**Summary of Product Characteristics**

## 1. NAME OF THE MEDICINAL PRODUCT

Lovima® 75 microgram film-coated tablets

## 2. QUALITATIVE AND QUANTITATIVE

Each film-coated tablet contains 75 microgram desogestrel.

Excipient(s) with known effect:

Lactose monohydrate 55.07 mg, soybean oil (maximum 0.026 mg).

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Film-coated tablet.

White round.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Oral contraception for women of child bearing age including adolescents.

### 4.2 Posology and method of administration

**How to take Lovima**

Tablets must be taken every day at about the same time so that the interval between two tablets always is 24 hours. The first tablet should be taken on the first day of menstrual bleeding. Thereafter one tablet each day is to be taken continuously, without taking any notice of possible bleeding. A new blister is started directly the day after the previous one.

**How to start Lovima**

*No preceding hormonal contraceptive use [in the past month]*

Tablet taking has to start on day 1 of the woman's natural cycle (day 1 is the first day of her menstrual bleeding). Starting on days 2-5 is allowed, but during the first cycle a barrier method is recommended for the first 7 days of tablet-taking.

*Following miscarriage or abortion:*

It is recommended to start tablet-taking immediately or within 5 days after miscarriage or abortion. In that case there is no need to use an additional method of contraception.

*Following delivery:*

Contraceptive treatment with Lovima after delivery can be initiated before the menstruations have returned. If more than 21 days have elapsed since delivery, pregnancy ought to be ruled out and an additional method of contraception should be used for the first week.

For additional information for breastfeeding women see section 4.6.

**How to start Lovima when changing from other contraceptive methods**

*Changing from a combined oral contraceptive (combined hormonal contraceptive (COC), vaginal ring, or transdermal patch).*

The woman should start with Lovima preferably on the day after the last active tablet (the last tablet containing the active substances) of her previous COC or on the day of removal of her vaginal ring or transdermal patch. In these cases, the use of an additional contraceptive is not necessary.

The woman may also start at the latest on the day following the usual tablet-free, patch-free, ring-free, or placebo tablet interval of her previous combined hormonal contraceptive, but during the first 7 days of tablet-taking an additional barrier method is recommended.

*Changing from a progestogen-only-method (minipill, injection, implant or from a progestogen-releasing intrauterine system (IUS)).*

The woman may switch

- from the minipill: on any day
- from an implant or the IUS: on the day of its removal
- from an injectable: when the next injection would be due.

*Use after Emergency Contraception*

If a woman wishes to start Lovima after using emergency hormonal contraception, it is advisable to start tablet taking on day 1 of the woman's natural cycle.

If it is considered necessary to start sooner or if Lovima is being resumed after inconsistent use, the following advice should be noted:

Levonorgestrel

Lovima can be started or restarted on the same day as emergency contraception containing levonorgestrel. Additional contraceptive measures (abstinence or barrier methods) are required for the first 7 days of Lovima use.

Ulipristal acetate

Lovima should be started or restarted no sooner than 5 days (120 hours) after emergency contraception containing ulipristal acetate, because the effectiveness of ulipristal can be reduced. (See section 4.5) Additional contraceptive measures (abstinence or barrier methods) are required during the 5 day delay before starting or restarting Lovima and for an additional 7 days after starting or restarting Lovima (12 days in total.)

Ulipristal acetate may conversely reduce the effectiveness of Lovima. Concomitant use is therefore not recommended. (see section 4.5)

**Management of missed tablets**

Contraceptive protection may be reduced if more than 36 hours have elapsed between two tablets. If the user is less than 12 hours late from her usual time of taking any tablet, she should take the missed tablet as soon as she remembers and take the next tablet at the usual. time, even if it leads to taking two tablets in one day.

If she is more than 12 hours late from her usual tablet taking time, the woman should immediately take the forgotten tablet and take the next tablet at the usual time, even if it leads to taking two tablets in one day. If more than one tablet has been missed, only one of the missed tablets should be taken immediately. In addition, she should use an additional barrier method of contraception for the next 7 days. Missed tablets at any time in the cycle can reduce the efficacy of Lovima and risk pregnancy, but missing a tablet in the first week after initiation of Lovima is an especially vulnerable time. The need for emergency contraception must be considered for any missed pills.

