״פורמט עלון זה נקבע ע״י משרד הבריאות ותוכנו נבדק ואושר״. עלון מאושר ינואר 2017
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1. NAME OF THE MEDICINAL PRODUCT

Ovaleap 300 IU/0.5 mL solution for injection
Ovaleap 450 IU/0.75 mL solution for injection
Ovaleap 900 IU/1.5 mL solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL of the solution contains 600 IU (equivalent to 44 micrograms) follitropin alfa*.

Ovaleap 300 IU/0.5 mL solution for injection
Each cartridge contains 300 IU (equivalent to 22 micrograms) follitropin alfa in 0.5 mL solution for injection.

Ovaleap 450 IU/0.75 mL solution for injection
Each cartridge contains 450 IU (equivalent to 33 micrograms) follitropin alfa in 0.75 mL solution for injection.

Ovaleap 900 IU/1.5 mL solution for injection
Each cartridge contains 900 IU (equivalent to 66 micrograms) follitropin alfa in 1.5 mL solution for injection.

*Follitropin alfa (recombinant human follicle-stimulating hormone [r-hFSH]) is produced in Chinese Hamster Ovary Cells (CHO $DHFR^-$) by recombinant DNA technology.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection (injection).

Clear, colourless solution.

The pH of the solution is 6.8-7.2.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

In adult women

- Anovulation (including polycystic ovarian syndrome) in women who have been unresponsive to treatment with clomifene citrate.
- Stimulation of multifollicular development in women undergoing superovulation for assisted reproductive technologies (ART) such as *in vitro* fertilisation (IVF), gamete intra-fallopian transfer (GIFT) and zygote intra-fallopian transfer (ZIFT).

- Ovaleap in association with a luteinising hormone (LH) preparation is recommended for the stimulation of follicular development in women with severe LH and FSH deficiency. In clinical trials these patients were defined by an endogenous serum LH level < 1.2 IU/L.

In adult men

- Ovaleap is indicated for the stimulation of spermatogenesis in men who have congenital or acquired hypogonadotropic hypogonadism with concomitant human chorionic gonadotropin (hCG) therapy.

4.2 Posology and method of administration

OVALEAP is a biosimilar medicinal product. Detailed information is available on the website of the Ministry of Health http://www.health.gov.il/hozer/dr_127.pdf

Special requirements

Treatment with follitropin alfa should be initiated under the supervision of a physician experienced in the treatment of fertility disorders.

Posology

The dose recommendations given for follitropin alfa are those in use for urinary FSH. Clinical assessment of follitropin alfa indicates that its daily doses, regimens of administration and treatment monitoring procedures should not be different from those currently used for urinary FSH-containing medicinal products. It is advised to adhere to the recommended starting doses indicated below.

Comparative clinical studies have shown that on average patients require a lower cumulative dose and shorter treatment duration with follitropin alfa compared with urinary FSH. Therefore, it is considered appropriate to give a lower total dose of follitropin alfa than generally used for urinary FSH, not only in order to optimise follicular development but also to minimise the risk of unwanted ovarian hyperstimulation (see section 5.1).

Women with anovulation (including polycystic ovarian syndrome)
Follitropin alfa may be given as a course of daily injections. In menstruating women treatment should commence within the first 7 days of the menstrual cycle.

A commonly used regimen commences at 75-150 IU FSH daily and is increased preferably by 37.5 or 75 IU at 7 or preferably 14 day intervals if necessary, to obtain an adequate, but not excessive, response. Treatment should be tailored to the individual patient's response as assessed by measuring follicle size by ultrasound and/or oestrogen secretion. The maximal daily dose is usually not higher than 225 IU FSH. If a patient fails to respond adequately after 4 weeks of treatment, that cycle should be abandoned and the patient should undergo further evaluation after which she may recommence treatment at a higher starting dose than in the abandoned cycle.

When an optimal response is obtained, a single injection of 250 micrograms recombinant human choriogonadotropin alfa (r-hCG) or 5,000 IU up to 10,000 IU hCG should be administered 24-48 hours after the last follitropin alfa injection. The patient is recommended to have coitus on the day of, and the day following, hCG administration. Alternatively intrauterine insemination (IUI) may be performed.

