ORGANON

For the use only of Registered Medical Practitioner or a Hospital or a Laboratory

DESOGESTREL AND ETHINYLESTRADIOL TABLETS IP

Femilon®

COMPOSITION

Each tablet contains 0.150 mg desogestrel IP and 0.020 mg ethinylestradiol IP.
Excipient: lactose < 80 mg.
For a full list of excipients, see section List of excipients

DOSAGE FORMS

Tablets for oral use.

Tablets are round, biconvex and 6 mm in diameter. They are coded on one side TR above 4 and on the reverse side Organon®.

INDICATIONS

Contraception.

POSOLOGY AND METHOD OF ADMINISTRATION

How to take FEMILON

Tablets must be taken in the order directed on the package every day at about the same time with some liquid as needed. One tablet is to be taken daily for 21 consecutive days. Each subsequent pack is started after a 7-day tablet-free interval, during which time a withdrawal bleed usually occurs. This usually starts 2-3 days after the last tablet and may not have finished before the next pack is started.

How to start taking FEMILON

No preceding hormonal contraceptive use [in the past month]

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

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

The woman should start with FEMILON preferably on the day after the last active tablet (the last tablet containing the active substances) of her previous COC, but at the latest on the day following the usual tablet-free interval or following the last placebo tablet of her previous COC. In case a vaginal ring or transdermal patch has been used, the woman should start using FEMILON preferably on the day of removal, but at the latest when the next application would have been due.

If the woman has been using her previous method consistently and correctly and if it is reasonably certain that she is not pregnant she may also switch from her previous combined hormonal contraceptive on any day of the cycle.

The hormone-free interval of the previous method should never be extended beyond its recommended length.

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

The woman may switch any day from the minipill (from an implant or the IUS on the day of its removal, from an injectable when the next injection would be due), but should in all of these cases be advised to additionally use a barrier method for the first 7 days of tablet-taking.

Following first-trimester abortion

The woman may start immediately. When doing so, she need not take additional contraceptive measures.

Following delivery or second-trimester abortion

For breastfeeding women see section 'Pregnancy and Lactation'.

Women should be advised to start at day 21 to 28 after delivery or second-trimester abortion. When starting later, the woman should be advised to additionally use a barrier method for the first 7 days of tablet-taking. However, if intercourse has already occurred, pregnancy should be excluded before the actual start of COC use or the woman has to wait for her first menstrual period.

The increased risk of VTE during the postpartum period should be considered when restarting FEMILON (see sections 'Special Warnings and precautions for use').

Management of missed tablets

If the user is **less than 12 hours late** in taking any tablet, contraceptive protection is not reduced. The woman should take the tablet as soon as she remembers and should take further tablets at the usual time.

If she is **more than 12 hours late** in taking any tablet, contraceptive protection may be reduced. The management of missed tablets can be guided by the following two basic rules:

1. tablet-taking must never be discontinued for longer than 7 days.
2. 7 days of uninterrupted tablet-taking are required to attain adequate suppression of the hypothalamic-pituitary-ovarian-axis.

Accordingly the following advice can be given in daily practice:

- **Week 1**

The user should take the last missed tablet as soon as she remembers, even if this means taking two tablets at the same time. She then continues to take tablets at her usual time. In addition, a barrier method such as a condom should be used for the next 7 days. If intercourse took place in the preceding 7 days, the possibility of a pregnancy should be considered. The more tablets are missed and the closer they are to the regular tablet-free interval, the higher the risk of a pregnancy.

- **Week 2**

The user should take the last missed tablet as soon as she remembers, even if this means taking two tablets at the same time. She then continues to take tablets at her usual time. Provided that the woman has taken her tablets correctly in the 7 days preceding the first missed tablet, there is no need to use extra contraceptive precautions. However, if this is not the case, or if she missed more than 1 tablet, the woman should be advised to use extra precautions for 7 days.

- **Week 3**

The risk of reduced reliability is imminent because of the forthcoming tablet-free interval. However, by adjusting the tablet-intake schedule, reduced contraceptive protection can still be prevented. By adhering to either of the following two options, there is therefore no need to use extra contraceptive precautions, provided that in the 7 days preceding the first missed tablet the woman has taken all tablets correctly. If this is not the case, the woman should be advised to follow the first of these two options and to use extra precautions for the next 7 days as well.

1. The user should take the last missed tablet as soon as she remembers, even if this means taking two tablets at the same time. She then continues to take tablets at her usual time. The next pack must be started as soon as the current pack is finished, i.e.: no gap should be left between packs. The user is unlikely to have a withdrawal bleed until the end of the second pack, but she may experience spotting or breakthrough bleeding on tablet-taking days.
2. The woman may also be advised to discontinue tablet-taking from the current pack. She should then have a tablet-free interval of up to 7 days, including the days she missed tablets, and subsequently continue with the next pack.

If the woman missed tablets and subsequently has no withdrawal bleed in the first normal tablet-free interval, the possibility of a pregnancy should be considered.

Advice in case of gastro-intestinal disturbances

In case of severe gastro-intestinal disturbance, absorption may not be complete and additional contraceptive measures should be taken.

If vomiting occurs within 3-4 hours after tablet taking, the advice concerning missed tablets, as given in Section 'Management of missed tablets', is applicable. If the woman does not want to change her normal tablet-taking schedule, she has to take the extra tablet(s) needed from another pack.

How to shift periods or how to delay a period

To delay a period, the woman should continue with another pack of FEMILON without a tablet-free interval. The extension can be carried on for as long as wished until the end of the second pack. During the extension the woman may experience breakthrough bleeding or spotting. Regular intake of FEMILON is then resumed after the usual 7-day tablet-free interval.

To shift her period to another day of the week than the woman is used to with her current scheme, she can be advised to shorten her forthcoming tablet-free interval by as many days as she likes. The shorter the interval, the higher the risk that she does not have a withdrawal bleed and will experience breakthrough bleeding and spotting during the second pack (just as when delaying a period).

Contraindications

Combined hormonal contraceptives (CHCs) should not be used in the presence of any of the conditions listed below. Should any of the conditions appear for the first time during CHC use, the product should be stopped immediately.