**Advice in case of gastrointestinal disturbances**

If vomiting occurs within 3-4 hours of tablet-taking, then the pill should be considered 'missed' and the advice for a missed tablet should be followed.
In the case of severe or persistent gastro-intestinal disturbance (vomiting or diarrhoea), absorption of Lovima may not be complete and contraceptive efficacy may be reduced. Additional contraceptive measures will be required for the duration of the illness and for the first 7 days of normal tablet-taking..

**Treatment surveillance**

Assessment of women prior to starting oral contraceptives (and at regular intervals thereafter) should include a personal and family medical history of each woman. Pregnancy should be excluded using the criteria given in section 4.4 and bleeding disturbances, such as oligomenorrhoea and amenorrhoea should be investigated by a physician before pharmacy supply can be considered. The interval between assessments to determine suitability for re-supply in pharmacy depends on the circumstances in each individual case but should not exceed 3 months for a first supply of Lovima and 12 months thereafter (see section 4.4). If the product may conceivably influence latent or manifest disease (see section 4.4), re-evaluation of supply should be timed accordingly.

The need for physical examination or further assessment by a doctor should be guided by the patient and family history and by the contraindications (section 4.3) and warnings (section 4.4) for this product. Gynaecological examination is rarely required prior to commencement or oral contraception, but may be indicated in cases of menstrual bleeding disturbances or other gynaecological symptoms e.g. pain or discharge. Breast examination is indicated for breast symptoms e.g. undiagnosed breast lumps.

All women should be encouraged to be 'breast aware' and report any changes noticed*. All women should be advised of the importance of taking part in routine cervical screening.

Despite the fact that Lovima is taken regularly, bleeding disturbances may occur. If bleeding is troublesome (for example if it becomes very frequent and irregular) another contraceptive method should be considered. If the symptoms persist, an organic cause should be ruled out.

Management of amenorrhoea during treatment depends on whether or not the tablets have been taken in accordance with the instructions and may include a pregnancy test.

The treatment should be stopped if a pregnancy occurs.

Women should be advised that Lovima does not protect against HIV (AIDS) and other sexually transmitted diseases. Condoms are the only contraceptive method which protect against sexually transmitted diseases.

Special populations

*Renal impairment*

No clinical studies have been performed in patients with renal impairment. There is no evidence that dose adjustment is required.

*Hepatic impairment*

No clinical studies have been performed in patients with hepatic insufficiency. Since the metabolism of steroid hormones might be impaired in patients with severe hepatic disease, the use of Lovima in these women is not indicated. (see section 4.3).

*Paediatric population*

The safety and efficacy of Lovima in adolescents below 18 years has not been established. No data are available. The benefits and risks of supply to adolescents under 16 years should be carefully considered.

Method of administration

Oral use.

**4.3 Contraindications**

- Active venous thromboembolic disorder.
- Presence or history of severe hepatic disease as long as liver function values have not returned to normal.
- Known or suspected sex-steroid sensitive malignancies.
- Undiagnosed vaginal bleeding.
- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Known allergy to peanut or soya.

**4.4 Special warnings and precautions for use**

Before any supply of Lovima from a pharmacy (initial or repeat supply) pregnancy in the woman concerned should be excluded. Pregnancy can be ruled out with reasonable certainty if the woman has no symptoms or signs of pregnancy and if she meets one or more of the following conditions:

- Has not had sexual intercourse since the last normal (natural) menstrual period, since childbirth, abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease.
- Has used a reliable alternative method of contraception correctly and consistently.
- Is within the first 5 days of the onset of a normal menstrual period.
- Is less than 21 days postpartum (non-breastfeeding women)
- Is fully breastfeeding, amenorrhoeic AND less than 6 months postpartum.
- Is within the first 5 days after abortion, miscarriage, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease.
- Has not had intercourse for >21 days AND has a negative high-sensitivity urine pregnancy test (able to detect hCG levels around 20 mIU/ml).

If any of the conditions/risk factors mentioned below is present the benefits of progestogen use should be weighed against the possible risks for each individual woman and discussed with the woman before she decides to start Lovima. In the event of aggravation, exacerbation, or first appearance of any of these conditions, the woman should contact her physician. The physician should then decide on whether the use of Lovima should be discontinued.