If an excessive response is obtained, treatment should be stopped and hCG withheld (see section 4.4). Treatment should recommence in the next cycle at a dose lower than that of the previous cycle.

Women undergoing ovarian stimulation for multiple follicular development prior to in vitro fertilisation or other ART
A commonly used regimen for superovulation involves the administration of 150-225 IU of follitropin alfa daily, commencing on days 2 or 3 of the cycle. Treatment is continued until adequate follicular development has been achieved (as assessed by monitoring of serum oestrogen concentrations and/or ultrasound examination), with the dose adjusted according to the patient's response, to usually not higher than 450 IU daily. In general adequate follicular development is achieved on average by the tenth day of treatment (range 5 to 20 days).

A single injection of 250 micrograms r-hCG or 5,000 IU up to 10,000 IU hCG is administered 24-48 hours after the last follitropin alfa injection to induce final follicular maturation.

Down-regulation with a gonadotropin-releasing hormone (GnRH) agonist or antagonist is now commonly used in order to suppress the endogenous LH surge and to control tonic levels of LH. In a commonly used protocol, follitropin alfa is started approximately 2 weeks after the start of agonist treatment, both being continued until adequate follicular development is achieved. For example, following two weeks of treatment with an agonist, 150-225 IU follitropin alfa are administered for the first 7 days. The dose is then adjusted according to the ovarian response.

Overall experience with IVF indicates that in general the treatment success rate remains stable during the first four attempts and gradually declines thereafter.

Women with anovulation resulting from severe LH and FSH deficiency
In LH and FSH deficient women (hypogonadotropic hypogonadism), the objective of follitropin alfa therapy in association with lutropin alfa is to develop a single mature Graafian follicle from which the oocyte will be liberated after the administration of hCG. Follitropin alfa should be given as a course of daily injections simultaneously with lutropin alfa. Since these patients are amenorrhoeic and have low endogenous oestrogen secretion, treatment can commence at any time.

A recommended regimen commences at 75 IU of lutropin alfa daily with 75-150 IU FSH. Treatment should be tailored to the individual patient's response as assessed by measuring follicle size by ultrasound and oestrogen response.

If an FSH dose increase is deemed appropriate, dose adaptation should preferably be after 7-14 day intervals and preferably by 37.5-75 IU increments. It may be acceptable to extend the duration of stimulation in any one cycle to up to 5 weeks.

When an optimal response is obtained, a single injection of 250 micrograms r-hCG or 5,000 IU up to 10,000 IU hCG should be administered 24-48 hours after the last follitropin alfa and lutropin alfa injections. The patient is recommended to have coitus on the day of, and on the day following, hCG administration. Alternatively, IUI may be performed.

Luteal phase support may be considered since lack of substances with luteotropic activity (LH/hCG) after ovulation may lead to premature failure of the corpus luteum.

If an excessive response is obtained, treatment should be stopped and hCG withheld. Treatment should recommence in the next cycle at a dose of FSH lower than that of the previous cycle.

Men with hypogonadotropic hypogonadism
Follitropin alfa should be given at a dose of 150 IU three times a week, concomitantly with hCG, for a minimum of 4 months. If after this period, the patient has not responded, the combination treatment may be continued; current clinical experience indicates that treatment for at least 18 months may be necessary to achieve spermatogenesis.

Special population

Elderly population
There is no relevant use of follitropin alfa in the elderly population. Safety and effectiveness of follitropin alfa in elderly patients have not been established.

Renal or hepatic impairment
Safety, efficacy and pharmacokinetics of follitropin alfa in patients with renal or hepatic impairment have not been established.

Paediatric population
There is no relevant use of follitropin alfa in the paediatric population.

Method of administration

Ovaleap is intended for subcutaneous administration. The first injection of Ovaleap should be performed under direct medical supervision. Self-administration of Ovaleap should only be performed by patients who are well motivated, adequately trained and have access to expert advice.

As the Ovaleap multidose cartridge is intended for several injections, clear instructions should be provided to the patients to avoid misuse of the multidose presentation.

The Ovaleap cartridge is designed for use in conjunction with the Ovaleap Pen only, which is separately available. For instructions on the administration with the Ovaleap Pen, see section 6.6.

