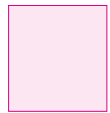


AÜBENSEITE

Elevin 30 micrograms/150 micrograms film-coated tablets

Elevin 30 micrograms/150 micrograms film-coated tablets

AÜBENSEITE



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

- What Elevin Tablets are and what they are used for
- What you need to know before you take Elevin Tablets
- How to take Elevin Tablets
- Possible side effects
- How to store Elevin Tablets
- Contents of the pack and other information

1. 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

General notes

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 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
- 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 organs
- 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.

Warnings and precautions

When should you contact your doctor?

Seek urgent medication 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 clot".

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

- 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 kidneys)
- if 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 medicine.
- if you have hereditary angioedema, products containing oestrogens may cause or worsen the symptoms. You should see your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing, or hives together with difficulty breathing.

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.

Blood clots can develop

- 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, they may be fatal.

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?
<ul style="list-style-type: none"> swelling of one leg or along a vein in the leg or foot especially when accompanied by: <ul style="list-style-type: none"> 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 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; <p>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').</p>	Deep vein thrombosis
<p>Symptoms most commonly occur in one eye:</p> <ul style="list-style-type: none"> immediate loss of vision or painless blurring of vision which can progress to loss of vision 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 	Pulmonary embolism
<ul style="list-style-type: none"> 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. <p>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.</p>	Retinal vein thrombosis (blood clot in the eye) Heart attack
<ul style="list-style-type: none"> swelling and slight blue discolouration of an extremity; severe pain in your stomach (acute abdomen) 	Stroke 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 taking.

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.
- 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).

	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	
Women using a combined hormonal contraceptive pill containing levonorgestrel	About 5-7 out of 10,000 women
Women using Elevin Tablets	About 5-7 out of 10,000 women

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 higher:

- 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 other factors listed.

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 can increase:

- 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 35 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 Tablets, 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 doctor.

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 investigate the cause.

What to do if no bleeding occurs in the gap week

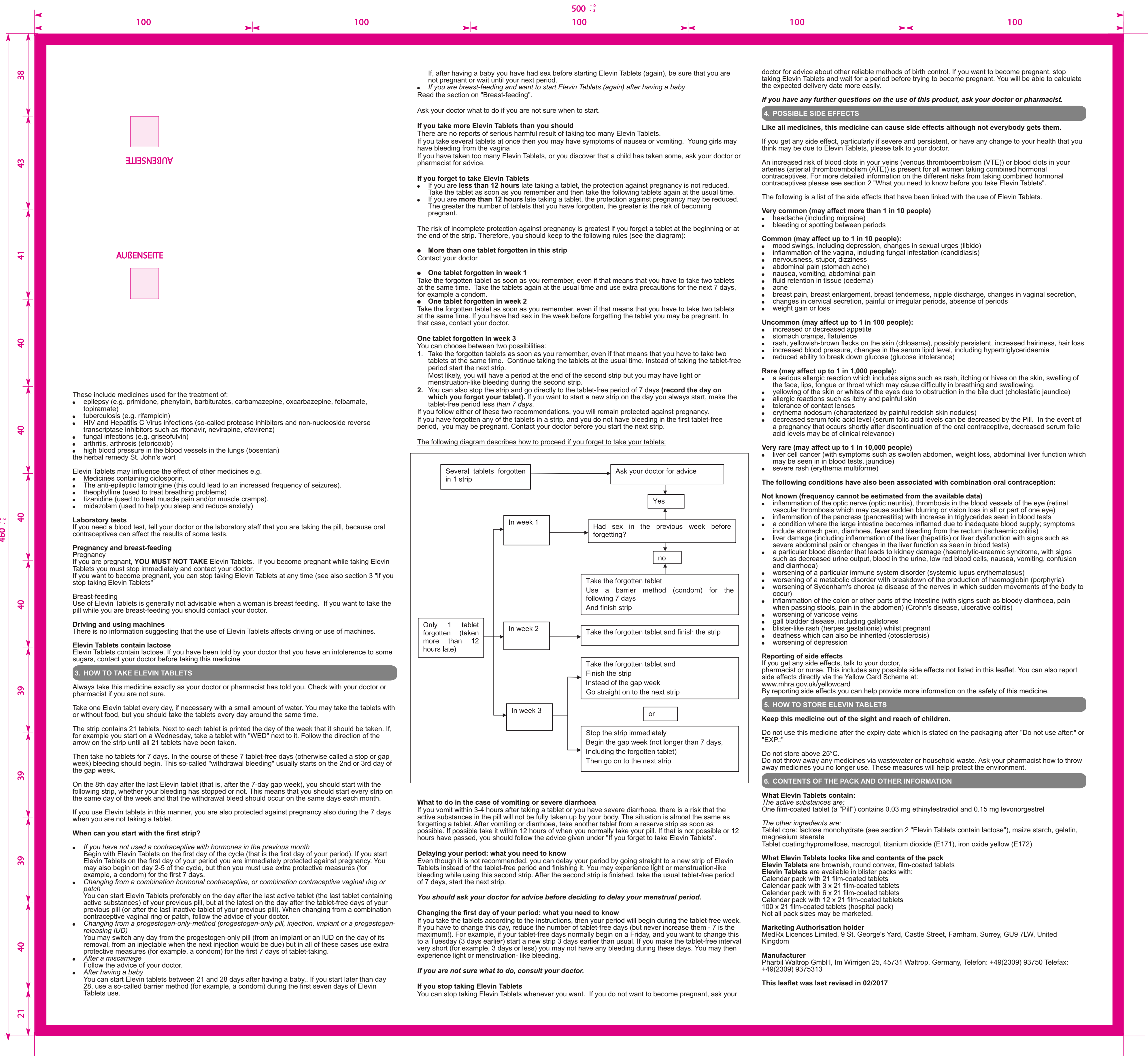
If you have taken the tablets correctly, have not had vomiting or severe diarrhoea and you have not taken any other medicines, it is highly unlikely that you are pregnant. If the expected bleeding does not happen twice in succession, you may be pregnant. Contact your doctor immediately. Do not start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

