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PROFESSIONAL INFORMATION

PATIENT INFORMATION LEAFLET

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SCHEDULING STATUS: S4

PROPRIETARY NAME AND PHARMACEUTICAL FORM:

ELOINE®
Film-coated tablets

Read all of this leaflet carefully before you start taking ELOINE
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- ELOINE 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 CONTAINS:

Active substances: The active substances are ethinylestradiol (0,02 mg) as betadex clathrate and drospirenone (3 mg).
The other ingredients are: Ferric oxide red (E172), hypromellose 5 cP, lactose monohydrate, magnesium stearate, maize starch, povidone K25, talc, titanium dioxide (E171).

WHAT ELOINE IS USED FOR:

ELOINE is a combined oral contraceptive ("the combined Pill") consisting of 24 pink tablets with active ingredients and 4 white inactive tablets (bottom row of the blister pack). Each active tablet contains a small amount of two different female hormones. These are drospirenone (a progestogen) and ethinylestradiol (an oestrogen). Because of the small amounts of hormones, ELOINE is considered a low-dose oral contraceptive. As all active tablets in the pack combine the same hormones in the same dose, it is considered a monophasic combined oral contraceptive.

- ELOINE is used to prevent pregnancy.
- ELOINE is used for the treatment of moderate acne vulgaris in women seeking oral contraception.
- ELOINE is also used for the treatment of symptoms of premenstrual dysphoric disorder (PMDD) in women who have chosen oral contraceptives as their method of birth control. The efficacy of ELOINE for PMDD was not assessed beyond 3 cycles.
- Each of the 24 light pink film-coated tablets contains an amount of the female hormones ethinylestradiol and drospirenone.
- Contraceptive pills that contain two hormones are called 'combined pills' or 'combined oral contraceptives'.

BEFORE YOU USE ELOINE:

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

Do not use ELOINE:

- If you are hypersensitive (allergic) to ethinylestradiol or drospirenone or any of the other ingredients of ELOINE tablets.
- If you have, or have ever had a disorder affecting the blood circulation: in particular, those conditions relating to thrombosis (the formation of a blood clot) in the blood vessels of the legs (deep vein thrombosis), the lungs (pulmonary embolism), the heart (heart attack), or other parts of the body. (See also the section later in this leaflet called "ELOINE and thrombosis".)
- If you have or have had a stroke (caused by a blood clot or a rupture of a blood vessel in the brain).

- 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 history 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 blood vessel damage.
- If you have jaundice (yellowing of the skin) or severe liver disease.
- 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 a severe kidney insufficiency or an acute failure of your kidney.
- If you have or have had a benign or malignant liver tumour.
- If you have any unexplained vaginal bleeding.
- If you are pregnant or think you might be pregnant.

If any of these conditions appear for the first time while using ELOINE, stop taking it at once and consult your doctor. In the meantime, use non-hormonal contraceptive measures. See also "General notes" in the next section.

General notes:

In this leaflet, several situations are described where you should stop taking ELOINE, or where the reliability of ELOINE 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 the rhythm or temperature methods. These methods can be unreliable because ELOINE alters the usual changes in temperature and cervical mucus that occur during the menstrual cycle.

Women should be advised that ELOINE does not protect against HIV infections (AIDS) and other sexually transmitted diseases (STDs). Women should be advised that additional barrier contraceptive measures are needed to prevent transmission of STDs and HIV infection.

Take special care with ELOINE:

If 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 ELOINE.

- 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 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);
- you or someone in your immediate family has or has had high blood levels of cholesterol or triglycerides (fatty substances);
- 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 disease affecting the skin all over the body);
- you have haemolytic uraemic syndrome (HUS, a disorder of blood coagulation causing failure of the kidneys);
- you have sickle cell disease (for example, sickle cell anaemia, or other sickle cell conditions);
- 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, a neurological 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 radiation;

- you have hereditary angioedema: exogenous oestrogens may induce or exacerbate symptoms of angioedema. You should see your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue and/or pharynx and/or difficulty swallowing or hives together with difficulty breathing.

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

ELOINE 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. The risk for venous thromboembolism is highest during the first year a woman ever uses the Pill.

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 the pills is two to threefold higher than for non-users of combined oral contraceptive pills who are not pregnant.

Blood clots can also occur very rarely 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 venous or arterial thromboembolic events may cause serious permanent disabilities, may be life-threatening or may even be fatal.

The risk of having a heart attack or stroke increases as you get older. It also increases the more you smoke.

When using ELOINE you should stop smoking, especially if you are older than 35 years of age.

If you develop high blood pressure while using ELOINE, you may be told to stop using it.