The risk for breast cancer increases in general with increasing age. During the use of combined oral contraceptives (COCs) the risk of having breast cancer diagnosed is slightly increased. This increased risk disappears gradually within 10 years after discontinuation of COC use and is not related to the duration of use, but to the age of the woman when using the COC. The expected number of cases diagnosed per 10,000 women who use combined COCs (up to 10 years after stopping) relative to never users over the same period has been calculated for the respective age groups and is presented in the table below.

| **Age group** | **Expected cases COC-users** | **Expected cases non-users** |
|---|---|---|
| 16-19 years | 4.5 | 4 |
| 20-24 years | 17.5 | 16 |
| 25-29 years | 48.7 | 44 |
| 30-34 years | 110 | 100 |
| 35-39 years | 180 | 160 |
| 40-44 years | 260 | 230 |

The risk in users of progestogen-only contraceptives (POCs), such as Lovima, is possibly of similar magnitude as that associated with COCs. However, for POCs the evidence is less conclusive. Compared to the risk of getting breast cancer ever in life, the increased risk associated with COCs is low. The cases of breast cancer diagnosed in COC users tend to be less advanced than in those who have not used COCs. The increased risk in COC users may be due to an earlier diagnosis, biological effects of the pill or a combination of both.

Since a biological effect of progestogens on liver cancer cannot be excluded an individual benefit/risk assessment should be made by a doctor in women with liver cancer.

When acute or chronic disturbances of liver function occur the woman should be referred to a specialist for examination and advice.

Epidemiological investigations have associated the use of COCs with an increased incidence of venous thromboembolism (VTE, deep venous thrombosis and pulmonary embolism). Although the clinical relevance of this finding for desogestrel used as a contraceptive in the absence of an oestrogenic component is unknown, Lovima should be discontinued in the event of a thrombosis. Discontinuation of Lovima should also be considered in case of long-term immobilisation due to surgery or illness. Women with a history of thrombo-embolic disorders should be made aware of the possibility of a recurrence on Lovima and should be alerted to seek urgent medical attention if they develop symptoms suggestive of VTE. Lovima should be stopped if VTE is confirmed or is strongly suspected pending the results of investigations.

Although progestogens may have an effect on peripheral insulin resistance and glucose tolerance, there is no evidence for a need to alter the therapeutic regimen in diabetics using progestogen-only pills. However, diabetic patients should consult their doctor before starting treatment and should be carefully observed during the first months of use.

If a sustained hypertension occurs during the use of Lovima, or if a significant increase in blood pressure does not adequately respond to antihypertensive therapy, the discontinuation of Lovima should be considered.

Treatment with desogestrel leads to decreased estradiol serum levels, to a level corresponding with the early follicular phase. It is as yet unknown whether the decrease has any clinically relevant effect on bone mineral density.

The protection with traditional progestogen-only pills against ectopic pregnancies is not as good as with combined oral contraceptives, which has been associated with the frequent occurrence of ovulations during the use of progestogen-only pills. Despite the fact that desogestrel consistently inhibits ovulation, ectopic pregnancy should be taken into account in the differential diagnosis if the woman presents with abdominal pain with or without amenorrhoea and with or without vaginal bleeding.

Chloasma may occasionally occur, especially in women with a history of chloasma gravidarum. Women with a tendency to chloasma should avoid exposure to the sun or ultraviolet radiation whilst taking Lovima.

The following conditions have been reported both during pregnancy and during sex steroid use, but an association with the use of progestogens has not been established: jaundice and/or pruritus related to cholestasis; gallstone formation; porphyria; systemic lupus erythematosus; haemolytic uraemic syndrome; Sydenham's chorea; herpes gestations; otosclerosis-related hearing loss; (hereditary) angioedema.

Depressed mood and depression are well known undesirable effects of hormonal contraceptive use (see section 4.8). Depression can be serious and is a well-known risk factor for suicidal behaviour and suicide. Women should be advised to contact their physician in case of mood changes and depressive symptoms, including shortly after initiating the treatment.

The efficacy of Lovima may be reduced in the event of missed tablets (Section 4.2), gastro-intestinal disturbances (Section 4.2), or concomitant medications that decrease the plasma concentration of etonogestrel, the active metabolite of desogestrel (Section 4.5).

Each tablet of this medicinal product contains 55.07 mg of lactose.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency, or glucose-galactose malabsorption should not take this medicine.

