

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:



PROPRIETARY NAME AND PHARMACEUTICAL FORM:

ELOINE® PLUS

Film-coated tablets

Read all of this leaflet carefully before you start taking ELOINE PLUS.

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

WHAT ELOINE PLUS CONTAINS:

Active substances: 24 pink hormone tablets contain the active substances ethinyloestradiol (0,02 mg), drospirenone (3 mg) and levomefolate calcium (0,451 mg). The 4 light orange hormone free tablets contain levomefolate calcium (0,451 mg).

The other ingredients are: croscarmellose Na, hydroxypropylcellulose, hypromellose, iron oxide red, iron oxide yellow, lactose monohydrate, macrogol 6000, magnesium stearate, microcrystalline cellulose, talc, titanium dioxide.

WHAT ELOINE PLUS IS USED FOR:

- ELOINE PLUS is used to prevent pregnancy and to improve the folate status in women who decide to use oral contraception.
- ELOINE PLUS is used for the treatment of moderate acne vulgaris in women seeking oral contraception.
- ELOINE PLUS is also used for the treatment of symptoms of premenstrual dysphoric disorder (PMDD) in women who have chosen oral contraceptive as their method of birth control. The efficacy of ELOINE PLUS for PMDD was not assessed beyond 3 cycles.
- Each of the 24 pink film-coated tablets contains a small amount of the female hormones ethinyloestradiol and drospirenone and the vitamin levomefolate calcium (which is also contained in the 4 light orange hormone-free film-coated tablets).
- Contraceptive pills that contain two hormones are called 'combined pills' or 'combined oral contraceptives'.

BEFORE YOU TAKE ELOINE PLUS:

Do not use ELOINE PLUS if you have any of the conditions listed below. If any of these apply to you, tell your doctor before starting to use ELOINE PLUS. Your doctor may advise you to use a different type of pill or an entirely different (non-hormonal) method of birth control.

Do not take ELOINE PLUS:

- if you are **allergic** (hypersensitive) to ethinyloestradiol, drospirenone, levomefolate calcium or any of the other ingredients in ELOINE PLUS. This may cause, for example, itching, rash or swelling
- if you have (or have ever had) a **blood clot** in a blood vessel of the leg (thrombosis), of the lung (pulmonary embolism) or other parts of the body
- if you have (or have ever had) a **heart attack** or **stroke** (caused by a blood clot or a rupture of a blood vessel in the brain)
- if you have (or have ever had) a **disease that can be an indicator (i) of a future heart attack**

(for example, angina pectoris which causes severe chest pain which may spread to the left arm) **or (ii) of a stroke** (for example, a minor stroke with no residual effects, a so-called transient ischaemic attack)

- if you have (or have ever had) a certain kind of **migraine** accompanied by e.g. visual symptoms, speech disability, or weakness or numbness in any part of your body
- if you have diabetes mellitus with damaged blood vessels
- if you have (or have ever had) **liver disease** (symptoms of which may be yellowing of the skin or itching over the whole body) and your liver is still not working normally
- if you have (or have ever had) a **cancer** that may grow under the influence of sex hormones (e.g. **of the breast or the genital organs**)
- if you have a severe kidney insufficiency or acute kidney failure
- if you have (or have ever had) a benign or malignant **tumour of the liver**
- if you have any **unexplained bleeding from the vagina**
- if you are pregnant or think you might be pregnant

General notes:

In this leaflet, several situations are described where you should stop using ELOINE PLUS, or where the reliability of ELOINE PLUS may be decreased. In such situations you should either not have sex 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 ELOINE PLUS alters the monthly changes of body temperature and cervical mucus.

ELOINE PLUS does not protect against HIV infection (AIDS) or any other sexually transmitted infections (STI). Additional barrier contraceptive measures are needed to prevent transmission of STIs and HIV.