4.3 Contraindications

- Hypersensitivity to the active substance follitropin alfa, FSH or to any of the excipients listed in section 6.1;
- tumours of the hypothalamus or pituitary gland;
- ovarian enlargement or ovarian cyst not due to polycystic ovarian syndrome;
- gynaecological haemorrhages of unknown aetiology;
- ovarian, uterine or mammary carcinoma.

Ovaleap must not be used when an effective response cannot be obtained, such as:
- primary ovarian failure;
- malformations of sexual organs incompatible with pregnancy;
- fibroid tumours of the uterus incompatible with pregnancy;
- primary testicular insufficiency.

4.4 Special warnings and precautions for use

Follitropin alfa is a potent gonadotropic substance capable of causing mild to severe adverse reactions and should only be used by physicians who are thoroughly familiar with infertility problems and their management.

Gonadotropin therapy requires a certain time commitment by physicians and supportive health professionals, as well as the availability of appropriate monitoring facilities. In women, safe and effective use of follitropin alfa calls for monitoring of ovarian response with ultrasound, alone or preferably in combination with measurement of serum oestradiol levels, on a regular basis. There may be a degree of interpatient variability in response to FSH administration, with a poor response to FSH in some patients and exaggerated response in others. The lowest effective dose in relation to the treatment objective should be used in both men and women.

Porphyria

Patients with porphyria or a family history of porphyria should be closely monitored during treatment with follitropin alfa. Deterioration or a first appearance of this condition may require cessation of treatment.

Treatment in women

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 appropriate specific treatment given.

Patients undergoing stimulation of follicular growth, whether as treatment for anovulatory infertility or ART procedures, may experience ovarian enlargement or develop hyperstimulation. Adherence to recommended follitropin alfa dose and regimen of administration and careful monitoring of therapy will minimise the incidence of such events. For accurate interpretation of the indices of follicle development and maturation, the physician should be experienced in the interpretation of the relevant tests.

In clinical trials, an increase of the ovarian sensitivity to follitropin alfa was shown when administered with lutropin alfa. If an FSH dose increase is deemed appropriate, dose adaptation should preferably be at 7-14 day intervals and preferably with 37.5-75 IU increments.

No direct comparison of follitropin alfa/LH versus human menopausal gonadotropin (hMG) has been performed. Comparison with historical data suggests that the ovulation rate obtained with follitropin alfa/LH is similar to that obtained with hMG.

Ovarian Hyperstimulation Syndrome (OHSS)
A certain degree of ovarian enlargement is an expected effect of controlled ovarian stimulation. It is more commonly seen in women with polycystic ovarian syndrome and usually regresses without treatment.

In distinction to uncomplicated ovarian enlargement, OHSS is a condition that can manifest itself with increasing degrees of severity. It comprises marked ovarian enlargement, high serum sex steroids and an increase in vascular permeability which can result in an accumulation of fluid in the peritoneal, pleural and, rarely, in the pericardial cavities.

The following symptomatology may be observed in severe cases of OHSS: abdominal pain, abdominal distension, severe ovarian enlargement, weight gain, dyspnoea, oliguria and gastrointestinal symptoms including nausea, vomiting and diarrhoea. Clinical evaluation may reveal hypovolaemia, haemoconcentration, electrolyte imbalances, ascites, haemoperitoneum, pleural effusions, hydrothorax, or acute pulmonary distress. Very rarely, severe OHSS may be complicated by ovarian torsion or thromboembolic events such as pulmonary embolism, ischaemic stroke or myocardial infarction.

Independent risk factors for developing OHSS include polycystic ovarian syndrome high absolute or rapidly rising serum oestradiol levels (e.g. > 900 pg/mL or > 3,300 pmol/L in anovulation; > 3,000 pg/mL or > 11,000 pmol/L in ART) and large number of developing ovarian follicles (e.g. > 3 follicles of ≥ 14 mm in diameter in anovulation; ≥ 20 follicles of ≥ 12 mm in diameter in ART).

Adherence to recommended follitropin alfa dose and regimen of administration can minimise the risk of ovarian hyperstimulation (see sections 4.2 and 4.8). Monitoring of stimulation cycles by ultrasound scans as well as oestradiol measurements are recommended to early identify risk factors.

