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film-coated tablets Elevin 30 micrograms/150 micrograms

Elevin 30 micrograms/150 micrograms film-coated tablets

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Package leaflet: Information for the patient

Elevin 30 micrograms/150 micrograms film-coated tablets

Active substances: ethinylestradiol and levonorgestrel

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet; you may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them. • If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects

not listed in this leaflet. See section 4 The product will be referred to as Elevin Tablets throughout the leaflet.

Important things to know about combined hormonal contraceptives (CHCs):

- They are one of the most reliable reversible methods of contraception if used correctly. . They slightly increase the risk of having a blood clot in the veins and arteries, especially in the first
- year or when restarting a combined hormonal contraceptive following a break of 4 or more weeks. • Please be alert and see your doctor if you think you may have symptoms of a blood clot (see section 2 "Blood clots").

What is in this leaflet

- 1. What Elevin Tablets are and what they are used for
- 2. What you need to know before you take Elevin Tablets 3. How to take Elevin Tablets
- 4. Possible side effects 5. How to store Elevin Tablets
- 6. Contents of the pack and other information

WHAT ELEVIN TABLETS ARE AND WHAT THEY ARE USED FOR?

Elevin Tablets is a contraceptive pill and is used to prevent pregnancy. Each tablet contains a small amount of two different female hormones, namely levonorgestrel and ethinylestradiol. Contraceptive pills that contain two hormones are called "combination" pills.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ELEVIN TABLETS

Before you start using Elevin Tablets, you should read the information on blood clots in section 2. It is particularly important to read the symptoms of a blood clot - see section 2 "Blood clots".

Before you can begin taking Elevin Tablets, your doctor will ask you some questions about your personal health history and that of your close relatives. The doctor will also measure your blood pressure, and, depending upon your personal situation, may also carry out some other tests

In this leaflet, several situations are described where you should stop using Elevin Tablets, or where the reliability of Elevin Tablets 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 Elevin Tablets alters the monthly changes of the body temperature and of the cervical mucus.

Elevin Tablets, like other hormonal contraceptives, do not protect against HIV infection (AIDS) or any other sexually transmitted disease.

When you should not use Elevin Tablets

You should not use Elevin Tablets if you have any of the conditions listed below. If you do have any of the conditions listed below, you must tell your doctor. Your doctor will discuss with you what other form of birth control would be more appropriate.

DO NOT TAKE ELEVIN TABLETS if you are pregnant or suspect to be pregnant

- if you have (or have ever had) a blood clot in a blood vessel of your legs (deep vein thrombosis, DVT), your lungs (pulmonary embolus, PE) or other organs.
- if you know you have a disorder affecting your blood clotting for instance, protein C deficiency, protein S deficiency, antithrombin-III deficiency, Factor V Leiden or antiphospholipid antibodies;
- if you need an operation or if you are off your feet for a long time (see section 'Blood clots');
- if you have ever had a heart attack or stroke
- if you have (or have ever had) angina pectoris (a condition that causes severe chest pain and may be a first sign of a heart attack) or transient ischaemic attack (TIA - temporary stroke symptoms);
- if you have any of the following diseases that may increase your risk of a clot in the arteries. severe diabetes with blood vessel damage
- very high blood pressure

- ➤ a very high level of fat in the blood (cholesterol or triglycerides)
- ➤ a condition known as hyperhomocysteinaemia
- and if you are smoking existing or previous pancreatitis if this is associated with severe hypertriglyceridaemia
- if you have (or have ever had) a type of migraine called 'migraine with aura'
- if you have (or have ever had) a liver disease and your liver function is still not normal if you have (or have ever had) a tumour in the liver
- if you have (or have ever had) or if you are suspected of having breast cancer or cancer of the genital
- if you have any unexplained bleeding from the vagina if you are allergic to ethinylestradiol or levonorgestrel, or any of the other ingredients of this medicine
- (listed in section 6). This may cause itching, rash or swelling if you have hepatitis C and are taking medicinal products containing ombitasvir/paritaprevir/ritonavir, dasabuvir glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir (see also in section Other medicines and Ethinylestradiol/Levonorgestrel)

Warnings and precautions

When should you contact your doctor?