Take special care with ELOINE PLUS:

In some situations you need to take special care while taking ELOINE PLUS or any other combined pill, and your doctor may need to examine you regularly. Consult your doctor before starting to use ELOINE PLUS if any of the following conditions apply to you or if any of them develop or worsen while you are taking ELOINE PLUS:

- if you smoke
- if you have diabetes
- if you are overweight
- if you have high blood pressure
- if you have a heart valve disorder or a certain heart rhythm disorder
- if you have an inflammation of your veins (superficial phlebitis)
- if you have varicose veins
- if anyone in your immediate family has ever had a blood clot (thrombosis in the leg, lung 'pulmonary embolism', or elsewhere), a heart attack or a stroke at a young age
- if you suffer from migraine
- if you have epilepsy
- if you have an increased potassium blood level (e.g. due to problems with your kidneys) and also use diuretics that may increase the potassium in your blood (ask your doctor if you're not sure)
- if you or someone in your immediate family has ever had high blood levels of cholesterol or triglycerides (fatty substances)
- if a close relative has or has ever had breast cancer
- if you have a disease of the liver or gall bladder
- if you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- if you have systemic lupus erythematosus (or SLE, a disease of the immune system)
- if you have haemolytic uremic syndrome (or 'HUS', a disorder of blood coagulation causing failure of the kidneys)
- if you have sickle cell disease
- if you have a condition that occurred for the first time or worsened during pregnancy or previous use of sex hormones (e.g. hearing loss, a metabolic disease called porphyria, a skin disease called herpes gestationis, or a neurological disease called Sydenham's chorea)
- if you have (or have ever had) golden brown pigment patches so-called 'pregnancy patches' especially on the face (chloasma). If this is the case, avoid direct exposure to sunlight or ultraviolet light

- if you suffer from vitamin B12 deficiency (for example due to a reduced B12 diet such as a strict vegetarian diet, due to a history of gastrointestinal surgery or certain types of gastritis) tell your doctor that you use ELOINE PLUS because folates may hide vitamin B12 deficiency
- if you have hereditary angioedema. Consult your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue or throat, and/or difficulty swallowing, or hives, together with difficulty breathing. Products containing oestrogens may induce or worsen symptoms of angioedema

If any of the above conditions appear for the first time, recur or worsen while using ELOINE PLUS, contact your doctor.

ELOINE PLUS and blood clots (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 a blood clot breaks away from the vein where it has formed, it may reach and block the arteries of the lungs, causing a so-called 'pulmonary embolism'. Blood clots can also occur very rarely in the blood vessels of the heart (causing a heart attack). Blood clots or a ruptured blood vessel in the brain may cause a stroke.

The risk of venous thromboembolism is highest during the first year of use. This increased risk is present after initially starting the combined pill or restarting (following a 4 week or greater pill free interval) the same or a different combined pill. Data from a large study suggest that this increased risk is mainly present during the first 3 months.

Overall the risk for venous thromboembolism in users of low oestrogen dose pills is two to threefold higher than for non-users of combined oral contraceptives (COCs) who are not pregnant. Venous or arterial thromboembolic events may cause serious permanent disabilities, may be life-threatening, or may even be fatal. Blood clots can occur in other parts of the body including the liver, gut, kidney, brain or eye.

The risk of venous or arterial blood clots (e.g. deep venous thrombosis, pulmonary embolism, heart attack) or stroke increases:

- with age
- if you are overweight
- if anyone in your immediate family has ever had a blood clot (thrombosis in the leg, lung 'pulmonary embolism', or elsewhere), a heart attack or a stroke at a young age, or if you or any of your relatives are known or suspected of having a hereditary blood clotting disorder increasing your risk for developing blood clots
- with prolonged immobilisation (for example, when you have your leg or legs in plaster or splints), major surgery, any surgery to the legs, or major trauma. In these situations it is better to stop taking the ELOINE PLUS (if the surgery is planned you should stop at least four weeks beforehand) and not to start again until two weeks after you are fully on your feet again
- if you smoke (the risk increases the more you smoke and the older you get, especially in women over 35 years of age). **When using ELOINE PLUS you should stop smoking, especially if you are older than about 35 years of age.**
- if you or someone in your immediate family has or has ever had high blood levels of cholesterol or triglycerides (fatty substances)
- if you have high blood pressure . **If you develop high blood pressure while using ELOINE PLUS, you may be told to stop using it.**
- if you suffer from migraine
- if you have a heart valve disorder or a certain heart rhythm disorder

Directly after giving birth, women are at an increased risk of blood clots so you should ask your doctor how soon after delivery you can start taking ELOINE PLUS.

ELOINE PLUS and cancer:

Breast cancer has been observed slightly more often in women using combined contraceptive pills.

