date:

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Store in the original package.
10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR
WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF
APPROPRIATE

Discard any unused solution.

11. NAME AND ADDRESS OF THE MARKETING AUTHORIZATION HOLDER

Marketing authorization holder: Ares-Serono (Europe) Ltd.
24 Gilbert Street
London W1Y 1RJ
U.K.

12. NUMBER(S) IN THE COMMUNITY REGISTER OF MEDICINAL PRODUCTS

EU/0/00/000/000

13. MANUFACTURER’S BATCH NUMBER

Batch No:

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE
PARTICULARS TO APPEAR ON THE OUTER PACKAGING

OVIDRELLE 250 MICROGRAMS, POWDER AND SOLVENT FOR SOLUTION FOR INJECTION, SOLVENT IN VIALS

1. NAME OF THE MEDICINAL PRODUCT

OVIDRELLE 250 micrograms powder and solvent for solution for injection.
Choriogonadotropin alfa.

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Composition: one vial delivers: Choriogonadotropin alfa 250 micrograms (6500 IU).

3. LIST OF EXCIPIENTS

Other ingredients: Sucrose, phosphoric acid, sodium hydroxide.
One vial of solvent contains: 1 ml water for Injections.

4. PHARMACEUTICAL FORM AND CONTENTS

10 vials of powder for solution for injection.
10 vials of solvent.
5. METHOD AND, IF NECESSARY, ROUTE(S) OF ADMINISTRATION

For subcutaneous use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use.

8. EXPIRY DATE

Expiry date:

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Store in the original package.
10. **SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

Discard any unused solution.

11. **NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

Marketing authorisation holder: Ares-Serono (Europe) Ltd.
24 Gilbert Street
London W1Y 1RJ
U.K.

12. **NUMBER(S) IN THE COMMUNITY REGISTER OF MEDICINAL PRODUCTS**

EU/0/00/000/000

13. **MANUFACTURER’S BATCH NUMBER**

Batch No:

14. **GENERAL CLASSIFICATION FOR SUPPLY**

Medicinal product subject to medical prescription.

15. **INSTRUCTIONS ON USE**
MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. **OVIDRELLE 250 MICROGRAMS, VIALS**

<table>
<thead>
<tr>
<th>OVIDRELLE 250 micrograms, VIAL LABEL TEXT</th>
<th>SOLVENT AMPOULE TEXT</th>
</tr>
</thead>
</table>

2. **1. NAME OF THE MEDICINAL PRODUCT AND IF NECESSARY ROUTE(S) OF ADMINISTRATION**

OVIDRELLE 250 micrograms  
Choriogonadotropin alfa

3. **2. METHOD OF ADMINISTRATION**

For subcutaneous use.

4. **3. EXPIRY DATE**

Exp: Exp:

5. **4. BATCH NUMBER**

Batch: Batch:

6. **5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT**

250 micrograms  
1 ml

Ares-Serono (Europe) Ltd.  
Ares-Serono (Europe) Ltd.
MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

7. OVIDRELLE 250 MICROGRAMS, VIALS

OVIDRELLE 250 micrograms, VIAL LABEL TEXT

8. 1. NAME OF THE MEDICINAL PRODUCT AND IF NECESSARY ROUTE(S) OF ADMINISTRATION

OVIDRELLE 250 micrograms Water for injections
Choriogonadotropin alfa

9. 2. METHOD OF ADMINISTRATION

For subcutaneous use.

10. 3. EXPIRY DATE

Exp: Exp:

11. 4. BATCH NUMBER

Batch: Batch:

12. 5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

250 micrograms 1 ml

Ares-Serono (Europe) Ltd. Ares-Serono (Europe) Ltd.
B. PACKAGE LEAFLET
Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What Ovidrelle is and what it is used for
2. Information necessary before you use Ovidrelle
3. How to use Ovidrelle
4. What are the possible side effects
5. Storing Ovidrelle

[Name of the medicinal product]

Ovidrelle 250 micrograms powder and solvent for solution for injection.

Choriogonadotropin alfa.

[Full statement of the active substance(s) and excipient(s)]

The active substance is choriogonadotropin alfa, each vial contains 285 micrograms.