**4.5 Interaction with other medicinal products and other forms of interaction**

**Interactions**

***Effect of other medicinal products on Lovima***

Interactions between hormonal contraceptives and other medicinal products may lead to breakthrough bleeding and/or contraceptive failure. The following interactions have been reported in the literature (mainly with combined contraceptives but occasionally also with progestogen-only contraceptives).

During treatment with medical charcoal, the absorption of the steroid in the tablet may be reduced and thereby the contraceptive efficacy may also be reduced. Under these circumstances, the advice as given for missed pills in section 4.2 is applicable.

***Substances increasing the clearance of contraceptive hormones (diminished contraceptive efficacy by enzyme induction):***

Hepatic metabolism: Interactions can occur with medicinal products that induce microsomal enzymes, which can result in increased clearance of sex hormones. Such products include: hydantoins, (e.g. phenytoin), barbiturates (e.g. phenobarbital), primidone, carbamazepine, rifampicin, and possibly also for oxcarbazepine, topiramate, rifabutin, felbamate, griseofulvin and products containing St. John's wort (Hypericum perforatum).

Maximal enzyme induction is not seen for 2-3 weeks, but may then be sustained for at least 4 weeks after cessation of drug therapy.

Women on treatment with any of these medicinal products should temporarily use a barrier method in addition to desogestrel.

With microsomal enzyme-inducing drugs, the barrier method should be used during the time of concomitant drug administration and for 28 days after their discontinuation. Women on long-term or chronic treatment with hepatic enzyme inducers should be referred to their doctor and a non-hormonal method of contraception should be considered.

***Substances with variable effects on the clearance of contraceptive hormones:***

When co-administered with hormonal contraceptives, many combinations of HIV protease inhibitors (e.g. ritonavir, nelfinavir) and non-nucleoside reverse transcriptase inhibitors (e.g. nevirapine) and/or combinations with Hepatitis C virus (HCV) medicinal products (e.g. boceprevir, telaprevir), can increase or decrease plasma concentrations of progestins. The net effect of these changes may be clinically relevant in some cases.

Therefore, the prescribing information of concomitant HIV/HCV medications should be consulted to identify potential interactions and any related recommendations. In case of any doubt, an additional barrier contraceptive method should be used by women on protease inhibitor or non-nucleoside reverse transcriptase inhibitor therapy.

***Substances decreasing the clearance of contraceptive hormones (enzyme inhibitors )***

Concomitant administration of strong (e.g. ketoconazole, itraconazole, clarithromycin) or moderate (e.g. fluconazole, diltiazem, erythromycin) CYP3A4 inhibitors may increase the serum concentrations of progestins, including etonogestrel, the active metabolites of desogestrel.

***Effect of Lovima on other medicinal products***

Hormonal contraceptives may interfere with the metabolism of other drugs. Accordingly, plasma and tissue concentrations may either increase (e.g. cyclosporin) or decrease (e.g. lamotrigine).

Note: The prescribing information of concomitant medications should be consulted to identify potential interactions.

Laboratory tests

Data obtained with COCs have shown that contraceptive steroids may influence the results of certain laboratory tests, including biochemical parameters of liver, thyroid, adrenal and renal function, serum levels of (carrier) proteins, e.g. corticosteroid binding globulin and lipid/lipoprotein fractions, parameters of carbohydrate metabolism and parameters of coagulation and fibrinolysis. The changes generally remain within the normal range. To what extent this also applies to progestogen-only contraceptives is not known.

***Emergency contraception containing ulipristal acetate***

Lovima and the emergency contraceptive ulipristal acetate both bind to the progesterone receptor. Concomitant use may result in reduced efficacy of both Lovima and ulipristal, and is therefore not recommended. Lovima should be started or restarted no sooner than 5 days (120 hours) after emergency contraception with ulipristal acetate (see section 4.2).

**4.6 Fertility, pregnancy and lactation**

Pregnancy

Lovima is not indicated during pregnancy. If pregnancy occurs during use of Lovima, further intake should be stopped.

Animal studies have shown that very high doses of progestogenic substances may cause masculinisation of female foetuses.

Extensive epidemiological studies have revealed neither an increased risk of birth defects in children born to women who used COCs prior to pregnancy, nor a teratogenic effect when COCs were taken inadvertently during early pregnancy. Pharmacovigilance data collected with various desogestrel-containing COCs also do not indicate an increased risk.