The risk of breast tumours becomes gradually less after stopping the combined hormonal contraceptive. It is important to regularly check your breasts and you should contact your doctor if you feel any lump.

Benign liver tumours, and **malignant liver tumours** have been reported. These tumours have led to life-threatening internal bleeding. Contact your doctor if you have unusually severe abdominal pain.

The most important risk factor for cervical cancer is persistent Human Papilloma Virus (HPV) infection. Studies suggest that long-term use of the pill increases a woman's risk of developing **cervical cancer**.

The afore mentioned tumours may be life-threatening or may have a fatal outcome.

Bleeding between periods:

For the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding) between your periods. Continue to take your tablets as normal. Irregular vaginal bleeding usually stops once your body has adjusted to ELOINE PLUS (usually after about 3 tablet-taking cycles). If it continues, becomes heavy or starts again, tell your doctor.

What to do if no bleeding occurs:

If you have taken all the tablets correctly, have not had any vomiting or severe diarrhoea and you have not taken any other medicines, it is highly unlikely that you are pregnant. Continue to take ELOINE PLUS as usual.

If you have taken the tablets incorrectly, or, if you have taken the tablets correctly but the expected bleeding does not happen twice in a row, you may be pregnant. Contact your doctor immediately. Do not start the next pack until you are sure that you are not pregnant.

Pregnancy and breastfeeding:

Do not take ELOINE PLUS if you are pregnant, or, if you think you may be pregnant. If you become pregnant while taking ELOINE PLUS, stop taking it immediately and contact your doctor. If you want to become pregnant, you can stop taking ELOINE PLUS at any time (see also "If you want to stop taking ELOINE PLUS"). If you stop ELOINE PLUS in order to become pregnant you should consider to continue to take folate supplements.

ELOINE PLUS should not be used during breastfeeding or before the breastfeeding mother has completely weaned her child.

Driving and using machinery:

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

Important information about some of the ingredients of ELOINE PLUS:

Lactose intolerance:

Each pink tablet contains 45 mg lactose and each light orange tablet contains 48 mg. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption who are on a lactose-free diet should take this amount into consideration.

Using other medicines with ELOINE PLUS:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of ELOINE PLUS with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

Some medicines can make ELOINE PLUS **less effective in preventing pregnancy**, or can cause unexpected bleeding. These include:

- medicines used for the treatment of:
 - epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate, felbamate);
 - tuberculosis (e.g. rifampicin);
 - HIV infections (e.g. ritonavir, nevirapine), other infections (antibiotics such as penicillins, tetracyclines, griseofulvin).
- the herbal remedy St. John's wort

The efficacy of levomefolate calcium in ELOINE PLUS **can be diminished** by:

- medicines containing methotrexate, trimethoprim, sulphasalazine, triamterene, cholestyramine, or by antiepileptics such as carbamazepine, phenytoin, phenobarbital, primidone or valproic acid.

ELOINE PLUS may **influence the effect** of other medicines, e.g.

- anti-epileptics such as lamotrigine and phenytoin;
- ciclosporin;
- methotrexate or pyrimethamine.

In theory your potassium levels may increase if you are taking ELOINE PLUS with other medicines that can also increase potassium levels.

Laboratory tests:

If you need a blood test or other laboratory tests tell your doctor or the laboratory staff that you are taking the Pill because oral contraceptives can affect the results of some tests.

HOW TO USE ELOINE PLUS:

Do not share medicines prescribed for you with others.

The ELOINE PLUS pack contains 28 tablets. Take your tablet at about the same time each day, with some liquid if necessary. Follow the direction of the arrows until all 28 tablets have been taken. Usually a period will start on day 2 to 3 after the last hormone-containing pink ELOINE PLUS tablet (i.e. while you are taking the last 4 hormone-free light orange tablets). Do not leave a gap between packs, i.e. start taking your next pack on the day after you have finished the current one, 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 every month.

When taken correctly, combined oral contraceptives, have a failure rate of approximately 1 % per year. The failure rate may increase when pills are missed or taken incorrectly.

When can you start with the first pack?

If you have not used a contraceptive with hormones during the previous month:

Start taking ELOINE PLUS on the first day of the cycle (that is, the first day of your period). Then follow the days in order. ELOINE PLUS will work immediately, it is not necessary to use an additional contraceptive method.