After reconstitution 250 micrograms, which is the equivalent of 6500 IU, is delivered because some choriogonadotropin alfa will be left in the vial, in the syringe and in the needle.

The other ingredients are sucrose, phosphoric acid, and sodium hydroxide.

The solvent is water for injections.
1. WHAT IS OVIDRELLE AND WHAT IS IT USED FOR?

Ovidrelle is a medicinal product containing choriogonadotropin alfa, which is very similar to chorionic gonadotrophin found naturally in humans, but it is made in laboratories by special recombinant DNA techniques. It belongs to the family of hormones called gonadotrophins, which are involved in the normal control of reproduction.

Ovidrelle is provided as a powder and solvent for solution for injection. It is available in packs containing 1, 2, or 10 vials of powder containing the active substance which are accompanied by the corresponding number of solvent containers.

Each vial of powder contains 285 micrograms of choriogonadotropin alfa and each container of solvent contains 1 ml of water for injections. When a vial is reconstituted with 1 ml of solvent, you will receive a dose of 250 micrograms.
[Therapeutic indications]

Ovidrelle is used in women undergoing assisted reproductive techniques such as in vitro fertilisation (IVF). Other medicines are given first to bring about the growth and development of several follicles, to produce eggs. Ovidrelle is then used to ripen (mature) these follicles.

Ovidrelle is also used in women who do not produce eggs (a condition called anovulation), or who produce too few eggs (oligo-ovulation). It is given to bring about the release of eggs (ovulation), after other medicines have been used to develop the follicles.

2. BEFORE YOU USE OVIDRELLE

[List of information necessary before taking the medicinal product]

You and your partner's fertility should be evaluated before the treatment is started.

[Contraindications]

Do not take Ovidrelle if the answer is ‘YES’ to any of the following:
• are you pregnant or breast-feeding?
• do you have ovarian enlargement or one or more large ovarian cysts?
• do you have unexplained vaginal bleeding?
• have you been diagnosed as having ovarian, uterine or breast cancer?
• have you had a tumour of the hypothalamus or pituitary gland?
• do you suffer from severe inflammation of the veins or blood clotting in the veins (active thrombo-embolic disorders)?
• do you have a known allergy to this or a similar medicine, or any of its ingredients?
• do you have any condition which would make a normal pregnancy impossible (e.g. absent uterus, ovaries which have not developed properly, fibroids) or have you been through menopause?
• have you had an extrauterine pregnancy within the last 3 months?

[Appropriate precautions for use; special warnings]

Take special care with Ovidrelle:

Treatment with Ovidrelle may increase your risk of developing a condition called ovarian hyperstimulation syndrome (OHSS) (see also ‘Possible side effects’). This is when the ovaries over-react to the treatment and develop too many follicles. The most common symptom is stomach pain. If you have significant stomach pain or discomfort, do not take the injection, and speak to your doctor or nurse as soon as possible. You should not have intercourse for at least 4 days, or otherwise you should use a barrier method for contraception.

Compared with natural conception, the frequency of multiple pregnancies and births is increased in patients receiving this treatment. The majority of these are twins. In assisted conception techniques, the number of babies is related to the number of embryos replaced.

Your risk of OHSS or multiple pregnancy is reduced if the usual dose of Ovidrelle is used, and you are monitored closely throughout your treatment cycle (e.g. blood tests for estradiol levels and ultrasound).

[Interactions with food and drink]
Not applicable

[Use by pregnant or breast-feeding women]

Pregnancy and breast-feeding
You should not take Ovidrelle if you are pregnant or breast-feeding.

[Effects on the ability to drive or to use machines]

Not applicable

[Interaction with other medicinal products]

Using other medicines:

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

3. HOW TO USE OVIDRELLE

[Instructions for proper use]

[Dosage]

How much Ovidrelle should I use and how often should I use it?

The dose of Ovidrelle is 1 vial (250 micrograms) given as a single injection. Your doctor will have explained exactly when to give the injection.
How should I administer Ovidrelle?

Ovidrelle is given by injection under the skin. Each vial is for single use only.

If you administer Ovidrelle to yourself, please carefully read the following instructions:

1. **Wash your hands.**
   It is important that your hands and the items you use be as clean as possible.