Seek urgent medical attention

- if you notice possible signs of a blood clot that may mean you are suffering from a blood clot in the leg (i.e. deep vein thrombosis), a blood clot in the lung (i.e. pulmonary embolism), a heart attack or a stroke (see 'Blood clots' section below).

For a description of the symptoms of these serious side effects please go to "How to recognise a blood

In some situations you need to take special care while using Elevin Tablets or any other combination pill, and your doctor may need to examine you regularly.

Tell your doctor if any of the following conditions develops or gets worse while you are using **Elevin Tablets**

Talk to your doctor or pharmacist before taking Elevin Tablets

- if a close relative has or has ever had breast cancer
- if you have a disease of the liver or the gallbladder
- if you have diabetes if you have depression
- if you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- if you have haemolytic uraemic syndrome (HUS a disorder of blood clotting causing failure of the
- f you have sickle cell anaemia (an inherited disease of the red blood cells) if you have elevated levels of fat in the blood (hypertriglyceridaemia) or a positive family history for this
- condition. Hypertriglyceridaemia has been associated with an increased risk of developing pancreatitis (inflammation of the pancreas) if you need an operation, or you are off your feet for a long time (see in section 2 'Blood clots')
- if you have just given birth you are at an increased risk of blood clots. You should ask your doctor how
- soon after delivery you can start taking Elevin Tablets
- if you have an inflammation in the veins under the skin (superficial thrombophlebitis) if you have varicose veins
- if you have epilepsy (see page 10 "Other medicines and Elevin Tablets")
- if you have systemic lupus erythematosus (SLE; a disease affecting your natural defence system) if you have a disease that first appeared during pregnancy or earlier use of sex hormones (for
- example, hearing loss, a blood disease called porphyria, skin rash with blisters during pregnancy (gestational herpes), a nerve disease causing sudden movements of the body (Sydenham's chorea)) if you have or have ever had chloasma (a discoloration of the skin especially of the face or neck
- known as "pregnancy patches"). If so, avoid direct sunlight or ultraviolet light while taking this • if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or
- difficulty swallowing or hives potentially with difficulty breathing contact a doctor immediately. Products containing estrogens may cause or worsen the symptoms of hereditary and acquired angioedema.

BLOOD CLOTS

Using a combined hormonal contraceptive such as Elevin Tablets, increases your risk of developing a blood clot compared with not using one. In rare cases a blood clot can block blood vessels and cause serious problems

• in veins (referred to as a 'venous thrombosis', 'venous thromboembolism' or VTE)

In the arteries (referred to as an 'arterial thrombosis', 'arterial thromboembolism' or ATE).

Recovery from blood clots is not always complete. Rarely, there may be serious lasting effects or, very rarely,

It is important to remember that the overall risk of a harmful blood clot due to Elevin Tablets is small.

HOW TO RECOGNISE A BLOOD CLOT

Seek urgent medical attention if you notice any of the following signs or symptoms.

Are you experiencing any of these signs?	What are you possibly suffering from?
 swelling of one leg or along a vein in the leg or foot especially when accompanied by: pain or tenderness in the leg which may be felt only when standing or walking increased warmth in the affected leg change in colour of the skin on the leg e.g. turning pale, red or blue 	Deep vein thrombosis
 sudden unexplained breathlessness or rapid breathing; sudden cough without an obvious cause, which may bring up blood; sharp chest pain which may increase with deep breathing; severe light headedness or dizziness; rapid or irregular heartbeat severe pain in your stomach; If you are unsure, talk to a doctor as some of these symptoms such as coughing or being short of breath may be mistaken for a milder condition such as a respiratory tract infection (e.g. a 'common cold'). 	Pulmonary embolisn
Symptoms most commonly occur in one eye: immediate loss of vision orpainless blurring of vision which can progress to loss of vision	Retinal vein thrombosis (blood clot in the eye)
 chest pain, discomfort, pressure, heaviness sensation of squeezing or fullness in the chest, arm or below the breastbone; fullness, indigestion or choking feeling; upper body discomfort radiating to the back, jaw, throat, arm and stomach; sweating, nausea, vomiting or dizziness; extreme weakness, anxiety, or shortness of breath; rapid or irregular heartbeats 	Heart attack
 sudden weakness or numbness of the face, arm or leg, especially on one side of the body; sudden confusion, trouble speaking or understanding; sudden trouble seeing in one or both eyes; sudden trouble walking, dizziness, loss of balance or coordination; sudden, severe or prolonged headache with no known cause; loss of consciousness or fainting with or without seizure. Sometimes the symptoms of stroke can be brief with an almost immediate and full recovery, but you should still seek urgent medical attention as you may be at risk of another stroke. 	Stroke
 swelling and slight blue discolouration of an extremity; severe pain in your stomach (acute abdomen) 	Blood clots blocking other blood vessels

BLOOD CLOTS IN A VEIN

What can happen if a blood clot forms in a vein?