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.

Some medicines

- can have an influence on the blood levels of Elevin Tablets
- can make them **less effective in preventing pregnancy**
- can cause unexpected bleeding



If, after having a baby you have had sex before starting Elevation Tablets (again), be sure that you are not pregnant or wait until your next period.

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

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

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

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):

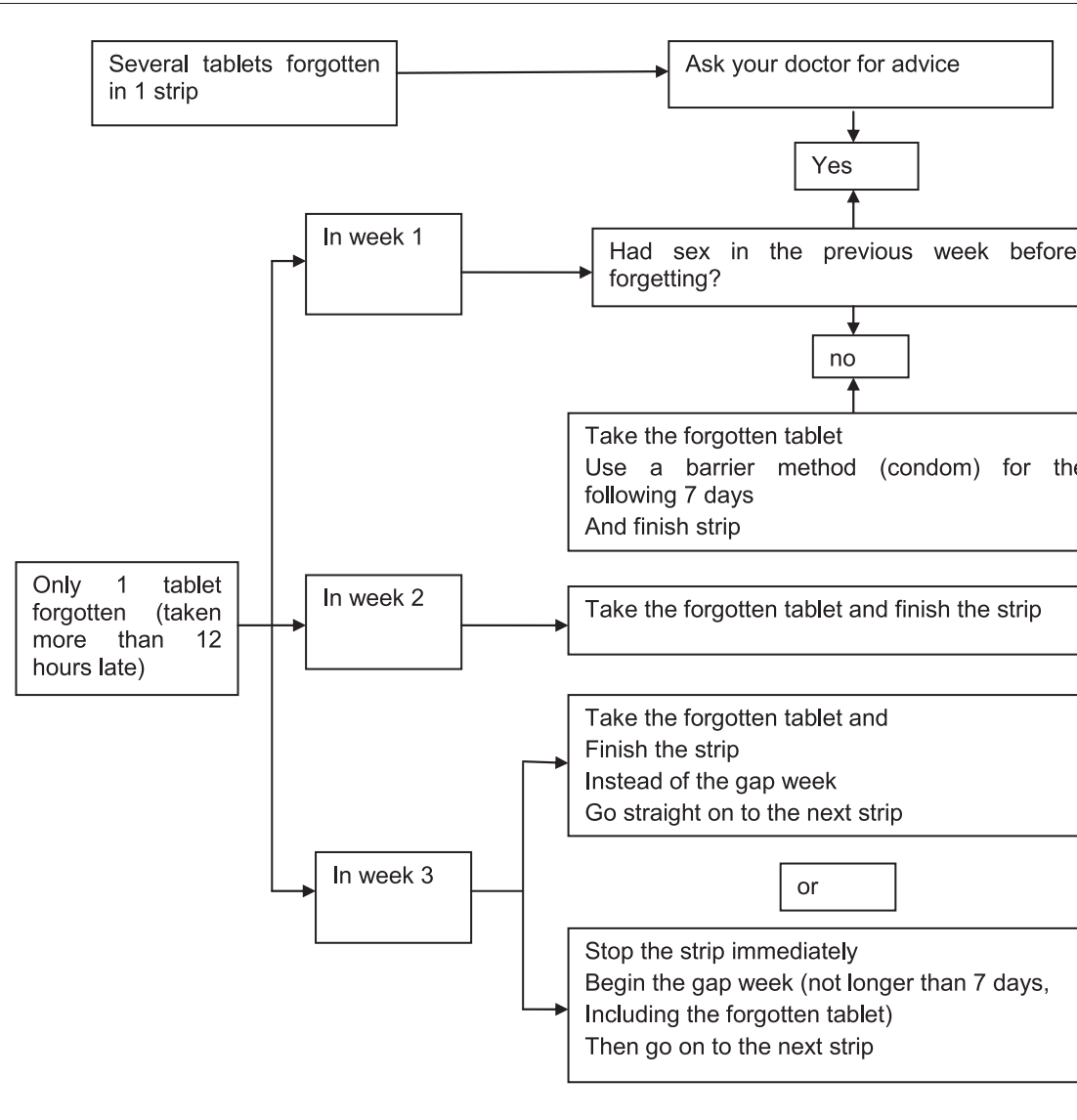
More than one tablet forgotten in this strip Contact your doctor

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.

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.

One tablet forgotten in week 3 You can choose between two possibilities: 1. Take the forgotten tablets as soon as you remember, even if that means that you have to take two tablets at the same time.

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.

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 Elevation Tablets instead of the tablet-free period and finishing it.

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 are not sure what to do, consult your doctor.

If you stop taking Elevation Tablets You can stop taking Elevation Tablets whenever you want.

doctor for advice about other reliable methods of birth control. If you want to become pregnant, stop taking Elevation Tablets and wait for a period before trying to become pregnant.

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 Elevation Tablets, please talk to your doctor.

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.