Breastfeeding

Based on clinical study data, desogestrel does not appear to influence the production or the quality (protein, lactose, or fat concentrations) of breast milk. However, there have been infrequent postmarketing reports of a decrease in breast milk production while using desogestrel. Small amounts of etonogestrel are excreted in the breast milk. As a result, 0.01 - 0.05 microgram etonogestrel per kg body weight per day may be ingested by the child (based on an estimated milk ingestion of 150 ml/kg/day). Like other progestogen-only pills, Lovima can be used during breast feeding.

Limited long-term follow-up data are available on children, whose mothers started using desogestrel during the 4th to 8th weeks post-partum. They were breast-fed for 7 months and followed up to 1.5 years (n=32) or to 2.5 years (n=14) of age. Evaluation of growth and physical and psychomotor development did not indicate any differences in comparison to nursing infants, whose mother used a copper-IUD.

Based on the available data Lovima may be used during lactation. The development and growth of a nursing infant, whose mother uses Lovima should, however, be carefully observed.

Fertility

Lovima is indicated for the prevention of pregnancy. For information on return to fertility (ovulation), see section 5.1.

### 4.7 Effects on ability to drive and use machines

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

### 4.8 Undesirable effects

The most commonly reported undesirable effect in the clinical trials is bleeding irregularity. Some kind of bleeding irregularity has been reported in up to 50% of women using desogestrel. Since desogestrel causes ovulation inhibition close to 100%, in contrast to other progestogen-only pills, irregular bleeding is more common than with other progestogen-only pills. In 20 - 30% of the women, bleeding may become more frequent, whereas in another 20% bleeding may become less frequent or totally absent. Vaginal bleeding may also be of longer duration. After a couple of months of treatment, bleedings tend to become less frequent. Information, counselling, and a bleeding diary can improve the woman's acceptance of the bleeding pattern.

The most commonly reported other undesirable effects in the clinical trials with desogestrel (> 2.5%) were acne, mood changes, breast pain, nausea and weight increase. The undesirable effects are mentioned in the table below.

All undesirable effects are listed by system organ class and frequency; common (≥1/100 to <1/10), uncommon (≥1/1,000 to <1/100) and rare (≥1/10.000 to <1/1,000).

| **System Organ Class (MedDRA)*** | **Frequency of adverse reactions** | | |
|---|---|---|---|
| | **Common** | **Uncommon** | **Rare** |
| Infections and infestations | | Vaginal infection | |
| Psychiatric disorders | Mood altered, Depressed mood, Libido decreased | | |
| Nervous system disorders | Headache | | |
| Eye disorders | | Contact lens intolerance | |
| Gastrointestinal disorders | Nausea | Vomiting | |

| | | | |
|---|---|---|---|
| Skin and subcutaneous tissue disorders | Acne | Alopecia | Rash, Urticaria, Erythema nodosum |
| Reproductive system and breast disorders | Breast pain, Menstruation irregular, Amenorrhoea | Dysmenorrhoea, Ovarian cyst | |
| General disorders and administration site condition | | Fatigue | |
| Investigations | Weight increased | | |

* MedDRA version 9.0

Breast discharge may occur during use of Lovima. On rare occasions, ectopic pregnancies have been reported (see section 4.4). In addition, (aggravation of) angioedema and/or aggravation of hereditary angioedema may occur (see section 4.4).

In women using (combined) oral contraceptives a number of (serious) undesirable effects have been reported. These include venous thromboembolic disorders, arterial thromboembolic disorders, hormone-dependent tumours (e.g. liver tumours, breast cancer), and chloasma, some of which are discussed in more detail in section 4.4.

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. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme; website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

### 4.9 Overdose

There have been no reports of serious adverse effects from overdose. Symptoms that may occur in this case are nausea, vomiting and, in young girls, slight vaginal bleeding. There are no antidotes and the treatment should be symptomatic.

## 5. PHARMACOLGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: hormonal contraceptives for systemic use, ATC code: G03AC09.

Mechanism of action

Lovima is a progestogen-only pill, which contains the progestogen desogestrel. Like other progestogen-only pills, Lovima is best suited for use during breast feeding and for women who may not or do not want to use oestrogens. In contrast to traditional progestogen-only pills, the contraceptive effect of Lovima is achieved primarily by inhibition of ovulation. Other effects include increased viscosity of the cervical mucus.