2. **Assemble everything you need.**
   Please note that alcohol swabs, syringes and needles are not contained in the package. Find a clean area and lay out everything:
   - two alcohol swabs,
   - one solvent ampoule,
   - one vial containing the medicinal product
   - one syringe,
   - one big needle for reconstitution,
   - a fine-bore needle for subcutaneous injection.
3. **Opening the ampoule of solvent:**

On the head of the solvent ampoule, you will see a small coloured dot. Directly below it is where the neck of the ampoule has been treated to make it easier to break. Gently flick the top section of the ampoule so that any fluid in the neck of the ampoule drops into the bottom chamber. Now press the ampoule firmly over the neck, and break the ampoule away from the coloured dot. Carefully place the open ampoule upright on the work-surface.

![Image of opening ampoule](image)

4. **Drawing up the solvent:**

Attach the **needle for reconstitution** to the syringe, with the syringe in one hand, pick up the open ampoule, insert the needle and draw up all of the solvent. Carefully set the syringe down on the work-surface, taking care not to touch the needle.

![Image of drawing up solvent](image)

5. **Preparation of the injection solution:**

Remove the protective cap from the **Ovidrelle powder vial**, pick up your syringe and slowly inject the solvent into the vial of Ovidrelle. Swirl gently. **Do not shake**. The powder should dissolve into a clear solution immediately.

![Image of dissolving powder](image)

Turn the vial upside down, gently draw the solution back into the syringe.

6. **Injection:**

Change the needle for the **fine-bore needle** and remove any air bubbles. If you see air bubbles in the syringe, hold the syringe with the needle pointing upwards and gently flick the syringe until all the air collects at the top. Gently push the plunger until the air bubbles are gone.

![Image of injecting solution](image)
Immediately inject the solution: Your doctor or nurse will have already advised you where to inject (e.g. tummy, front of thigh). Wipe the chosen area with an alcohol swab. Firmly pinch the skin together and insert the needle at a 45° to 90° angle using a dart-like motion. Inject under the skin, as you were taught. Do not inject directly into a vein. Inject the solution by pushing gently on the plunger. Take as much time as you need to inject all the solution. Immediately withdraw the needle and clean the skin with an alcohol swab using a circular motion.

7. **Dispose of all used items:**
Once you have finished your injection, immediately discard all needles and empty glass containers in a sharps container. Any unused solution must be discarded.

[Symptoms in case of overdose and actions to be taken]

**What should I do if I use more Ovidrelle than I should?**

If too much Ovidrelle is used, there is a possibility that ovarian hyperstimulation syndrome may occur, which is further described under ‘Take special care with Ovidrelle’ and ‘Possible side effects’. You should consult your doctor if symptoms of this syndrome occur.

[Actions to be taken when one or more doses have been missed]

What should I do if I forget to take Ovidrelle?

**You should contact your doctor.**

[Indication of the risk of withdrawal effects]

Not applicable.

4. **POSSIBLE SIDE EFFECTS**

[Description of side effects]
Like all medicines, Ovidrelle can have side effects. The majority of side effects seen to date have been mild or moderate. The most frequent side effects reported have been tiredness, pain and local reactions at the site of injection.

Ovarian hyperstimulation syndrome has been observed in approximately 4% of the patients in clinical trials; most of these cases were mild or moderate in nature.

Abdominal pain, nausea and vomiting, headache, injection site inflammation and reaction, dizziness, diarrhoea, depression, irritability, restlessness and breast pain have also been reported in some cases.

Extrauterine pregnancy, ovarian torsion and other complications may arise from the assisted conception techniques your doctor may use.

If you notice any side effects not mentioned in this leaflet or if you are concerned, please speak to your doctor or pharmacist.

5. STORING OVIDRELLE

[Storage conditions and expiry date]

Keep out of the reach and sight of children.

Do not store above 25°C. Store in the original package.

It is important not to use the medicine after the expiry date shown on the powder label or carton.

Once the medicine is reconstituted (made up with the solvent), it should be used immediately.

[Where appropriate, warning against certain visible signs of deterioration]

Do not use Ovidrelle if you notice any visible signs of deterioration.
The reconstituted solution should not be administered if it contains particles or is not clear.