The risk of having deep venous thrombosis is temporarily increased as a result of an operation or immobilisation (for example, when you have your leg or legs in plaster or splints). In women who use ELOINE the risk may be yet higher. Tell your doctor you are using ELOINE well in advance of any expected hospitalisation or surgery. Your doctor may tell you to stop taking ELOINE several weeks before surgery or at the time of immobilisation. Your doctor will also tell you when you can start taking ELOINE again after you are back on your feet.

If you notice possible signs of a thrombosis, stop taking ELOINE and consult your doctor immediately.

ELOINE and cancer:

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.

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.

The most important risk factor for cervical cancer is persistent human papilloma virus infection. Some studies have indicated that long-term use of the Pill may further contribute to this increased risk but there continues to be controversy about the extent to which this finding is attributable to other factors, e.g. cervical screening and sexual behaviour, including use of barrier contraceptives.

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

Regular check-ups:

When you are using ELOINE, your doctor will tell you to return for regular check-ups.

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 *"Before you use ELOINE"* and *"Do not use ELOINE"*; do not forget about the items related to your immediate family);
- you feel a lump in your breast;
- you are going to use other medications (see also *"Using other medicines with ELOINE"*);
- you are to be immobilised or are to have surgery (consult 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 told to by your doctor).

Stop taking tablets and see your doctor immediately if you notice possible signs of thrombosis, myocardial infarction or a stroke:

- 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 have 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.

The situations and symptoms mentioned above are described and explained in more detail elsewhere in this leaflet.

Pregnancy and breastfeeding:

ELOINE 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 ELOINE, you should consult your doctor as soon as possible.

ELOINE is not recommended for use during breastfeeding. If you wish to take ELOINE while breastfeeding, please seek the advice of your doctor.

Driving and using machinery:

No effects have been observed that would show that taking ELOINE would influence your ability to drive.

Important information about some of the ingredients of ELOINE:

Each light pink tablet contains 48 mg lactose and each white tablet contains 52 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:

If you are using other medicines on a regular basis, including complementary or traditional medicines, the use of ELOINE with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice. They can tell you if you need to take additional contraceptive precautions, and if so, for how long.

Some medicines may stop ELOINE from working properly. These include medicines used for the treatment of epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate, felbamate); tuberculosis (e.g. rifampicin, rifabutin) and HIV infections (e.g. ritonavir, nevirapine); antibiotics (e.g. penicillins, tetracyclines, griseofulvin) for some other infectious diseases; and the herbal remedy St. John's Wort (primarily used for the treatment of depressive moods). Some medicines (e.g. ketoconazole, erythromycin, cyclosporin) may inhibit the metabolism of ELOINE. The Pill may also interfere with the working of other medicines, e.g. medicines containing cyclosporin, or the anti-epileptic lamotrigine.

There is a potential for an increase in serum potassium if you are taking ELOINE tablets with other medicines that may increase serum potassium levels. Such medicines include angiotension-ll-receptor antagonists, diuretics that may increase the potassium in your blood, and aldosterone antagonists. However, in studies in women taking drospirenone (combined with oestradiol) together with an ACE inhibitor or indomethacin, no significant difference in the potassium blood level could be observed.

HOW TO USE ELOINE:

When and how to take the tablets:

The ELOINE pack contains 28 tablets (24 active tablets and 4 inactive tablets). The first course of ELOINE is started on the first day of the menstrual period (day 1 of the cycle) from the white section of the pack by selecting the appropriate tablet for that day of the week (e.g. "MO" for Monday). The tablet is swallowed whole with some liquid. Thereafter one tablet must be taken daily for 28 days following the direction shown by the arrows. It does not matter at what time of the day the tablet is taken, but once you have selected a particular time, the tablet should be taken as near as possible at the same time each day. Withdrawal bleeding usually starts on day 2 or 3 after starting the inactive tablets and may not have finished before the next pack is started. Each subsequent pack is started in the white section the day after the last tablet of the current pack. If you start ELOINE during the latter part of the week, the very first cycle may be slightly shortened.

Starting your first pack of ELOINE:

When no hormonal contraceptive has been used in the past month:

Start taking ELOINE on the first day of your cycle, i.e. the first day of menstrual bleeding. Take the tablet marked with that day of the week from the white section of the pack. For example, if your period starts on a Friday, take the tablet marked "FR". Then take 1 tablet every day following the directions shown by the arrows. During the first cycle an additional barrier method is recommended for the first 7 days of tablet-taking.

When changing from another combined pill, vaginal ring or transdermal (contraceptive) patch:

You should start with ELOINE preferably on the day after the last active tablets of your previous combined oral contraceptive, but at the latest on the day following the usual tablet-free or inactive tablet interval of your previous combined oral contraceptive. In case you have used a vaginal ring or transdermal patch, you should start using ELOINE preferably on the day of removal, but at the latest when the next application would have been due. If you follow these instructions, it is not necessary to use an additional contraceptive method.