If you take more ELOINE PLUS than you should:

There are no reports of serious harmful effects of taking too many ELOINE PLUS tablets.

If you take several hormone-containing tablets at once, you may feel sick or vomit. Young girls may have bleeding from the vagina.

If you have taken too many ELOINE PLUS tablets, or you discover that a child has taken some, ask your doctor or pharmacist for advice.

If you forget to take ELOINE PLUS:

Missed hormone-free light orange film-coated tablets can be disregarded. However, they should be

discarded to avoid unintentionally prolonging the hormone-free light orange tablet phase. The following advice only refers to **missed hormone-containing pink** film-coated tablets:

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

1. Active tablet-taking must never be discontinued for longer than 4 days;
2. 7 days of uninterrupted hormone-containing tablet-taking are required to attain adequate suppression of the hypothalamic-pituitary-ovarian-axis.

What to do if you vomit or have severe diarrhoea:

If you vomit or have severe diarrhoea after taking any of the pink tablets, the active ingredients in that 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. Therefore, follow the advice under 'If you forget to take ELOINE PLUS'. If you have severe diarrhoea, please contact your doctor. Vomiting or diarrhoea while taking the 4 hormone-free light orange film-coated tablets at the end of your blister does not have an influence on the contraceptive reliability.

If you want to stop taking ELOINE PLUS:

You can stop taking ELOINE PLUS at any time. If you do not want to become pregnant, ask your doctor for advice about other reliable methods of birth control. If you want to become pregnant, stop taking ELOINE PLUS and wait for a menstrual period before starting to try to become pregnant.

POSSIBLE SIDE EFFECTS:

Not all side effects reported for ELOINE PLUS are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

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

Serious side effects:

See also section "Take special care with ELOINE PLUS", "ELOINE PLUS and blood clots" and "ELOINE PLUS and cancer" for side effects, including serious reactions, associated with the use of ELOINE PLUS. Please read these sections carefully and consult your doctor at once where appropriate.

The following side effects were reported in studies with Yasmin and are also regarded as being representative for ELOINE PLUS:

Frequent side effects: depressive mood, headache, migraine, nausea, breast pain including breast tenderness, leukorrhoea (vaginal discharge), vaginal moniliasis (fungal infection), menstrual disorder, intermenstrual bleeding (bleeding irregularities usually subside during continued treatment).

Less frequent side effects: body weight changes, fluid retention, changes in interest in sex, high blood pressure, low blood pressure, vomiting, acne, eczema, itching, vaginitis (vaginal inflammation), hypacusia (hearing impairment), thromboembolism (blood clots including embolism), asthma, breast discharge.

Other side effects that have been reported are: allergic reactions (hypersensitivity), altered mood, contact lens intolerance, abdominal pain, diarrhoea, rash, urticaria (hives), skin disorders such as erythema nodosum or multiforme, breast enlargement.

If you have hereditary angioedema (swelling which involve lips, eyes or tongue) medicines containing

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Dosage form: Film-coated tablet
Product proprietary name: ELOINE PLUS

certain female sex hormones (oestrogens) may induce or worsen the symptoms of angioedema (see section "When to take special care with ELOINE PLUS").

If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

STORING AND DISPOSING OF ELOINE PLUS:

Store at or below 30 °C.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Keep the blister strip in the pouch, in the original carton until required for use.

Do not use after expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF ELOINE PLUS:

ELOINE PLUS is packed in colourless transparent high barrier PVC/PE.EVOH.PE/PCTFE/aluminium blisters containing 24 pink film-coated hormonal tablets plus 4 light orange hormone-free film-coated tablets per blister strip packed in a hermetic pouch (PET/Al/PE). The pouch is packed into an outer cardboard carton..

Pack sizes: 28 tablets: 1 x (24 + 4) tablets.

IDENTIFICATION OF ELOINE PLUS:

24 pink, round, biconvex active film-coated tablets, with one side embossed with "Z+" in a regular hexagon, while the other side is blank PLUS 4 light orange, round, biconvex hormone-free film-coated tablets, with one side embossed with "M+" in a regular hexagon, while the other side is blank.

REGISTRATION NUMBER:

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NAME AND ADDRESS OF REGISTRATION HOLDER:

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