- Presence or history of venous thrombosis (deep venous thrombosis, pulmonary embolism).
- Presence or history of arterial thrombosis (myocardial infarction, cerebrovascular accident) or prodromal conditions (e.g. transient ischaemic attack, angina pectoris).
- Known predisposition for venous or arterial thrombosis, such as Activated Protein C (APC) resistance, antithrombin-III deficiency, protein C deficiency, protein S deficiency, hyperhomocysteinaemia, and antiphospholipid antibodies.
- History of migraine with focal neurological symptoms (see section 'Special Warning and Precautions for use').
- Diabetes mellitus with vascular involvement.
- The presence of a severe or multiple risk factor(s) for venous or arterial thrombosis may also constitute a contraindication (see section 'Special Warning and Precautions for use').
- Major surgery with prolonged immobilisation (see section 'Special Warning and Precautions for use').
- Pancreatitis or a history thereof if associated with severe hypertriglyceridaemia.
- Presence or history of severe hepatic disease as long as liver function values have not returned to normal.
- Presence or history of liver tumours (benign or malignant).
- Known or suspected sex steroid-influenced malignancies (e.g., of the genital organs or the breasts).
- Undiagnosed vaginal bleeding.
- Known or suspected pregnancy.
- Hypersensitivity to any of the active substances of FEMILON or to any of the excipients.

FEMILON is contraindicated for use with the Hepatitis C virus combination drug regimen ombitasvir/paritaprevir/ritonavir with or without dasabuvir (see section 'Special Warning and Precautions for use').

Special warnings and Precautions for use

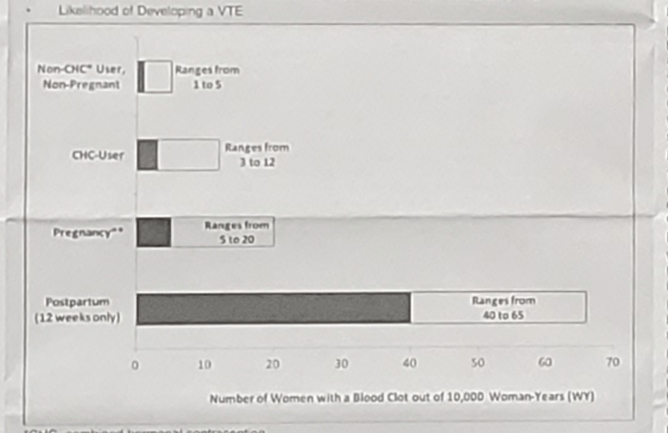
Warnings

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

Throughout this section the general term combined hormonal contraceptive (CHC) is used when data exist for oral and non-oral contraceptives. The term combined oral contraceptive (COC) is used when data exist only for oral contraceptives.

1. Circulatory Disorders

- Epidemiological studies have shown an association between the use of CHCs and an increased risk of arterial and venous thrombotic and thromboembolic diseases such as myocardial infarction, stroke, deep venous thrombosis, and pulmonary embolism. These events occur rarely.
- The use of CHCs is associated with an increased risk of venous thromboembolism (VTE) manifesting as deep venous thrombosis and/or pulmonary embolism. The risk is highest during the first year a woman ever uses a CHC. The risk is also increased after initially starting a CHC or restarting the same or different CHC after a break in use of 4 weeks or more.
- Some epidemiological studies have suggested that women using low-dose COCs with third generation progestogens, including desogestrel, have an increased risk of VTE compared with those using low-dose COCs with the progestogen levonorgestrel. These studies indicate an approximate 2-fold increase in risk, which would correspond to an additional 1-2 cases of VTE per 10 000 women years of use. However, data from other studies have not shown this 2-fold increase in risk.
- Overall, the incidence of VTE in users of low estrogen dose (< 0.05 mg ethinylestradiol) CHCs ranges from about 3 to 12 cases per 10 000 women years compared to 1 to 5 cases per 10 000 women years in non-CHC users. The incidence of VTE occurring during CHC use is less than the incidence associated with pregnancy (i.e. 5 to 20 cases per 10 000 women years). VTE is fatal in 1-2% of cases.
- The figure below shows the risk of developing a VTE for women who are not pregnant and do not use CHCs, for women who use CHCs, for pregnant women, and for women in the postpartum period. To put risk of developing a VTE into perspective: If 10,000 women who are not pregnant and do not use CHCs are followed for one year, between 1 and 5 of these women will develop VTE.
- Likelihood of Developing a VTE



*CHC=combined hormonal contraception
**Pregnancy data based on actual duration of pregnancy in the reference studies. Based on a model assumption that pregnancy duration is nine months, the rate is 7 to 27 per 10,000 WY.

- Extremely rarely, thrombosis has been reported to occur in other blood vessels, e.g., hepatic, mesenteric, renal, cerebral or retinal veins and arteries, in CHC users.
- Symptoms of venous or arterial thrombotic/thromboembolic events or of a cerebrovascular accident can include: unilateral leg pain and/ or swelling; sudden severe pain in the chest, whether or not it radiates to the left arm; sudden breathlessness; sudden onset of coughing; any unusual, severe, prolonged headache; sudden partial or complete loss of vision; diplopia; slurred speech or aphasia; vertigo; collapse with or without focal seizure; weakness or very marked numbness suddenly affecting one side or one part of the body; motor disturbances; 'acute' abdomen.
- The risk of venous thromboembolism increases with:
  - increasing age;
  - a positive family history (i.e. venous thromboembolism ever in a sibling or parent at a relatively early age). If a hereditary predisposition is suspected, the woman should be referred to a specialist for advice before deciding about any hormonal contraceptive use;
  - obesity (body mass index over 30 kg/m2);
  - prolonged immobilisation, major surgery, any surgery to the legs, or major trauma. In these situations it is advisable to discontinue COC use (in the case of elective surgery at least four weeks in advance) and not to resume until two weeks after complete remobilisation. See also section 'Contraindications';
  - and possibly also with superficial thrombophlebitis and varicose veins. There is no consensus about the possible role of these conditions in the etiology of venous thromboembolism.
- The risk of arterial thromboembolic complications increases with:
  - increasing age;
  - smoking (with heavier smoking and increasing age the risk further increases, especially in women over 35 years of age);
  - dyslipoproteinaemia;
  - obesity (body mass index over 30 kg/m2);
  - hypertension;
  - migraine;
  - valvular heart disease;
  - atrial fibrillation;
  - a positive family history (i.e. arterial thrombosis ever in a sibling or parent at a relatively early age). If a hereditary predisposition is suspected, the woman should be referred to a specialist for advice before deciding about any hormonal contraceptive use.
- The increased risk of thromboembolism in the puerperium must be considered (for information on "Pregnancy and Lactation" see section 'Pregnancy and Lactation').
- Other medical conditions which have been associated with adverse circulatory events include diabetes mellitus, systemic lupus erythematosus, haemolytic uraemic syndrome, chronic inflammatory bowel disease (Crohn's disease or ulcerative colitis) and sickle cell disease.
- An increase in frequency or severity of migraine during COC use (which may be prodromal of a cerebrovascular event) may be a reason for immediate discontinuation of the COC.
- Biochemical factors that may be indicative of hereditary or acquired predisposition for venous or arterial thrombosis include Activated Protein C (APC) resistance, hyperhomocysteinaemia, antithrombin-III deficiency, protein C deficiency, protein S deficiency, antiphospholipid antibodies (anticardiolipin antibodies, lupus anticoagulant).
- When considering risk/benefit, the physician should take into account that adequate treatment of a condition may reduce the associated risk of thrombosis.