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

You may switch any day from the minipill, from an implant or the IUS on the day of its removal, and from an injectable when the next injection would be due, but in all these cases you are advised to use an additional barrier method for the first 7 days of tablet-taking.

After having a baby:

If you are breastfeeding and want to take ELOINE, you should discuss this first with your doctor, who will advise you.

After a miscarriage or an abortion:

Your doctor will advise you.

If you take more ELOINE than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre. 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 ELOINE, ask your doctor for advice. Taking the white tablets from the bottom row of the blister is harmless because they do not contain active ingredients.

If you forget to take ELOINE:

- If you are **less than 12 hours** late in taking an active tablet, the reliability of the Pill is maintained. Take the tablet as soon as you remember and take the next tablet at the usual time.
- If you are **more than 12 hours late** in taking any active tablet, the reliability of the Pill may be reduced. The more consecutive active tablets you have missed, the higher the risk that the contraceptive effect is decreased. There is a particularly high risk of becoming pregnant if you miss tablets in the week before or in the week after the inactive tablets. Therefore, you should follow the rules given below.

More than one tablet forgotten in a pack:

Ask your doctor for advice.

1 tablet missed in the first 7 days of active tablet-taking (1st 7 days after the inactive tablets):

Take the missed tablet as soon as you remember (even if this means taking two tablets at the same time) and take the next tablet at the usual time. Use extra contraceptive precautions (barrier method) for the next 7 days.

If you have had sexual intercourse in the week before missing the tablet, there is a possibility of becoming pregnant, so tell your doctor immediately.

1 tablet missed in the second 7 days of active tablet-taking:

Take the missed tablet as soon as you remember (even if this means taking two tablets at the same time) and take the next tablet at the usual time. Provided that you have taken all your tablets correctly in the 7 days before the missed tablet, the reliability of the Pill is maintained and you need not use extra contraceptive precautions. If this is not the case use extra precautions for 7 days.

1 tablet missed in the third 7 days of active tablet-taking (the last 7 days before the inactive tablets):

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

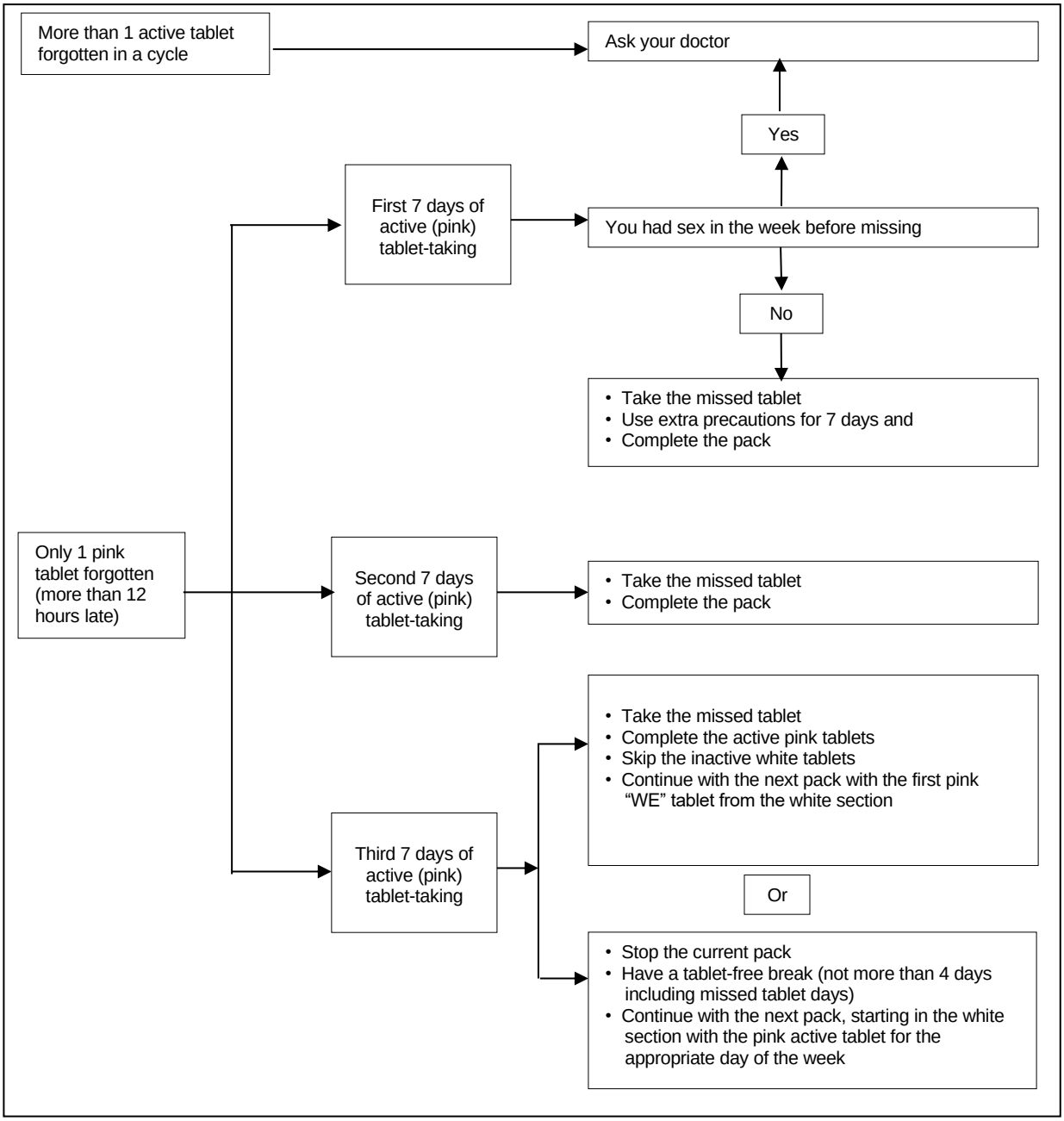
1. Take the missed tablet as soon as you remember (even if this means taking two tablets at the same time) and take the next tablets at the usual time until the active tablets are used up. The 4 inactive tablets must be discarded, (i.e. discard the current pack after taking the last pink tablet on “FR”). Start the next pack right away, with the first pink “WE” tablet from the white section. You may not have a withdrawal bleed until the end of the active tablets in the second pack, but you may have spotting or breakthrough bleeding on active tablet-taking days.