Ovidrelle is for single use only. Any unused solution should be discarded.

This leaflet was last approved on {date}
Further Information

For any information about this medicinal product, please contact your local representative of Ares-Serono (Europe) Ltd.

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I-00176 Roma
Tel: +39-06-70 38 41
Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What Ovidrelle is and what it is used for
2. Information necessary before you use Ovidrelle
3. How to use Ovidrelle
4. What are the possible side effects
5. Storing Ovidrelle

[Name of the medicinal product]

Ovidrelle 250 micrograms powder and solvent for solution for injection.

Choriogonadotropin alfa.

[Full statement of the active substance(s) and excipient(s)]

The active substance is choriogonadotropin alfa, each vial contains 285 micrograms.

After reconstitution 250 micrograms, which is the equivalent of 6500 IU, is delivered because some choriogonadotropin alfa will be left in the vial, in the syringe and in the needle.

The other ingredients are sucrose, phosphoric acid, and sodium hydroxide.

The solvent is water for injections.
Marketing Authorisation holder: Ares-Serono (Europe) Ltd, 24 Gilbert Street, London W1Y 1RJ, United Kingdom

Manufacturer: Industria Farmaceutica Serono S.p.A., Zona Industriale di Modugno, I-70123 Bari, Italy

1. WHAT IS OVIDRELLE AND WHAT IS IT USED FOR?

Ovidrelle is a medicine containing choriogonadotropin alfa, which is very similar to chorionic gonadotrophin found naturally in humans, but it is made in laboratories by special recombinant DNA techniques. It belongs to the family of hormones called gonadotrophins, which are involved in the normal control of reproduction.

Ovidrelle is provided as a powder and solvent for solution for injection. It is available in packs containing 1, 2, or 10 vials of powder containing the active substance which are accompanied by the corresponding number of solvent containers.

Each vial of powder contains 285 micrograms of choriogonadotropin alfa and each container of solvent contains 1 ml of water for injections. When one vial is reconstituted with 1 ml of solvent you will receive a dose of 250 micrograms.
[Therapeutic indications]

Ovidrelle is used in women undergoing assisted reproductive techniques such as in vitro fertilisation (IVF). Other medicines are given first to bring about the growth and development of several follicles, to produce eggs. Ovidrelle is then used to ripen (mature) these follicles.

Ovidrelle is also used in women who are not producing eggs (a condition called anovulation) or in women who produce too few eggs (oligo-ovulation). It is given to bring about the release of eggs (ovulation), after other medicines have been used to develop the follicles.

2. BEFORE YOU USE OVIDRELLE

[List of information necessary before taking the medicinal product]

You and your partner's fertility should be evaluated before the treatment is started.

[Contraindications]

Do not take Ovidrelle if the answer is ‘YES’ to any of the following:
• are you pregnant or breast-feeding?
• do you have ovarian enlargement or one or more large ovarian cysts?
• do you have unexplained vaginal bleeding?
• have you been diagnosed as having ovarian, uterine or breast cancer?
• have you had a tumour of the hypothalamus or pituitary gland?
• do you suffer from severe inflammation of the veins or blood clotting in the veins (active thrombo-embolic disorders)?
• do you have a known allergy to this or a similar medicine, or any of its ingredients?
• do you have any condition which would make a normal pregnancy impossible (e.g. absent uterus, ovaries which have not developed properly, fibroids) or have you been through menopause?
• have you had an extrauterine pregnancy within the last 3 months?

[Appropriate precautions for use; special warnings]

Take special care with Ovidrelle:

Treatment with Ovidrelle may increase your risk of developing a condition called ovarian hyperstimulation syndrome (OHSS) (see also ‘Possible side effects’). This is when the ovaries over-react to the treatment and develop too many follicles. The most common symptom is stomach pain. If you have significant stomach pain or discomfort, do not take the injection, and speak to your doctor or nurse as soon as possible. You should not have intercourse for at least 4 days, or otherwise you should use a barrier method for contraception.

Compared with natural conception, the frequency of multiple pregnancies and births is increased in patients receiving this treatment. The majority of these are twins. In assisted conception techniques, the number of babies is related to the number of embryos replaced.