2. Tumours

- The most important risk factor for cervical cancer is persistent human papilloma virus (HPV) infection. Epidemiological studies have indicated that long-term use of COCs contributes to this increased risk, but there continues to be uncertainty about the extent to which this finding is attributable to confounding effects, like increased cervical screening and difference in sexual behavior including use of barrier contraceptives, or a causal association.
- A meta-analysis from 54 epidemiological studies reported that there is a slightly increased relative risk (RR = 1.24) of having breast cancer diagnosed in women who are currently using COCs. The excess risk gradually disappears during the course of the 10 years after cessation of COC use. Because breast cancer is rare in women under 40 years of age, the excess number of breast cancer diagnoses in current and recent COC users is small in relation to the overall risk of breast cancer. The breast cancers diagnosed in ever-users tend to be less advanced clinically than the cancers diagnosed in never-users.
- In another epidemiological study of 1.8 million Danish women followed an average of 10.9 years, the reported RR of breast cancer among COC users increased with longer duration of use compared with women who never used COCs (overall RR = 1.19; RR ranged from 1.17 for 1 to less than 5 years of use to 1.46 after more than 10 years of use). The reported absolute risk difference (number of breast cancer cases between never-users compared with current and recent COC users) was small: 13 per 100.000 women- years.
- Epidemiological studies do not provide evidence for causation. The observed pattern of increased risk may be due to an earlier diagnosis of breast cancer in COC users, the biological effects of COCs or a combination of both.
- In rare cases, benign liver tumours, and even more rarely, malignant liver tumours have been reported in users of COCs. In isolated cases, these tumours have led to life-threatening intra-abdominal haemorrhages. A hepatic tumour should be considered in the differential diagnosis when severe upper abdominal pain, liver enlargement or signs of intra-abdominal haemorrhage occur in women taking COCs.

3. Hepatitis C

- During clinical trials with the HCV combination drug regimen ombitasvir /paritaprevir/ritonavir with and without dasabuvir, ALT elevations greater than 5 times the upper limit of normal (ULN) were significantly more frequent in women using ethinylestradiol-containing medications such as CHCs. FEMILON must be discontinued prior to starting therapy with the combination drug regimen ombitasvir/paritaprevir/ritonavir with or without dasabuvir (see section 'Contraindications' and 'Interaction with other medicinal products and other forms of interaction'). FEMILON can be restarted approximately 2 weeks following completion of treatment with the combination drug regimen.

4. Other conditions

- Women with hypertriglyceridaemia, or a family history thereof, may be at an increased risk of pancreatitis when using COCs.
- Although small increases in blood pressure have been reported in many women taking COCs, clinically relevant increases are rare. A relationship between COC use and clinical hypertension has not been established. However, if a sustained clinically significant hypertension develops during the use of a COC then it is prudent for the physician to withdraw the COC and treat the hypertension. Where considered appropriate, COC use may be resumed if normotensive values can be achieved with antihypertensive therapy.
- The following conditions have been reported to occur or deteriorate with both pregnancy and COC use, but the evidence of an association with COC use is inconclusive: jaundice and/or pruritus related to cholestasis; gallstone formation; porphyria; systemic lupus erythematosus; haemolytic uraemic syndrome; Sydenham's chorea; herpes gestationis; otosclerosis-related hearing loss; (hereditary) angioedema.
- Acute or chronic disturbances of liver function may necessitate the discontinuation of COC use until markers of liver function return to normal. Recurrence of cholestatic jaundice which occurred first during pregnancy or previous use of sex steroids necessitates the discontinuation of COCs.
- Although COCs 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 low-dose COCs (containing <0.05 mg ethinylestradiol). However, diabetic women should be carefully observed while taking COCs.
- Crohn's disease and ulcerative colitis have been associated with COC use.
- 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 COCs.
- FEMILON contains < 80 mg lactose per tablet. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption who are on lactose-free diet should take this amount into consideration.

When counselling the choice of contraceptive method(s), all the above information should be taken into account.

Medical Examination/Consultation

Prior to the initiation or reinstitution of FEMILON a complete medical history (including family history) should be taken and pregnancy must be ruled out. Blood pressure should be measured and if clinically indicated a physical examination should be performed, guided by the contra-indications (section 'Contraindications') and warnings (section 'Special Warning and Precautions for use'). The woman should also be instructed to carefully read the user leaflet and to adhere to the advice given. The frequency and nature of further periodic checks should be based on established practice guidelines and be adapted to the individual woman.

Women should be advised that oral contraceptives do not protect against HIV infections (AIDS) and other sexually transmissible diseases.

Reduced efficacy

The efficacy of FEMILON may be reduced in the event of e.g., missed tablets (Section 'Management of missed tablets'), gastro-intestinal disturbances (Section 'Advice in gastro-intestinal disturbances') or concomitant medications that decrease the plasma concentration of etonogestrel, the active metabolite of desogestrel (Section 'Interactions').

Reduced cycle control

With all COCs, irregular bleeding (spotting or breakthrough bleeding) may occur, especially during the first months of use. Therefore, the evaluation of any irregular bleeding is only meaningful after an adaptation interval of about three cycles.

If bleeding irregularities persist or occur after previously regular cycles, then non-hormonal causes should be considered and adequate diagnostic measures are indicated to exclude malignancy or pregnancy. These may include curettage.

In some women withdrawal bleeding may not occur during the tablet-free interval. If the COC has been taken according to the directions described in Section 'Posology and method of administration', it is unlikely that the woman is pregnant. However, if the COC has not been taken according to these directions prior to the first missed withdrawal bleed or if two withdrawal bleeds are missed, pregnancy must be ruled out before COC use is continued.

Interaction with other medicinal products and other forms of interaction

Interactions

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

Interactions between oral contraceptives and other medicinal products may lead to breakthrough bleeding and/or oral contraceptive failure. The following interactions have been reported in the literature:

Hepatic metabolism: Interactions can occur with medicinal or herbal products that induce microsomal enzymes, specifically cytochrome P450 enzymes (CYP), which can result in increased clearance reducing plasma concentrations of sex hormones and may decrease the effectiveness of combined oral contraceptives, including FEMILON. These products include phenytoin, phenobarbital, primidone, bosentan, carbamazepine, rifampicin, and possibly also oxcarbazepine, topiramate, felbamate, griseofulvin, some HIV protease inhibitors (e.g., ritonavir) and non-nucleoside reverse transcriptase inhibitors (e.g., efavirenz), and products containing the herbal remedy St. John's wort.