There is evidence to suggest that hCG plays a key role in triggering OHSS and that the syndrome may be more severe and more protracted if pregnancy occurs. Therefore, if signs of ovarian hyperstimulation occur such as serum oestradiol level > 5,500 pg/mL or > 20,200 pmol/L and/or ≥ 40 follicles in total, it is recommended that hCG be withheld and the patient be advised to refrain from coitus or to use barrier contraceptive methods for at least 4 days. OHSS may progress rapidly (within 24 hours) or over several days to become a serious medical event. It most often occurs after hormonal treatment has been discontinued and reaches its maximum at about 7 to 10 days following treatment. Therefore, patients should be followed for at least 2 weeks after hCG administration.

In ART, aspiration of all follicles prior to ovulation may reduce the occurrence of hyperstimulation.

Mild or moderate OHSS usually resolves spontaneously. If severe OHSS occurs, it is recommended that gonadotropin treatment be stopped if still ongoing and that the patient be hospitalised and appropriate therapy be started.

Multiple pregnancy
In patients undergoing ovulation induction, the incidence of multiple pregnancy is increased compared with natural conception. The majority of multiple conceptions are twins. Multiple pregnancy, especially of high order, carries an increased risk of adverse maternal and perinatal outcomes.

To minimise the risk of multiple pregnancy, careful monitoring of ovarian response is recommended.

In patients undergoing ART procedures the risk of multiple pregnancy is related mainly to the number of embryos replaced, their quality and the patient age.

The patients should be advised of the potential risk of multiple births before starting treatment.

Pregnancy loss
The incidence of pregnancy loss by miscarriage or abortion is higher in patients undergoing stimulation of follicular growth for ovulation induction or ART than following natural conception.

Ectopic pregnancy
Women with a history of tubal disease are at risk of ectopic pregnancy, whether the pregnancy is obtained by spontaneous conception or with fertility treatments. The prevalence of ectopic pregnancy after ART, was reported to be higher than in the general population.

Reproductive system neoplasms
There have been reports of ovarian and other reproductive system neoplasms, both benign and malignant, in women who have undergone multiple treatment regimens for infertility treatment. It is not yet established whether or not treatment with gonadotropins increases the risk of these tumours in infertile women.

Congenital malformation
The prevalence of congenital malformations after ART may be slightly higher than after spontaneous conceptions. This is thought to be due to differences in parental characteristics (e.g. maternal age, sperm characteristics) and multiple pregnancies.

Thromboembolic events
In women with recent or ongoing thromboembolic disease or women with generally recognised risk factors for thromboembolic events, such as personal or family history, treatment with gonadotropins may further increase the risk for aggravation or occurrence of such events. In these women, the benefits of gonadotropin administration need to be weighed against the risks. It should be noted however that pregnancy itself as well as OHSS also carry an increased risk of thromboembolic events.

Treatment in men
Elevated endogenous FSH levels are indicative of primary testicular failure. Such patients are unresponsive to follitropin alfa/hCG therapy. Follitropin alfa should not be used when an effective response cannot be obtained.

Semen analysis is recommended 4 to 6 months after the beginning of treatment as part of the assessment of the response.

Sodium content

Ovaleap contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially “sodium-free”.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant use of follitropin alfa with other medicinal products used to stimulate ovulation (e.g. hCG, clomifene citrate) may potentiate the follicular response, whereas concurrent use of a GnRH agonist or antagonist to induce pituitary desensitisation may increase the dose of follitropin alfa needed to elicit an adequate ovarian response. No other clinically significant medicinal product interaction has been reported during follitropin alfa therapy.

4.6 Fertility, pregnancy and lactation

Pregnancy

There is no indication for use of Ovaleap during pregnancy. Data on a limited number of exposed pregnancies (less than 300 pregnancy outcomes) indicate no malformative or foeto/neonatal toxicity of follitropin alfa.

No teratogenic effect has been observed in animal studies (see section 5.3). In case of exposure during pregnancy, clinical data are not sufficient to exclude a teratogenic effect of follitropin alfa.

Breast-feeding

Ovaleap is not indicated during breast-feeding.

Fertility

Ovaleap is indicated for use in infertility (see section 4.1).