Your risk of OHSS or multiple pregnancy is reduced if the usual dose of Ovidrelle is used, and you are monitored closely throughout your treatment cycle (e.g. blood tests for estradiol levels and ultrasound).

[Interactions with food and drink]
Pregnancy and breast-feeding

You should not take Ovidrelle if you are pregnant or breast-feeding.

[Effects on the ability to drive or to use machines]

Not applicable

[Interaction with other medicinal products]

Using other medicines:

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

3. HOW TO USE OVIDRELLE

[Instructions for proper use]

[Dosage]

How much Ovidrelle should I use and how often should I use it?

The dose of Ovidrelle is 1 vial (250 micrograms) given as a single injection. Your doctor will have explained exactly when to give the injection.
[Method and/or route(s) of administration]

How should I administer Ovidrelle?

Ovidrelle is given by injection under the skin. Each vial is for single use only.

[Frequency of administration]

[Duration of treatment]

Sometimes the injection will be given to you by a doctor or nurse, or you or your partner may be trained to give the injection at home.

If you administer Ovidrelle to yourself, please carefully read the following instructions:

1. **Wash your hands.**

   It is important that your hands and the items you use be as clean as possible.

2. **Assemble everything you need.**

   Please note that alcohol, swabs, syringes and needles are not contained in the package. Find a clean area and lay out everything:
   - two alcohol swabs,
   - one solvent vial,
   - one vial containing the medicinal product
   - one syringe,
   - one big needle for reconstitution,
   - a fine-bore needle for subcutaneous injection.
3. **Drawing up the solvent:**

Remove the protective cap from the solvent vial. Attach the **needle for reconstitution** (the bigger needle) to the syringe and draw up some air into the syringe by pulling the plunger to approximately the 1 ml mark. Then, insert the needle into the vial, push the plunger to expel the air, turn the vial upside down and gently draw up all the solvent. Set the syringe down carefully on the work-surface taking care not to touch the needle.

4. **Preparing the injection solution:**

Remove the protective cap from the Ovidrelle **powder vial**, pick up your syringe and slowly inject the solvent into the vial of Ovidrelle. Swirl gently. **Do not shake.** The powder should dissolve into a clear solution immediately.

Turn the vial upside down, gently draw the solution back into the syringe.

5. **Injection:**

Change the needle for the **fine-bore needle** and remove any air bubbles: If you see air bubbles in the syringe, hold the syringe with the needle pointing upwards and gently flick the syringe until all the air collects at the top. Gently push the plunger until the air bubbles are gone.

Immediately inject the solution: Your doctor or nurse will have already advised you where to inject (e.g. tummy, front of thigh). Wipe the chosen area with an alcohol swab. Firmly pinch the skin together and insert the needle at a 45° to 90° angle using a dart-like motion. Inject under the skin, as you were taught. Do not inject directly into a vein. Inject the solution by pushing gently on the plunger. Take as much time as you need to inject all the solution. Immediately withdraw the needle and clean the skin with an alcohol swab using a circular motion.

6. **Dispose of all used items:**

Once you have finished your injection, immediately discard all needles and empty glass containers in a sharps container. Any unused solution must be discarded.
Symptoms in case of overdose and actions to be taken

What should I do if I use more Ovidrelle than I should?

If too much Ovidrelle is used, there is a possibility that ovarian hyperstimulation syndrome may occur, which is further described under ‘Take special care with Ovidrelle’ and ‘Possible side effects’. You should consult your doctor if symptoms of this syndrome occur.

Actions to be taken when one or more doses have been missed

What should I do if I forget to take Ovidrelle?

You should contact your doctor.

Indication of the risk of withdrawal effects

Not applicable.

4. POSSIBLE SIDE EFFECTS

Description of side effects

Like all medicines, Ovidrelle can have side effects. The majority of side effects seen to date have been mild or moderate. The most frequent side effects reported have been tiredness, pain and local reactions at the site of injection.

Ovarian hyperstimulation syndrome has been observed in approximately 4% of the patients in clinical studies; most of these cases were mild or moderate in nature.

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5. STORING OVIDRELLE

[Storage conditions and expiry date]

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