Enzyme induction can occur after a few days of treatment. Maximum enzyme induction is generally observed within a few weeks. After drug therapy is discontinued, enzyme induction can last for about 28 days.

When co-administered with hormonal contraceptives, many combinations of HIV protease inhibitors (e.g., 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, including etonogestrel, the active metabolite of desogestrel, or estrogens. The net effect of these changes may be clinically relevant in some cases.

Women receiving any of the above mentioned hepatic enzyme-inducing medicinal or herbal products should be advised that the efficacy of FEMILON may be reduced. A barrier contraceptive method should be used in addition to FEMILON during administration of the hepatic enzyme-inducing medicinal product, and for 28 days after discontinuation of the hepatic enzyme-inducing medicinal product.

If concomitant drug administration runs beyond the end of the tablets in the current COC pack, the next COC pack should be started right away without the usual tablet-free interval.

For women on long term therapy with enzyme-inducing medicinal products, an alternative method of contraception unaffected by enzyme-inducing medicinal products should be considered.

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

Oral contraceptives may affect the metabolism of other drugs. Accordingly, plasma and tissue concentrations may either increase (e.g., ciclosporin) or decrease (e.g., lamotrigine).

During clinical trials with the HCV combination drug regimen ombitasvir / paritaprevir/ ritonavir with and without dasabuvir, ALT elevations greater than 5 times the upper limit of normal (ULN) were significantly more frequent in women using ethinylestradiol-containing medications such as CHCs. FEMILON must be discontinued prior to starting therapy with the combination drug regimen ombitasvir/ paritaprevir/ ritonavir with or without dasabuvir (see section 'Contraindications' and 'Special warnings and precautions for use'). FEMILON can be restarted approximately 2 weeks following completion of treatment with the combination drug regimen.

Laboratory Tests

The use of contraceptive steroids may influence the results of certain laboratory tests, including biochemical parameters of liver, thyroid, adrenal and renal function, plasma levels of (carrier) proteins, e.g. corticosteroid binding globulin and lipid/lipoprotein fractions, parameters of carbohydrate metabolism and parameters of coagulation and fibrinolysis. Changes generally remain within the normal laboratory range.

Pregnancy and lactation

FEMILON is not indicated during pregnancy. If pregnancy occurs during treatment with FEMILON, further intake should be stopped. However, most 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.

Lactation may be influenced by COCs as they may reduce the quantity and change the composition of breast milk. Therefore, the use of COCs should generally not be recommended until the nursing mother has completely weaned her child. Small amounts of the contraceptive steroids and/or their metabolites may be excreted with the milk, but there is no evidence that this adversely affects infant health.

Effects on ability to drive and use machines

No effects on ability to drive and use machines have been observed.

Undesirable effects

Possibly related undesirable effects that have been reported in clinical trials or observational studies with FEMILON or CHC users in general are listed in the table below:

System Organ Class	Common (≥ 1/100)	Uncommon (≥ 1/1000 and <1/100)	Rare (< 1/1000)
Immune system disorders			Hypersensitivity
Metabolism and nutrition disorders		Fluid retention	
Psychiatric disorders	Depressed mood, mood altered	Libido decreased	Libido increased
Nervous system disorders	Headache	Migraine	
Eye disorders			Contact lens intolerance
Vascular disorders			Venous thromboembolism[2] Arterial thromboembolism[2]
Gastrointestinal disorders	Nausea, abdominal pain	Vomiting, diarrhea	
Skin and subcutaneous tissue disorders		Rash, urticaria	Erythema nodosum, erythema multiforme
Reproductive system and breast disorders	Breast pain, breast tenderness	Breast enlargement	Vaginal discharge, breast discharge
Investigations	Weight increased		Weight decreased

1 The most appropriate MedDRA term to describe a certain adverse reaction is listed. Synonyms or related conditions are not listed, but should be taken into account as well.
2 Incidence in observational cohort studies of ≥ 1/10000 to < 1/1000 women-years.

A number of undesirable effects have been reported in women using combined oral contraceptives, which are discussed in more detail in Section 'Special Warnings and Precautions for Use'. These include: venous thromboembolic disorders; arterial thromboembolic disorders; hypertension; hormone-dependent tumours (e.g. liver tumours, breast cancer); chloasma.

Overdose

There have been no reports of serious deleterious 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 further treatment should be symptomatic.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

ATC classification G03A A09.

The contraceptive effect of COCs is based on the interaction of various factors, the most important of which are seen as the inhibition of ovulation and the changes in the cervical secretion. As well as protection against pregnancy, COCs have several positive properties which, next to the negative properties (see Warnings, Undesirable effects), can be useful in deciding on the method of birth control. The cycle is more regular and the menstruation is often less painful and bleeding is lighter. The latter may result in a decrease in the occurrence of iron deficiency. Apart from this, with the higher-dosed COCs (50 µg ethinylestradiol), there is evidence of a reduced risk of fibrocystic tumours of the breasts, ovarian cysts, pelvic inflammatory disease, ectopic pregnancy and endometrial and ovarian cancer. Whether this also applies to lower-dosed COCs remains to be confirmed.

Pharmacokinetic properties

Desogestrel

ABSORPTION

Orally administered desogestrel is rapidly and completely absorbed and converted to etonogestrel. Peak serum concentrations are reached at about 1.5 hours. Bioavailability is 62 - 81 %.

DISTRIBUTION

Etonogestrel is bound to serum albumin and to sex hormone binding globulin (SHBG). Only 2 - 4 % of the total serum drug concentrations are present as free steroid, 40 - 70 % are specifically bound to SHBG. The ethinylestradiol-induced increase in SHBG influences the distribution over the serum proteins, causing an increase of the SHBG-bound fraction and a decrease of the albumin-bound fraction. The apparent volume of distribution of desogestrel is 1.5 l/kg.

METABOLISM

Etonogestrel is completely metabolized by the known pathways of steroid metabolism. The metabolic clearance rate from serum is about 2 ml/min/kg. No interaction was found with the co-administered ethinylestradiol.

ELIMINATION

Etonogestrel serum levels decrease in two phases. The terminal disposition phase is characterized by a half-life of approximately 30 hours. Desogestrel and its metabolites are excreted at a urinary to biliary ratio of about 6:4.

STEADY-STATE CONDITIONS

Etonogestrel pharmacokinetics are influenced by SHBG levels, which are increased threefold by ethinylestradiol. Following daily ingestion, drug serum levels increase about two- to threefold, reaching steady state conditions during the second half of the treatment cycle.