4.7 Effects on ability to drive and use machines

Ovaleap has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Summary of the safety profile

The most commonly reported adverse reactions are headache, ovarian cysts and local injection site reactions (e.g. pain, erythema, haematoma, swelling and/or irritation at the site of injection).

Mild or moderate OHSS has been commonly reported and should be considered as an intrinsic risk of the stimulation procedure. Severe OHSS is uncommon (see section 4.4).

Thromboembolism may occur very rarely (see section 4.4).

Tabulated list of adverse reactions

The following definitions apply to the frequency terminology used hereafter:
Very common ≥ 1/10;
Common ≥ 1/100 to < 1/10;
Uncommon ≥ 1/1,000 to < 1/100;
Rare ≥ 1/10,000 to < 1/1,000;
Very rare < 1/10,000;
Not known cannot be estimated from the available data.

Treatment in women

Table 1: Adverse reactions in women

System organ class	Frequency	Adverse reaction
Immune system disorders	Very rare	Mild to severe hypersensitivity reactions, including anaphylactic reactions and shock
Nervous system disorders	Very common	Headache
Vascular disorders	Very rare	Thromboembolism (both in association with and separate from OHSS)
Respiratory, thoracic and mediastinal disorders	Very rare	Exacerbation or aggravation of asthma
Gastrointestinal disorders	Common:	Abdominal pain, abdominal distension, abdominal discomfort, nausea, vomiting, diarrhoea
Reproductive system and breast disorders	Very common	Ovarian cysts
	Common	Mild or moderate OHSS (including associated symptomatology)
	Uncommon	Severe OHSS (including associated symptomatology) (see section 4.4)
	Rare	Complication of severe OHSS
General disorders and administration site conditions	Very common	Injection site reactions (e.g. pain, erythema, haematoma, swelling and/or irritation at the site of injection)

Treatment in men

Table 2: Adverse reactions in men

System organ class	Frequency	Adverse reaction
Immune system disorders	Very rare	Mild to severe hypersensitivity reactions, including anaphylactic reactions and shock
Respiratory, thoracic and mediastinal disorders	Very rare	Exacerbation or aggravation of asthma
Skin and subcutaneous tissue disorders	Common:	Acne
Reproductive system and breast disorders	Common	Gynaecomastia, varicocele
General disorders and administration site conditions	Very common	Injection site reactions (e.g. pain, erythema, haematoma, swelling and/or irritation at the site of injection)
Investigations	Common	Weight gain

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form
http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il.

4.9 Overdose

The effects of an overdose of follitropin alfa are unknown, nevertheless, there is a possibility that OHSS may occur (see section 4.4).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Sex hormones and modulators of the genital systems, gonadotropins, ATC code: G03GA05.

Pharmacodynamic effects

In women, the most important effect resulting from parenteral administration of FSH is the development of mature Graafian follicles. In women with anovulation, the object of follitropin alfa therapy is to develop a single mature Graafian follicle from which the ovum will be liberated after the administration of hCG.

Clinical efficacy and safety in women

In clinical trials, patients with severe FSH and LH deficiency were defined by an endogenous serum LH level < 1.2 IU/L as measured in a central laboratory. However, it should be taken into account that there are variations between LH measurements performed in different laboratories.

In clinical studies comparing r-hFSH (follitropin alfa) and urinary FSH in ART (see table 3 below) and in ovulation induction, follitropin alfa was more potent than urinary FSH in terms of a lower total dose and a shorter treatment period needed to trigger follicular maturation.

In ART, follitropin alfa at a lower total dose and shorter treatment period than urinary FSH, resulted in a higher number of oocytes retrieved when compared to urinary FSH.

Table 3: Results of study GF 8407 (randomised parallel group study comparing efficacy and safety of follitropin alfa with urinary FSH in ART)		
	follitropin alfa (n = 130)	urinary FSH (n = 116)
Number of oocytes retrieved	11.0 ± 5.9	8.8 ± 4.8
Days of FSH stimulation required	11.7 ± 1.9	14.5 ± 3.3
Total dose of FSH required (number of FSH 75 IU ampoules)	27.6 ± 10.2	40.7 ± 13.6
Need to increase the dose (%)	56.2	85.3
Differences between the 2 groups were statistically significant ($p < 0.05$) for all criteria listed.		