- The use of combined hormonal contraceptives has been connected with an increase in the risk of blood clots in the vein (venous thrombosis). However, these side effects are rare. Most frequently, they occur in the first year of use of a combined hormonal contraceptive.
- If a blood clot forms in a vein in the leg or foot it can cause a deep vein thrombosis (DVT).
- If a blood clot travels from the leg and lodges in the lung it can cause a pulmonary embolism. Very rarely a clot may form in a vein in another organ such as the eye (retinal vein thrombosis).

When is the risk of developing a blood clot in a vein highest?

The risk of developing a blood clot in a vein is highest during the first year of taking a combined hormonal contraceptive for the first time. The risk may also be higher if you restart taking a combined hormonal contraceptive (the same product or a different product) after a break of 4 weeks or more After the first year, the risk gets smaller but is always slightly higher than if you were not using a combined hormonal contraceptive

When you stop Elevin Tablets your risk of a blood clot returns to normal within a few weeks.

What is the risk of developing a blood clot? The risk depends on your natural risk of VTE and the type of combined hormonal contraceptive you are

The overall risk of a blood clot in the leg or lung (DVT or PE) with Elevin Tablets is small

Out of 10,000 women who are not using any combined hormonal contraceptive and are not pregnant,

about 2 will develop a blood clot in a year.

	Risk of developing a blood clot in a year
	About 2 out of 10,000 women
Women who are not using a combined hormonal	
pill/patch/ring and are not pregnant	
	About 5-7 out of 10,000 women
pill containing levonorgestrel	
Women using Elevin Tablets	About 5-7 out of 10,000 women

- Out of 10,000 women who are using a combined hormonal contraceptive that contains levonorgestrel
- such as Elevin Tablets about 5-7 will develop a blood clot in a year. The risk of having a blood clot will vary according to your personal medical history (see "Factors that

increase your risk of a blood clot" below).

Factors that increase your risk of a blood clot in a vein The risk of a blood clot with Elevin Tablets is small but some conditions will increase the risk. Your risk is

- if you are very overweight (body mass index or BMI over 30kg/m2);
- if one of your immediate family has had a blood clot in the leg, lung or other organ at a young age (e.g. below the age of about 50). In this case you could have a hereditary blood clotting disorder; if you need to have an operation, or if you are off your feet for a long time because of an injury or illness, or you have your leg in a cast. The use of Elevin Tablets may need to be stopped several
- weeks before surgery or while you are less mobile. If you need to stop Elevin Tablets ask your doctor when you can start using it again. as you get older (particularly above about 35 years);

if you gave birth less than a few weeks ago

The risk of developing a blood clot increases the more conditions you have.

Air travel (>4 hours) may temporarily increase your risk of a blood clot, particularly if you have some of the It is important to tell your doctor if any of these conditions apply to you, even if you are unsure. Your doctor may decide that Elevin Tablets need to be stopped.

If any of the above conditions change while you are using Elevin Tablets, for example a close family member experiences a thrombosis for no known reason; or you gain a lot of weight, tell your doctor.

BLOOD CLOTS IN AN ARTERY

What can happen if a blood clot forms in an artery?

Like a blood clot in a vein, a clot in an artery can cause serious problems. For example, it can cause a heart attack or a stroke.

Factors that increase your risk of a blood clot in an artery It is important to note that the risk of a heart attack or stroke from using Elevin Tablets is very small but

with increasing age (beyond about 35 years);
if you smoke. When using a combined hormonal contraceptive like Elevin Tablets you are advised to stop smoking. If you are unable to stop smoking and are older than 30 your doctor may advise you to use a different type of contraceptive; if you are overweight;

if you have high blood pressure;

if a member of your immediate family has had a heart attack or stroke at a young age (less than about 50). In this case you could also have a higher risk of having a heart attack or stroke;

if you, or someone in your immediate family, have a high level of fat in the blood (cholesterol or triglycerides):

if you get migraines, especially migraines with aura; if you have a problem with your heart (valve disorder, disturbance of the rhythm called atrial fibrillation) if you have diabetes.