The following is a list of the side effects that have been linked with the use of Elevation 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, inflammation of the vagina, abdominal pain, nausea, vomiting, fluid retention in tissue (oedema).

- Uncommon (may affect up to 1 in 100 people) increased or decreased appetite, stomach cramps, rash, yellowish-brown flecks on the skin (chloasma), increased blood pressure, reduced ability to break down glucose.

- Rare (may affect up to 1 in 1,000 people) allergic reaction which includes signs such as rash, itching or hives on the skin, swelling of the face, lips, tongue or throat.

- 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 blood tests), severe rash (erythema multiforme).

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

- Not known (frequency cannot be estimated from the available data) inflammation of the optic nerve (optic neuritis), thrombosis in the blood vessels of the eye, inflammation of the pancreas (pancreatitis), liver damage (including inflammation of the liver (hepatitis) or liver dysfunction).

Reporting of side effects If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

5. HOW TO STORE ELEVATION TABLETS

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

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

Do not store above 25°C. Do not throw away any medicines via wastewater or household waste.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Elevation 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 "Elevation Tablets contain lactose"), maize starch, gelatin, magnesium stearate.

What Elevation Tablets looks like and contents of the pack Elevation Tablets are brownish, round convex, film-coated tablets. Elevation Tablets are available in blister packs with: Calendar pack with 21 film-coated tablets.

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