Ethinylestradiol

ABSORPTION

Orally administered ethinylestradiol is rapidly and completely absorbed. Peak serum concentrations are reached within 1-2 hours. Absolute bioavailability as a result of presystemic conjugation and first-pass metabolism is approximately 60%.

DISTRIBUTION

Ethinylestradiol is highly but non-specifically bound to serum albumin (approximately 98.5%) and induces an increase in the serum concentrations of SHBG. An apparent volume of distribution of about 5 l/kg was determined.

METABOLISM

Ethinylestradiol is subject to presystemic conjugation in both small bowel mucosa and the liver. Ethinylestradiol is primarily metabolized by aromatic hydroxylation but a wide variety of hydroxylated and methylated metabolites are formed, and these are present as free metabolites and as conjugates with glucuronides and sulfate. The metabolic clearance rate is about 5 ml/min/kg.

ELIMINATION

Ethinylestradiol serum levels decrease in two disposition phases, the terminal disposition phase is characterized by a half-life of approximately 24 hours. Unchanged drug is not excreted, ethinylestradiol metabolites are excreted at a urinary to biliary ratio of 4:6. The half-life of metabolite excretion is about 1 day.

STEADY-STATE CONDITIONS

Steady state concentrations are reached after 3-4 days when serum drug levels are higher by 30 - 40% as compared to single dose.

Preclinical safety data

Preclinical data reveal no special hazard for humans when COCs are used as recommended. This is based on conventional studies of repeated dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction. However, it must be borne in mind that sex steroids can promote the growth of certain hormone-dependent tissues and tumours.

PHARMACEUTICAL PARTICULARS

List of excipients

silica colloidal anhydrous
lactose monohydrate
potato starch
povidone
stearic acid
all-rac-alpha-tocopherol

Incompatibilities

Not applicable

Shelf life

36 months

Special precautions for storage

Store your tablets below 30°C in the original package. Do not freeze. Store protected from light and moisture.

Nature and contents of container

PVC/aluminium blister, which is packed in an aluminium laminated sachet.
Pack sizes: 21, 3 x 21 and 6 x 21 tablets.
Each blister contains 21 tablets.

Marketing Authorization Holder and Manufacturer

Manufactured by:
N.V. Organon,
6 Kloosterstraat,
5349 AB, Oss,
The Netherlands

Imported and Marketed by:
Organon (India) Private Limited,
A subsidiary of Organon & Co., Jersey City, NJ, USA
S. No. 120 – 121, Gala No. 1-C, Bldg. No. B-3, City Link Warehouses Complex,
Mumbai - Nashik Highway, Vadapa, Bhiwandi,
Dist. Thane 421302, Maharashtra, India.

DESOGESTREL AND ETHINYLESTRADIOL TABLETS IP

Femilon®

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 any further questions, please ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

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

Composition and type of Pill

FEMILON is a combined oral contraceptive ("the combined Pill"). Each tablet contains a small amount of two different female hormones. These are desogestrel (a progestogen) and ethinylestradiol (an estrogen). Because of the small amounts of hormones, FEMILON is considered a low-dose oral contraceptive. As all tablets in the pack combine the same hormones in the same dose, it is considered a monophasic combined oral contraceptive.

Why use FEMILON?

FEMILON is used to prevent pregnancy.

When taken correctly (without missing tablets), the chance of becoming pregnant is very low.

2. BEFORE YOU START TO USE FEMILON

2.1 When should you not use FEMILON

Do not use FEMILON if you have any of the conditions listed below. If anything on this list applies to you, tell your doctor before starting to use FEMILON. Your doctor may advise you to use a different type of Pill or an entirely different (non-hormonal) method of birth control.

- If you have, or have had in the past a blood clot (thrombosis) in a blood vessel of the leg, lung (embolus) or other organs.
- If you have or have had in the past a heart attack or stroke.
- If you have or have ever had a condition that may be a first sign of a heart attack (such as angina pectoris or chest pain) or stroke (such as transient ischaemic attack or small *reversible stroke*).
- If you have a disturbance of blood clotting (for example, protein C deficiency).
- If you have major surgery (e.g., an operation) and your ability to move around is limited for a long period of time (see section 2.2.3 "The Pill and Thrombosis").
- If you have (had) a type of migraine called "migraine with aura".
- If you have diabetes mellitus with blood vessel damage.
- If you have a serious risk factor, or several risk factors for developing thrombosis, this may also be a reason why you cannot use FEMILON (See also section 2.2.3 "The Pill and Thrombosis").
- If you have or have had a pancreatitis (an inflammation of the pancreas) associated with high levels of fatty substances in your blood.
- If you have jaundice (yellowing of the skin) or have (had) severe liver disease and your liver is not yet working normally.
- If you have or have had a cancer that may grow under the influence of sex hormones (e.g. of the breast or the genital organs).
- If you have or have had a liver tumour.
- If you have any unexplained vaginal bleeding.
- If you are pregnant or think you might be pregnant.
- If you are allergic to any of the ingredients of FEMILON.

If any of these conditions appear for the first time while using the Pill, stop taking it at once and tell your doctor. In the meantime, use a non-hormonal contraceptive. See also "General Notes" in section 2.2.1.

Do not use FEMILON if you have Hepatitis C and are taking the combination drug regimen ombitasvir/ paritaprevir/ ritonavir, with or without dasabuvir (see section 2.2.5 "The Pill and using Other Medicines").

2.2 When do you need to take special care with FEMILON?

2.2.1 General notes

In this leaflet, several situations are described where you should stop taking the Pill, or where the reliability of the Pill may be decreased. In such situations you should not have sexual intercourse or you should take extra non-hormonal contraceptive precautions, e.g. use a condom or another barrier method. Do not use rhythm or temperature methods. These methods can be unreliable because the Pill alters the usual changes in temperature and cervical mucus that occur during the menstrual cycle.

FEMILON, like all contraceptive Pills, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

FEMILON has been prescribed for you personally. Do not share it with others.

2.2.2 What do you need to know before using FEMILON

If the combined Pill is used in the presence of any of the conditions listed below you may need to be kept under close observation. Your doctor can explain this to you. Therefore, if any of these apply to you, tell your doctor before starting to use FEMILON.