If you have more than one of these conditions or if any of them are particularly severe the risk of developing a blood clot may be increased even more. If any of the above conditions change while you are using Elevin Tabelts, for example you start smoking, a close family member experiences a thrombosis for no known reason; or you gain a lot of weight, tell your

Elevin tablets and cancer

Breast cancer has been observed slightly more often in women using combination pills, but it is not known whether this is caused by the treatment. For example it may be that more tumours are detected in women on combined pills because they are examined by their doctor more often. The occurrence of breast tumours becomes gradually less after stopping the combination hormonal contraceptives. It is important to regularly check your breasts and you should contact your doctor if you feel any lump. In rare cases, benign liver tumours, and in even fewer cases malignant liver tumours have been reported in pill users. Contact your doctor if you have unusual severe abdominal pain.

Bleeding between periods

During the first few months that you are taking Elevin Tablets, you may have unexpected bleeding (bleeding outside the gap week). If this bleeding lasts longer than a few months, or if it begins after some months, your doctor must find out what is wrong.

What to do if no bleeding occurs in the gap week

If you have taken the tablets correctly, have not had vomiting or severe diarrhoea and you have not taken any other medicines, it is highly unlikely that you are pregnant. If the expected bleeding does not happen twice in succession, you may be pregnant. Contact your doctor immediately. Do not start the next strip until you are sure that you are not pregnant.

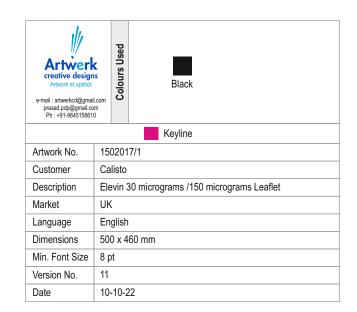
Psychiatric disorders Some women using hormonal contraceptives including Elevin Tablets have reported depression or

not take Elevin Tablets"

depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible. Other medicines and Elevin Tablets

Tell your doctor which medicines or herbal products you are already using, have recently used or might use. Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist) that you take Elevin Tablets. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long, or whether the use of another medicine you need must be changed.

Do not use Elevin Tablets if you have Hepatitis C and are taking medicinal products containing ombitasvir/paritaprevir/ritonavir, dasabuvir, glecaprevir/pibrentasvir or sofosbuvir/velpatasvir/voxilaprevir, as these products may cause increases in liver function blood test results (increase in ALT liver enzyme). Your doctor will prescribe another type of contraceptive prior to start of the treatment with these medicinal Elevin Tablets can be restarted approximately 2 weeks after completion of this treatment. See section "Do



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Some medicines

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• can have an influence on the blood levels of Elevin Tablets • can make them less effective in preventing pregnancy

 can cause unexpected bleeding These include

medicines used for the treatment of:

epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, felbamate, topiramate)

tuberculosis (e.g. rifampicin)

HIV and Hepatitis C Virus infections (so-called protease inhibitors and non-nucleoside reverse

transcriptase inhibitors such as ritonavir, nevirapine, efavirenz) fungal infections (e.g. griseofulvin)

arthritis, arthrosis (etoricoxib) high blood pressure in the blood vessels in the lungs (bosentan)

the herbal remedy St. John's wort

Elevin Tablets may influence the effect of other medicines e.g.

 medicines containing ciclosporin. the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures).

theophylline (used to treat breathing problems) tizanidine (used to treat muscle pain and/or muscle cramps).

midazolam (used to help you sleep and reduce anxiety)

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

Pregnancy and breast-feeding Pregnancy If you are pregnant, **YOU MUST NOT TAKE** Elevin Tablets. If you become pregnant while taking Elevin Tablets you must stop immediately and contact your doctor. If you want to become pregnant, you can stop taking Elevin Tablets at any time (see also section 3 "if you stop taking Elevin Tablets"

Breast-feeding Use of Elevin Tablets is generally not advisable when a woman is breast feeding. If you want to take the pill while you are breast-feeding you should contact your doctor.