Clinical efficacy and safety in men

In men deficient in FSH, follitropin alfa administered concomitantly with hCG for at least 4 months induces spermatogenesis.

5.2 Pharmacokinetic properties

Following intravenous administration, follitropin alfa is distributed to the extracellular fluid space with an initial half-life of around 2 hours and eliminated from the body with a terminal half-life of about one day. The steady state volume of distribution and total clearance are 10 L and 0.6 L/h, respectively. One-eighth of the follitropin alfa dose is excreted in the urine.

Following subcutaneous administration, the absolute bioavailability is about 70 %. Following repeated administration, follitropin alfa accumulates 3-fold achieving a steady-state within 3-4 days. In women whose endogenous gonadotropin secretion is suppressed, follitropin alfa has nevertheless been shown to effectively stimulate follicular development and steroidogenesis, despite unmeasurable LH levels.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of single and repeated dose toxicity and genotoxicity additional to that already stated in other sections of this SmPC.

Impaired fertility has been reported in rats exposed to pharmacological doses of follitropin alfa (≥ 40 IU/kg/day) for extended periods, through reduced fecundity.

Given in high doses (≥ 5 IU/kg/day) follitropin alfa caused a decrease in the number of viable foetuses without being a teratogen and dystocia similar to that observed with urinary Menopausal Gonadotropin (hMG). However, since Ovaleap is not indicated in pregnancy, these data are of limited clinical relevance.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium dihydrogen phosphate dihydrate
Sodium hydroxide (2 M) (for pH adjustment)

Mannitol
Methionine
Polysorbate 20
Benzyl alcohol
Benzalkonium chloride
Water for injections

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

2 years.

Shelf life and storage conditions after first opening
The cartridge in-use in the pen may be stored for a maximum of 28 days. Do not store above 25 °C.
The patient should write down in the patient diary provided with the Ovaleap Pen the date of first use.

The pen cap must be put back on the pen after each injection in order to protect from light.

6.4 Special precautions for storage

Store in a refrigerator (2 °C - 8 °C).

Do not freeze.

Keep the cartridge in the outer carton in order to protect from light.

Before opening and within its shelf life, the medicinal product may be removed from the refrigerator, without being refrigerated again, for up to 3 months. Do not store above 25 °C. The product must be discarded if it has not been used after 3 months.

For storage conditions after first opening of the medicinal product, see section 6.3.

6.5 Nature and contents of container

Ovaleap 300 IU/0.5 mL solution for injection
Cartridge (type I glass) with a rubber piston (bromobutyl rubber) and a crimp-cap (aluminium) with a septum (bromobutyl rubber), containing 0.5 mL of solution.
Injection needles (stainless steel; 0.33 mm x 12 mm, 29 G x ½")

Pack size of 1 cartridge and 10 injection needles.

Ovaleap 450 IU/0.75 mL solution for injection
Cartridge (type I glass) with a rubber piston (bromobutyl rubber) and a crimp-cap (aluminium) with a septum (bromobutyl rubber), containing 0.75 mL of solution..
Injection needles (stainless steel; 0.33 mm x 12 mm, 29 G x ½")

Pack size of 1 cartridge and 10 injection needles.

Ovaleap 900 IU/1.5 mL solution for injection
Cartridge (type I glass) with a rubber piston (bromobutyl rubber) and a crimp-cap (aluminium) with a septum (bromobutyl rubber), containing 1.5 mL of solution..
Injection needles (stainless steel; 0.33 mm x 12 mm, 29 G x ½")

Pack size of 1 cartridge and 20 injection needles.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

The solution must not be used if it contains particles or if the solution is not clear.

Ovaleap is designed for use in conjunction with the Ovaleap Pen only. The instructions for use of the pen must be followed carefully.

Each cartridge must be used by a single patient only.

Empty cartridges must not be refilled. Ovaleap cartridges are not designed to allow any other medicinal product to be mixed in the cartridges. Discard used needles immediately after injection.

7 REGISTRATION NUMBER

157-82-34716-00

8. MANUFACTURER

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9. LICENCE HOLDER

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