- you smoke;
- you have diabetes;
- you are overweight;
- you have high blood pressure;
- you have a heart valve disorder or a certain heart rhythm disorder;
- you have an inflammation of your veins (superficial phlebitis);
- you have varicose veins;
- anyone in your immediate family has had a thrombosis, a heart attack or a stroke;
- you suffer from migraine;
- you suffer from epilepsy;
- you or someone in your immediate family have or have had high cholesterol or triglycerides (fats in the blood);
- anyone in your immediate family has had breast cancer;
- you have liver or gallbladder disease;
- you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease);
- you have systemic lupus erythematosus (SLE, a chronic connective tissue disease affecting the skin all over the body);
- you have haemolytic uraemic syndrome (HUS, a disorder of blood clotting causing failure of the kidneys);
- you have sickle cell disease (a rare blood disease);
- you have an operation or if your ability to move around is limited for a long period of time (see section 2.2.3 "The Pill and Thrombosis");
- if you have recently given birth you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start using FEMILON (see section 2.2.3 "The Pill and Thrombosis");
- you have a condition that occurred for the first time or got worse during pregnancy or previous use of sex hormones (e.g., hearing loss, a disease called porphyria, a skin disease called herpes gestationis, a disease called Sydenham's chorea);
- you have or have had chloasma (yellowish brown pigmentation patches on the skin, particularly of the face); if so, avoid too much exposure to the sun or ultraviolet light.

If any of the above conditions appear for the first time, come back or get worse while using the Pill, you should contact your doctor.

2.2.3 The Pill and Thrombosis

A thrombosis is the formation of a blood clot which may block a blood vessel.

A thrombosis sometimes occurs in the deep veins of the legs (deep venous thrombosis). If this blood clot breaks away from the veins where it is formed, it may reach and block the arteries of the lungs, causing a so-called 'pulmonary embolism'. Deep venous thrombosis is a rare occurrence. It can develop whether or not you are taking the Pill. The risk is higher in Pill-users than in non-users. The chance of getting a thrombosis is highest during the first year after you start using the Pill for the very first time. The risk is also higher if you restart using the Pill (the same product or a different product) after a break of 4 weeks or more.

The risk is not as high as the risk of developing a thrombosis during pregnancy.

The risk of getting a deep venous thrombosis for women using Pills with desogestrel may be slightly higher than for women using Pills with levonorgestrel. The absolute numbers remain very small. If 10 000 women use a Pill with levonorgestrel for one year, 2 women would get a thrombosis. If 10 000 women use a Pill with desogestrel for a year approximately 3 to 4 women would get a thrombosis. For comparison, if 10 000 women get pregnant, approximately 5-20 would get a thrombosis. These findings are based on the results of some studies. Other studies did not find a higher risk for Pills with desogestrel.

Blood clots can also occur very rarely in an artery (arterial thrombosis), for example in the blood vessels of the heart (causing a heart attack) or the brain (causing a stroke).

Extremely rarely blood clots can occur in the liver, gut, kidney or eye.

Very occasionally thrombosis may cause serious permanent disabilities or may even be fatal.

The risk of venous thrombosis in users of combined pills increases:
- with increasing age,
- if you are overweight,
- if one of your close relatives has had a blood clot (thrombosis) in the leg, lung, or other organ at a young age,
- if you must have an operation, if your ability to move around is limited for long period of time or if you have had a serious accident. It is important to tell your doctor in advance that you are using FEMILON as the treatment may have to be stopped. Your doctor will tell you when to start FEMILON again. This is usually about two weeks after you are able to move around. See also section 2.1 "When should you not use FEMILON".
- if you gave birth less than a few weeks ago

The risk of arterial thrombosis in users of combined pills increases:
- **if you smoke. You are strongly advised to stop smoking when you use FEMILON, especially if you are older than 35 years.**
- if you have an increased fat content in your blood (cholesterol or triglycerides)
- if you have high blood pressure
- if you have migraine
- if you have a problem with your heart (valve disorder, a disturbance of the heart rhythm)

If you notice possible signs of a thrombosis, stop taking the Pill and consult your doctor immediately (See also "When should you contact your doctor?").

2.2.4 The Pill and Cancer

The information given below was obtained from studies of women who used combined oral hormonal contraceptives, such as the combined pill, and from an additional study that included both oral and non-oral hormonal contraceptive-users.

In studies with the combined pill, breast cancer has been diagnosed slightly more often in women who use the Pill than in women of the same age who do not use the Pill. This slight increase in the numbers of breast cancer diagnoses gradually disappears during the course of the 10 years after stopping use of the Pill. It is not known whether the difference is caused by the Pill. It may be that the women were examined more often, so that the breast cancer was noticed earlier.

In the additional study that included both oral and non-oral hormonal contraceptive-users, the occurrence of breast cancer was reported to increase the longer the women used the contraceptive. The difference in the reported risk of breast cancer between women who had never used the contraceptive and those who had used the contraceptive was small: 13 additional cases of breast cancer per 100,000 women-years.

In rare cases benign liver tumours and even more rarely, malignant liver tumours have been reported in users of the Pill. These tumours may lead to internal bleeding. Contact your doctor immediately if you have severe pain in your abdomen.

Cervical cancer is caused by an infection with the human papilloma virus. It has been reported to occur more often in women using the Pill for a long time. It is unknown if this finding is due to the use of hormonal contraceptives or to sexual behaviour and other factors (such as better cervical screening).

2.2.5 The Pill and using Other Medicines

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines or herbal products, even those not prescribed. Also tell any other doctor or dentist who prescribes another medicine (or your pharmacist) that you use FEMILON.

Some medicines may stop FEMILON from working properly. These include medicines used for the treatment of:
- epilepsy (e.g., primidone, phenytoin, Phenobarbital, carbamazepine, oxcarbazepine, topiramate, felbamate);
- tuberculosis (e.g., rifampicin);
- HIV infections (e.g., ritonavir, nelfinavir, nevirapine, efavirenz);
- Hepatitis C virus infection (e.g., boceprevir, telaprevir);
- other infectious diseases (e.g., griseofulvin);
- High blood pressure in the blood vessels of lungs (bosentan);
- depressive moods (herbal remedy St. John's wort)

If you are taking medicines or herbal products that might make FEMILON less effective, a barrier contraceptive method should also be used. Since the effect of another medicine on FEMILON may last up to 28 days after stopping the medicine, it is necessary to use the additional barrier contraceptive method for that long.

FEMILON may also interfere with how other medicines work causing either an increase in effect (instance.g., ciclosporin) or a decrease in effect (e.g.,lamotrigine).

Do not use FEMILON if you have Hepatitis C and are taking the combination drug regimen ombitasvir/ paritaprevir/ ritonavir, with or without dasabuvir as this may cause increases in liver function blood test results (increase in ALT liver enzyme). FEMILON can be restarted approximately 2 weeks after completion of treatment with the combination drug regimen. (See section 2.1 "When should you not use FEMILON?")

Laboratory tests

If you are having any blood or urinary test, tell your health care professional that you are using FEMILON as it may affect the results of some tests.

2.2.6 The Pill and Pregnancy

FEMILON must not be used by women who are pregnant, or who think they may be pregnant. If you suspect that you are pregnant while you are already using FEMILON, you should tell your doctor as soon as possible.