Driving and using machines There is no information suggesting that the use of Elevin Tablets affects driving or use of machines.

Elevin Tablets contain lactose

Elevin Tablets contain lactose. If you have been told by your doctor that you have an intolerence to some sugars, contact your doctor before taking this medicine

3. HOW TO TAKE ELEVIN TABLETS

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or

Take one Elevin tablet every day, if necessary with a small amount of water. You may take the tablets with or without food, but you should take the tablets every day around the same time.

The strip contains 21 tablets. Next to each tablet is printed the day of the week that it should be taken. If, for example you start on a Wednesday, take a tablet with "WED" next to it. Follow the direction of the arrow on the strip until all 21 tablets have been taken.

Then take no tablets for 7 days. In the course of these 7 tablet-free days (otherwise called a stop or gap week) bleeding should begin. This so-called "withdrawal bleeding" usually starts on the 2nd or 3rd day of

On the 8th day after the last Elevin tablet (that is, after the 7-day gap week), you should start with the following strip, whether your bleeding has stopped or not. This means that you should start every strip on the same day of the week and that the withdrawal bleed should occur on the same days each month.

If you use Elevin tablets in this manner, you are also protected against pregnancy also during the 7 days when you are not taking a tablet.

When can you start with the first strip?

• If you have not used a contraceptive with hormones in the previous month Begin with Elevin Tablets on the first day of the cycle (that is the first day of your period). If you start Elevin Tablets on the first day of your period you are immediately protected against pregnancy. You may also begin on day 2-5 of the cycle, but then you must use extra protective measures (for example, a condom) for the first 7 days.

 Changing from a combination hormonal contraceptive, or combination contraceptive vaginal ring or You can start Elevin Tablets preferably on the day after the last active tablet (the last tablet containing active substances) of your previous pill, but at the latest on the day after the tablet-free days of your previous pill (or after the last inactive tablet of your previous pill). When changing from a combination

contraceptive vaginal ring or patch, follow the advice of your doctor. • Changing from a progestogen-only-method (progestogen-only pill, injection, implant or a progestogen-You may switch any day from the progestogen-only pill (from an implant or an IUD on the day of its

removal, from an injectable when the next injection would be due) but in all of these cases use extra protective measures (for example, a condom) for the first 7 days of tablet-taking. After a miscarriage

Follow the advice of your doctor.

pharmacist for advice.

You can start Elevin tablets between 21 and 28 days after having a baby.. If you start later than day 28, use a so-called barrier method (for example, a condom) during the first seven days of Elevin Tablets use. If, after having a baby you have had sex before starting Elevin Tablets (again), be sure that you are

not pregnant or wait until your next period. If you are breast-feeding and want to start Elevin Tablets (again) after having a baby Read the section on "Breast-feeding".

Ask your doctor what to do if you are not sure when to start.

If you take more Elevin Tablets than you should There are no reports of serious harmful result of taking too many Elevin Tablets.

If you take several tablets at once then you may have symptoms of nausea or vomiting. Young girls may have bleeding from the vagina. If you have taken too many Elevin Tablets, or you discover that a child has taken some, ask your doctor or

If you forget to take Elevin Tablets • If you are less than 12 hours late taking a tablet, the protection against pregnancy is not reduced.

Take the tablet as soon as you remember and then take the following tablets again at the usual time. If you are more than 12 hours late taking a tablet, the protection against pregnancy may be reduced. The greater the number of tablets that you have forgotten, the greater is the risk of becoming pregnant.

The risk of incomplete protection against pregnancy is greatest if you forget a tablet at the beginning or at the end of the strip. Therefore, you should keep to the following rules (see the diagram):

More than one tablet forgotten in this strip

Contact your doctor One tablet forgotten in week 1

Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Take the tablets again at the usual time and use extra precautions for the next 7 days, for example a condom.

 One tablet forgotten in week 2 Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. If you have had sex in the week before forgetting the tablet you may be pregnant. In that case, contact your doctor.