or

2. Stop taking tablets from your current pack, have a tablet-free break of 4 days or less **(also count the day you missed your tablet)** and then continue with the next pack, starting in the white section with the pink active tablet for the appropriate day of the week.

If you have forgotten tablets in a pack and you do not have your period as expected, you may be pregnant. Consult your doctor before you start the next pack.

What to do if you forget tablets:



Inactive tablet-taking:

The white tablets are inactive tablets and missing these can be disregarded. However, the missed inactive tablets should be discarded to avoid unintentionally prolonging the inactive tablet phase.

What to do if:

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

If you vomit, or have severe diarrhoea after taking active tablets, the active ingredients of your ELOINE 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 for missed tablets. If you have severe diarrhoea, please contact your doctor. Vomiting or diarrhoea while taking tablets from the inactive white tablets does not have an influence on the contraceptive reliability.

You want to delay a period:

You can delay your period if you start with your next pack of ELOINE tablets immediately after finishing the active pink tablets of your current pack (do not take the inactive white tablets). You can continue with this pack for as long as you wish, e.g. until this pack is empty, to get a period approximately 3 weeks later than usual. While using the second pack you may have some breakthrough bleeding or spotting on active tablet-taking days.

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 continue to take your tablets as normal. Irregular vaginal bleeding usually stops once your body has adjusted to the Pill (usually after about 3 tablet-taking cycles). If it continues, becomes heavy or starts again, tell your doctor.

You have missed a period:

If you've missed a period, consult your doctor.

When you want to stop taking ELOINE:

You can stop taking ELOINE at any time you want. If you stop because you want to get pregnant, it is generally recommended that you wait until you have had a natural period before trying to conceive. This helps you to work out when the baby will be due.

If you do not want to become pregnant, ask your doctor about other methods of birth control.

POSSIBLE SIDE EFFECTS:

ELOINE can have side effects.

Not all side effects reported for ELOINE 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.

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).

Rare side effects:

Thromboembolism (blood clots including embolism), asthma, breast discharge, hypacusia (hearing impairment).

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 certain female sex hormones (oestrogens) may induce or worsen the symptoms of angioedema.

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

STORING AND DISPOSING OF ELOINE:

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.
Store at or below 30 ºC.
Do not use after expiry date stated on the carton.
Keep the blister strips in the original carton until required for use.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF ELOINE:

ELOINE is presented as a blister pack containing 28 film-coated tablets. Blister packs consist of transparent films made of polyvinyl chloride and metallic foils made of aluminium (mat side hot sealable).

IDENTIFICATION OF ELOINE:

24 Light pink, active, round film-coated tablets with convex faces, one side embossed with the letters “DS” in a regular hexagon. 4 White, inactive, round film-coated tablets with convex faces, one side embossed with the letters “DP” in a regular hexagon.

REGISTRATION NUMBER:

44/21.8.2/0957

NAME AND ADDRESS OF REGISTRATION HOLDER:

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