2.2.7 The Pill and Breast-feeding

FEMILON is not usually recommended for use during breast-feeding. If you wish to take the Pill while breast-feeding, please ask your doctor.

2.2.8 The Pill and Driving and Using machines

There are no observed effects.

2.2.9 Important information about some of the ingredients of FEMILON

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before starting with FEMILON.

2.3 When should you contact your doctor?

Regular check-ups

When you are using the Pill, your doctor will tell you to return for regular check-ups. You should usually have a check-up every year.

Contact your doctor as soon as possible if:
- you notice any changes in your own health, especially involving any of the items mentioned in this leaflet (see also section 2.1 "*When should you not use FEMILON*" and section 2.2.2 "*What do you need to know before using FEMILON*"), do not forget about changes in the health of your immediate family);
- you feel a lump in your breast;
- you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives together with difficulty breathing;
- you are going to use other medicines (see also section 2.2.5 "*The Pill and Other Medicines*");
- your ability to move around is limited for a long period of time or you are to have surgery (tell your doctor at least four weeks in advance);
- you have unusual, heavy vaginal bleeding;
- you forgot tablets in the first week of the pack and had intercourse in the seven days before;
- you have severe diarrhoea;
- you miss your period twice in a row or suspect you are pregnant (do not start the next pack until your doctor tells you).

Stop taking tablets and see your doctor immediately if you notice possible signs of thrombosis:
- an unusual cough;
- severe pain in the chest which may reach the left arm;
- breathlessness;
- any unusual, severe, or prolonged headache or migraine attack;
- partial or complete loss of vision, or double vision;
- slurring or speech disability;
- sudden changes to your hearing, sense of smell, or taste;
- dizziness or fainting;
- weakness or numbness in any part of your body;
- severe pain in your abdomen;
- severe pain or swelling in either of your legs.

For more information, see section 2.2.3 in this leaflet.

2.4 More about hormonal contraceptives

The combined Pill may also have non-contraceptive health benefits.
- Your period may be lighter and shorter. As a result, the risk of anaemia may be lower. Your period pains may become less severe or may completely disappear.
- In addition, some serious disorders have been reported to occur less frequently in users of Pills containing 50 µg of ethinylestradiol ('high-dose Pills'). These are benign breast disease, ovarian cysts, pelvic infections (pelvic inflammatory disease or PID), ectopic pregnancy (pregnancy in which the embryo implants outside of the uterus) and cancer of the endometrium (lining of the womb) and ovaries. This may also be the case for low-dose Pills but this has not been confirmed.

3. HOW DO YOU USE FEMILON?

3.1 When and how to take the tablets

The FEMILON pack contains 21 tablets. On the pack, each tablet is marked with the day of the week on which it is to be taken. Take your tablet at about the same time each day, with some liquid if necessary. Follow the direction of the arrows until all 21 tablets have been taken. During the next 7 days you take *no* tablets. A period should begin during these 7 days (the withdrawal bleed). Usually it will start on day 2-3 after the last FEMILON tablet. Start taking your next pack on the 8th day even if your period continues. This means that you will always start new packs on the same day of the week, and also that you have your withdrawal bleed on about the same days each month.

3.2 Starting your first pack of FEMILON

- *When no hormonal contraceptive has been used in the past month.*
  Start taking FEMILON on the first day of your cycle, i.e. the first day of menstrual bleeding. Take a tablet marked with that day of the week. For example, if your period starts on a Friday, take a tablet marked Friday. Then follow the days in order. FEMILON will work immediately, it is not necessary to use an additional contraceptive method.

You may also start on days 2-5 of your cycle, but if you do, make sure you also use an additional contraceptive method (barrier method) for the first 7 days of tablet-taking in the first cycle.

- *When changing from another combined hormonal contraceptive (combined oral contraceptive pill (COC), vaginal ring, or transdermal patch)*
  You can start taking FEMILON the day after you take the last tablet from your present Pill pack (this means no tablet-free break). If your present Pill pack also contains inactive tablets you can start FEMILON on the day after taking the last **active** tablet (if you are not sure which this is, ask your doctor or pharmacist). You can also start later, but never later than the day following the tablet-free break of your present Pill (or the day after the last inactive tablet of your present Pill). In case you use a vaginal ring or transdermal patch, it is best to start using FEMILON on the day you remove the ring or patch. You can also start, at the latest, on the day you would have started using the next ring or patch.

  If you have used the Pill, patch or ring consistently and correctly and if you are sure that you are not pregnant, you can also stop taking the Pill or remove the ring or patch on any day and start using FEMILON immediately.

  If you follow these instructions, it is not necessary to use an additional contraceptive method.
- *When changing from a progestogen-only pill (minipill).*
  You can stop taking the minipill any day and start taking FEMILON the next day, at the same time. But if you are having intercourse, make sure you also use an additional contraceptive method (a barrier method) for the first 7 days that you are taking FEMILON.
- *When changing from a progestogen-only injectable, implant or a progestogen releasing intrauterine device (IUD)*
  Start using FEMILON when your next injection is due or on the day that your implant or IUD is removed. But if you are having intercourse, make sure you also use an additional contraceptive method (a barrier method) for the first 7 days that you are taking FEMILON.
- *After having a baby.*
  If you have just had a baby, your doctor may tell you to wait until after your first normal period before you start taking FEMILON. Sometimes it is possible to start sooner. Your doctor will advise you. If you are breast-feeding and want to take FEMILON, you should talk to your doctor first.
- *After a miscarriage or an abortion.*
  Your doctor will advise you.

3.3 If too many FEMILON tablets are taken (overdose)

There have been no reports of serious harmful effects from taking too many FEMILON tablets at one time. If you have taken several tablets at a time, you may have nausea, vomiting or vaginal bleeding. If you discover that a child has taken FEMILON, ask your doctor for advice.

3.4 What to do if...

... you forget tablets
- If you are **less than 12 hours late** in taking a tablet, the reliability of the Pill is maintained. Take the tablet as soon as you remember and take the next tablets at the usual times.
- If you are **more than 12 hours late** in taking any tablet, the reliability of the Pill may be reduced. The more consecutive tablets you have missed, the higher the risk that the contraceptive efficacy is decreased. There is a particularly high risk of becoming pregnant if you miss tablets at the beginning or at the end of the pack. Therefore you should follow the rules given below (see also the diagram below).

More than one tablet forgotten in a pack

Ask your doctor for advice.

1 tablet missed in week 1

Take the missed tablet as soon as you remember (even if this means taking two tablets at the same time) and take the next tablets at the usual time. Use extra contraceptive precautions (barrier method) for the next 7 days. If you had sexual intercourse in the week before missing the tablets, it's possible that you could be pregnant. So tell your doctor immediately.