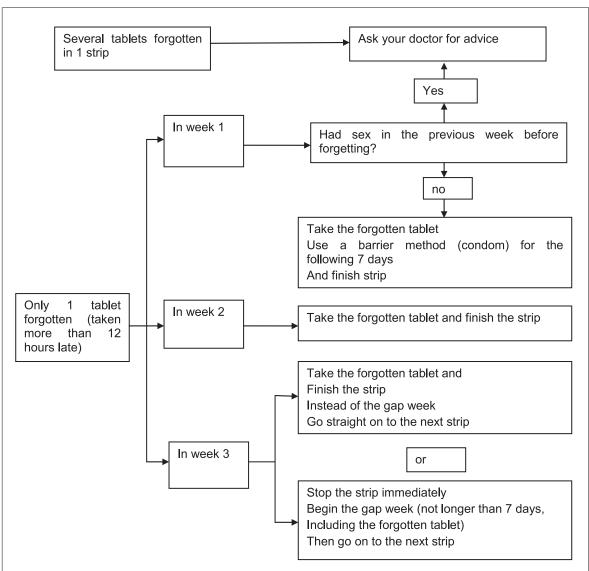
One tablet forgotten in week 3 You can choose between two possibilities: Take the forgotten tablets as soon as you remember, even if that means that you have to take two

tablets at the same time. Continue taking the tablets at the usual time. Instead of taking the tablet-free period start the next strip. Most likely, you will have a period at the end of the second strip but you may have light or menstruation-like bleeding during the second strip.

2. You can also stop the strip and go directly to the tablet-free period of 7 days (record the day on which you forgot your tablet). If you want to start a new strip on the day you always start, make the tablet-free period less than 7 days. If you follow either of these two recommendations, you will remain protected against pregnancy.

If you have forgotten any of the tablets in a strip, and you do not have bleeding in the first tablet-free period, you may be pregnant. Contact your doctor before you start the next strip.

The following diagram describes how to proceed if you forget to take your tablets:



What to do in the case of vomiting or severe diarrhoea

If you vomit within 3-4 hours after taking a tablet or you have severe diarrhoea, there is a risk that the active substances in the pill will not be fully taken up by your body. The situation is almost the same as forgetting a tablet. After vomiting or diarrhoea, take another tablet from a reserve strip as soon as possible. If possible take it within 12 hours of when you normally take your pill. If that is not possible or 12 hours have passed, you should follow the advice given under "If you forget to take Elevin Tablets".

Delaying your period: what you need to know

Even though it is not recommended, you can delay your period by going straight to a new strip of Elevin Tablets instead of the tablet-free period and finishing it. You may experience light or menstruation-like bleeding while using this second strip. After the second strip is finished, take the usual tablet-free period of 7 days, start the next strip.

You should ask your doctor for advice before deciding to delay your menstrual period.

Changing the first day of your period: what you need to know

If you take the tablets according to the instructions, then your period will begin during the tablet-free week. If you have to change this day, reduce the number of tablet-free days (but never increase them - 7 is the maximum!). For example, if your tablet-free days normally begin on a Friday, and you want to change this to a Tuesday (3 days earlier) start a new strip 3 days earlier than usual. If you make the tablet-free interval very short (for example, 3 days or less) you may not have any bleeding during these days. You may then experience light or menstruation-like bleeding.

If you are not sure what to do, consult your doctor.

If you stop taking Elevin Tablets

You can stop taking Elevin Tablets whenever you want. 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 Elevin Tablets and wait for a period before trying to become pregnant. You will be able to calculate the expected delivery date more easily.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects although not everybody gets them.

If you get any side effect, particularly if severe and persistent, or have any change to your health that you think may be due to Elevin Tablets, please talk to your doctor.

Serious side effects

Contact a doctor immediately if you experience any of the following symptoms of angioedema: swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing (see also section "Warnings and precautions").

An increased risk of blood clots in your veins (venous thromboembolism (VTE)) or blood clots in your arteries (arterial thromboembolism (ATE)) is present for all women taking combined hormonal contraceptives. For more detailed information on the different risks from taking combined hormonal contraceptives please see section 2 "What you need to know before you take Elevin Tablets".

The following is a list of the side effects that have been linked with the use of Elevin Tablets.