Clinical efficacy and safety

When studied for 2 cycles, using a definition of ovulation as a progesterone level greater than 16 nmol/L for 5 consecutive days, the ovulation incidence was found to be 1% (1/103) with a 95% confidence interval of 0.02% - 5.29% in the ITT group (user and method failures). Ovulation inhibition was achieved from the first cycle of use. In this study, when desogestrel was discontinued after 2 cycles (56 continuous days), ovulation occurred on average after 17 days (range 7-30 days).

In a comparative efficacy trial (which allowed a maximum time of 3 hours for missed pills) the overall ITT Pearl-Index found for desogestrel was 0.4 (95% confidence interval 0.09% - 1.20%), compared to 1.6 (95% confidence interval 0.42% - 3.96%) for 30 µg levonorgestrel.

The Pearl-Index for desogestrel is comparable to the one historically found for COCs in the general COC-using population.

Treatment with desogestrel leads to decreased estradiol levels, to a level corresponding to the early follicular phase. No clinically relevant effects on carbohydrate metabolism, lipid metabolism, and haemostasis have been observed.

Paediatric population

No clinical data on efficacy and safety are available in adolescents below 18 years.

**5.2 Pharmacokinetic properties**

*Absorption*

After oral dosing of desogestrel (DSG) is rapidly absorbed and converted into etonogestrel (ENG). Under steady-state conditions, peak serum levels are reached 1.8 hours after tablet-intake and the absolute bioavailability of ENG is approximately 70%.

*Distribution*

ENG is 95.5-99% bound to serum proteins, predominantly to albumin and to a lesser extent to SHBG.

*Biotransformation*

DSG is metabolised via hydroxylation and dehydrogenation to the active metabolite ENG. ENG is metabolised via sulphate and glucuronide conjugation.

*Elimination*

ENG is eliminated with a mean half-life of approximately 30 hours, with no difference between single and multiple dosing. Steady-state levels in plasma are reached after 4-5 days. The serum clearance after IV administration of ENG is approximately 10 l per hour. Excretion of ENG and its metabolites either as free steroid or as conjugates, is with urine and faeces (ratio 1.5:1). In lactating women, ENG is excreted in breast milk with a milk/serum ratio of 0.37-0.55. Based on these data and an estimated milk intake of 150 ml/kg/day, 0.01 - 0.05 microgram etonogestrel may be ingested by the infant.

Special populations

*Effect of renal impairment*

No studies were performed to evaluate the effect of renal disease on the pharmacokinetics of DSG.

*Effect of hepatic impairment*

No studies were conducted to evaluate the effect of hepatic disease on the pharmacokinetics of DSG. However, steroid hormones may be poorly metabolized in women with impaired liver function.

*Ethnic groups*

No studies were performed to assess pharmacokinetics in ethnic groups

**5.3 Preclinical safety data**

Toxicological studies did not reveal any effects other than those, which can be explained from the hormonal properties of desogestrel.

Environmental Risk Assessment (ERA)

The active substance etonogestrel shows an environmental risk

## 6. PHARMACEUTICAL PARTICULARS

**6.1 List of excipients**

Tablet core:

Lactose monohydrate

Maize starch

Povidone K30 (E1201)

d-α-Tocopherol (E307)

Soybean oil

Silica, colloidal hydrated (E551)

Silica, colloidal anhydrous (E551)

Stearic acid (E570)

Coating:

Hypromellose 2910 (E464)

Polyethylene Glycol

Titanium Dioxide (E 171)

**6.2 Incompatibilities**

Not applicable.

**6.3 Shelf life**

3 years

### 6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

### 6.5 Nature and contents of container

Blisters of aluminium push-through foil and PVC/PVDC film. The blister packs may come with a blister holder.

Pack sizes:

1 x 28 film-coated tablets

3 x 28 film-coated tablets

6 x 28 film-coated tablets

Not all pack sizes may be marketed.

### 6.6 Special precautions for disposal and other handling

The active substance etonogestrel shows an environmental risk to fish.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

## 7. MARKETING AUTHORISATION HOLDER

Maxwellia Ltd, Alderley Park, Alderley Edge, England, SK10 4TG

## 8. MARKETING AUTHORISATION NUMBER(S)

PL 42807/0002

## 9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation – 02/07/2013

Date of latest renewal – 28/03/2018

## 10. DATE OF REVISION OF THE TEXT

TBC