1 tablet missed in week 2

Take the missed tablet as soon as you remember (even if this means taking two tablets at the same time) and take the next tablets at the usual time.

The reliability of the Pill is maintained. You need not use extra contraceptive precautions.

1 tablet missed in week 3

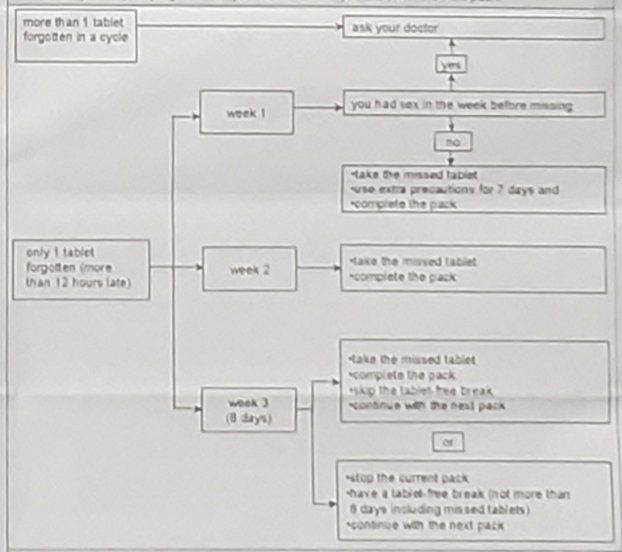
You may choose either of the following options, without the need for extra contraceptive precautions.

1. Take the missed tablet as soon as you remember (even if this means taking two tablets at the same time) and take the next tablets at the usual time. Start the next pack as soon as the current pack is finished so that **no gap is left between packs.** You may not have a withdrawal bleed until the end of the second pack but you may have spotting or breakthrough bleeding on tablet-taking days.

   Or

2. Stop taking tablets from your current pack, have a tablet-free break of 7 days or less (**including the day you missed your tablet**) and then start the next pack. If you do this, you can always start your next pack on the same day of the week as you usually do.

- If you have forgotten tablets in a pack and you do not have your period in the first normal tablet-free break, you may be pregnant. Tell your doctor before you start with the next pack.



... you suffer from gastro-intestinal disturbances (e.g., vomiting, severe diarrhoea)

If you vomit, or have severe diarrhoea, the active ingredients of your FEMILON tablet may not have been completely absorbed. If you vomit within 3 to 4 hours after taking your tablet, this is like missing a tablet. You must follow the advice for missed tablets. If you have severe diarrhoea, please tell your doctor.

... you want to delay your period

You can delay your period if you start with your next pack of FEMILON immediately after finishing your current pack. You can continue with this pack for as long as you wish, until this pack is empty. When you wish your period to begin, just stop tablet-taking. While using the second pack you may have some breakthrough bleeding or spotting on tablet-taking days. Start with your next pack after the usual 7-day tablet-free break.

... you want to change the starting day of your period

If you take your tablets correctly, you will have your period on about the same day every 4 weeks. If you want to change this day, just shorten, (never lengthen) the next tablet-free break. For example, if your period usually starts on a Friday and in future you want it to start on Tuesday (3 days earlier) start your next pack 3 days sooner than you usually do. If you make your tablet-free break very short (e.g. 3 days or less), you may not bleed during the break. You may have some breakthrough bleeding or spotting while using the next pack.

... you have unexpected bleeding

With all Pills, for the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding) between your periods. You may need to use sanitary protection, but keep taking your tablets as usual. Irregular vaginal bleeding usually stops once your body has adjusted to the Pill (usually after about 3 months). If bleeding continues, becomes heavy or starts again, tell your doctor.

... you have missed a period

If you have taken all of your tablets at the right time, and you have not vomited, or used other medicines then you are very unlikely to be pregnant. Keep taking FEMILON as usual.

If you miss your period twice in a row, you may be pregnant. Tell your doctor immediately. Do not start the next pack of FEMILON until your doctor has checked you are not pregnant.

3.5 If you want to stop taking FEMILON

You can stop taking FEMILON at any time you want. If you do not want to become pregnant, ask your doctor about other methods of birth control.

If you stop taking FEMILON because you want to get pregnant, you should wait until you have had a natural period before trying to conceive. This helps you to work out when the baby will be due.

4. POSSIBLE SIDE EFFECTS

Like all medicines, FEMILON can have side effects, although not everybody gets them.

Tell your doctor if you notice any unwanted effect, especially if severe or persistent, or if there is a change in your health that you think might be caused by the Pill.

Serious reactions seen with the Pill, as well as the related symptoms, are described in the sections 2.2.3 and 2.2.4 "The Pill and Thrombosis/The Pill and Cancer".

Common (occurring in more than one per 100 users):
- depressed mood, mood changes
- headache
- nausea, abdominal pain
- breast pain, breast tenderness
- increase in body weight.

Uncommon (occurring in more than one per 1000 users but not more than one per 100 users):
- fluid retention
- decreased sexual drive
- migraine
- vomiting, diarrhoea
- rash, hives
- breast enlargement.

Rare (occurring in less than one per 1000 users):
- hypersensitivity reactions
- blood clot in a vein
- blood clot in an artery
- increased sexual drive
- contact lens intolerance
- erythema nodosum, erythema multiforme (these are skin conditions)
- breast secretion, vaginal secretion
- decrease in body weight.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE FEMILON

Do not use FEMILON after the expiry date stated on the package.

Store your tablets below 30°C in the original package. Do not freeze. Store protected from light and moisture.

Do not use the product if you notice, for example, colour change in the tablet, crumbling of the tablet or any other visible signs of deterioration.

Keep FEMILON out of sight and reach of children.

6. FURTHER INFORMATION

6.1 What FEMILON contains
- The active substances are: ethinylestradiol (0.020 mg) and desogestrel (0.150 mg).
- The other ingredients are: silica colloidal anhydrous; lactose monohydrate; potato starch; povidone; stearic acid; all-rac-alpha-tocopherol.

6.2 What FEMILON looks like and content of the pack

FEMILON comes in 1, 3 or 6 strips of 21 tablets packed in a ply carton.

The tablets are biconvex, round and 6 mm in diameter. Each tablet is marked TR above 4 on one side and Organon" on the reverse side.

6.3 Shelf Life

36 months.

6.4 Last revision of this package leaflet

This leaflet is updated on based on S-CCPP-MKE276A-MCL21-TB-112018

IF YOU HAVE ANY FURTHER QUESTIONS FOR FEMILON, PLEASE CONSULT YOUR DOCTOR OR PHARMACIST.

If you want to report an adverse experience related to this product, please contact us at: Tel: 91 2267866599; e-mail: dpoc.india@organon.com

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