Very common (may affect more than 1 in 10 people) headache (including migraine)

bleeding or spotting between periods

Common (may affect up to 1 in 10 people): mood swings, including depression, changes in sexual urges (libido)

inflammation of the vagina, including fungal infestation (candidiasis) nervousness, stupor, dizziness

abdominal pain (stomach ache) nausea, vomiting, abdominal pain

fluid retention in tissue (oedema)

breast pain, breast enlargement, breast tenderness, nipple discharge, changes in vaginal secretion, changes in cervical secretion, painful or irregular periods, absence of periods

weight gain or loss

Incommon (may affect up to 1 in 100 people). increased or decreased appetite

stomach cramps, flatulence, diarrhoea rash, yellowish-brown flecks on the skin (chloasma), possibly persistent, increased hairiness, hair loss increased blood pressure, changes in the serum lipid level, including hypertriglyceridaemia

reduced ability to break down glucose (glucose intolerance)

Rare (may affect up to 1 in 1,000 people): • a serious allergic reaction which includes signs such as rash, itching or hives on the skin, swelling of the face, lips, tongue or throat (angioedema) which may cause difficulty in breathing and swallowing.

yellowing of the skin or whites of the eyes due to obstruction in the bile duct (cholestatic jaundice) allergic reactions such as itchy and painful skin tolerance of contact lenses

erythema nodosum (characterized by painful reddish skin nodules) decreased serum folic acid level (serum folic acid levels can be decreased by the Pill. In the event of a pregnancy that occurs shortly after discontinuation of the oral contraceptive, decreased serum folic

acid levels may be of clinical relevance) severe rash (erythema multiforme)

Very rare (may affect up to 1 in 10,000 people) • liver cell cancer (with symptoms such as swollen abdomen, weight loss, abdominal liver function which

may be seen in in blood tests, jaundice)

The following conditions have also been associated with combination oral contraception:

inflammation of the optic nerve (optic neuritis), thrombosis in the blood vessels of the eye (retinal vascular thrombosis which may cause sudden blurring or vision loss in all or part of one eye) inflammation of the pancreas (pancreatitis) with increase in triglycerides seen in blood tests

a condition where the large intestine becomes inflamed due to inadequate blood supply; symptoms include stomach pain, diarrhoea, fever and bleeding from the rectum (ischaemic colitis) liver damage (including inflammation of the liver (hepatitis) or liver dysfunction with signs such as severe abdominal pain or changes in the liver function as seen in blood tests)

a particular blood disorder that leads to kidney damage (haemolytic-uraemic syndrome, with signs such as decreased urine output, blood in the urine, low red blood cells, nausea, vomiting, confusion and diarrhoea) worsening of a particular immune system disorder (systemic lupus erythematosus) worsening of a metabolic disorder with breakdown of the production of haemoglobin (porphyria)

worsening of Sydenham's chorea (a disease of the nerves in which sudden movements of the body to

inflammation of the colon or other parts of the intestine (with signs such as bloody diarrhoea, pain when passing stools, pain in the abdomen) (Crohn's disease, ulcerative colitis)

Not known (frequency cannot be estimated from the available data)

worsening of varicose veins gall bladder disease, including gallstones

blister-like rash (herpes gestationis) whilst pregnant deafness which can also be inherited (otosclerosis)

worsening of depression

Reporting of side effects Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ELEVIN TABLETS

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the packaging after "Do not use after:" or

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw

away medicines you no longer use. These measures will help protect the environment.

. CONTENTS OF THE PACK AND OTHER INFORMATION What Elevin Tablets contain:

The active substances are: One film-coated tablet (a "Pill") contains 0.03 mg ethinylestradiol and 0.15 mg levonorgestrel

The other ingredients are: Tablet core: lactose monohydrate (see section 2 "Elevin Tablets contain lactose"), maize starch, gelatin, magnesium stearate

Tablet coating:hypromellose, macrogol, titanium dioxide (E171), iron oxide yellow (E172) What Elevin Tablets looks like and contents of the pack Elevin Tablets are brownish, round convex, film-coated tablets **Elevin Tablets** are available in blister packs with:

Calendar pack with 21 film-coated tablets Calendar pack with 3 x 21 film-coated tablets Calendar pack with 6 x 21 film-coated tablets Calendar pack with 12 x 21 film-coated tablets 100 x 21 film-coated tablets (hospital pack)

Marketing Authorisation holder MedRx Licences Limited, 9 St. George's Yard, Castle Street, Farnham, Surrey, GU9 7LW, United

Not all pack sizes may be marketed

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