

Elevin 30 micrograms/150 micrograms film-coated tablets

Active substances: ethinylestradiol and levonorgestrel

Read all of this leaflet carefully *before* you start taking the tablets

- 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 personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If one of the listed side-effects seriously affects you, or if you experience undesirable effects not listed in this leaflet, please notify your physician or pharmacist.

The product will be referred to as Elevin Tablets throughout the leaflet.

In this leaflet:

1. What Elevin Tablets are and what they are used for
2. Before you take Elevin Tablets
3. How to take Elevin Tablets
4. What are the possible side-effects?
5. How to store Elevin Tablets
6. Further 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. BEFORE YOU TAKE ELEVIN TABLETS

General Notes

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 intercourse or you should take extra non-hormonal contraceptive precautions, e.g., use a condom or another barrier method. Do not use rhythm or temperature methods. These methods can be unreliable because 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.

DO NOT TAKE ELEVIN TABLETS

Do not take Elevin tablets if you have or have had:

- a **blood clot** (thrombosis) in a blood vessel of the leg, lung (embolus) or other organs
- a **heart attack or stroke**
- a disease that can be a **predictor of a heart attack** (for example, angina pectoris, which causes severe pain in the chest) or **of a stroke** (for example, a transient stroke with no residual effects).
- a disease that may increase the risk of a **thrombosis** in the arteries. This applies to the following diseases:
 - Diabetes with damaged blood vessels
 - Very high blood pressure
 - A very high level of fat in the blood (cholesterol or triglycerides)
- a **disturbance of blood clotting** (for example, protein C deficiency)
- a certain form of **migraine** (with so-called focal neurological symptoms)
- an **inflammation of the pancreas** (pancreatitis)
- **liver disease** and your liver function is still not normal
- a **tumour in the liver**
- or if you are suspected as having **breast cancer or cancer of the genital organs**
- any **unexplained bleeding from the vagina**

Do not take this medicine if you are **allergic** (hypersensitive) to ethinylestradiol or levonorgestrel, or any of the other ingredients of Elevin Tablets. This can be recognised by itching, rash, or swelling.

TAKE SPECIAL CARE WITH ELEVIN TABLETS

If any of the following conditions applies to you, **you must inform your doctor** before starting to use Elevin Tablets. You must also consult your doctor if **any of the following conditions develops or worsens** during the use of Elevin Tablets. If you have:

- A **close relative** who has or has had **breast cancer**
- A **disease of the liver or gallbladder**
- **Diabetes**
- **Depression**
- **Crohn's disease or ulcerative colitis** (inflammatory bowel disease)
- **Haemolytic uraemic syndrome** (a blood disease that causes kidney damage)
- **Sickle cell anaemia** (an inherited disease of the red blood cells)
- **Epilepsy** (see "Taking other medicines")
- **Systemic Lupus Erythematosus** (a disease of the immune system)
- A **disease** that first **appeared during pregnancy** or earlier use of **sex hormones** (for example, **hearing loss, porphyria** (a disease of the blood), **gestational herpes** (skin rash with vesicles during pregnancy), **Sydenham's chorea** (a disease of the nerves in which sudden movements of the body occur)).
- **Chloasma** (golden brown pigment patches, so called 'pregnancy patches', especially on the face). If this is the case, avoid direct exposure to sunlight or ultraviolet light.
- **Hereditary angioedema**, products containing estrogens may induce or worsen 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.**

ELEVIN TABLETS AND THROMBOSIS

Venous thrombosis

The use of any combination pill, including Elevin Tablets, increases a woman's risk of developing a **venous thrombosis** (formation of a blood clot in vessels).

The risk of venous thrombosis in users of combined pills increases:

- With **increasing age**
- If you are **overweight**
- If one of your **close relatives** has had a **blood clot** (thrombosis) in the leg, lung, or other organ at a young age
- If you must have an **operation** (surgery), any prolonged period of **immobilisation**, or if you have had a serious accident. It is important to tell your doctor in advance that you are using Elevin Tablets as the treatment may have to be stopped. Your doctor will tell you when to start Elevin Tablets again. This is usually about two weeks after you are back on your feet.

Arterial thrombosis

The use of combination pills has been connected with an increase of the risk of arterial thrombosis (obstruction of an artery), for example, in the blood vessels of the heart (heart attack) or the brain (stroke).

The risk of arterial thrombosis in users of combined pills increases if you:

- **Smoke. You are strongly advised to stop smoking when you use Elevin Tablets, especially if you are older than 35 years**
- Have an **increased fat content in your blood** (cholesterol or triglycerides)
- Have **high blood pressure**
- Have **migraine**
- Have a **problem with your heart** (valve disorder, a disturbance of the heart rhythm)

STOP TAKING Elevin Tablets and contact your doctor immediately if you notice possible signs of thrombosis, such as;

- **Severe pain** and/or **swelling** in one of your legs
- **Sudden severe pain in the chest** which may reach the left arm
- Sudden **breathlessness**
- Sudden **cough** without an obvious cause
- Any unusual, severe or long-lasting **headache or worsening of migraine**
- **Partial or complete blindness** or double vision
- Difficulty in speaking or inability to speak
- **Giddiness or fainting**
- Weakness, strange feeling, or numbness in any part of the body

Elevin tablets and cancer

Breast cancer has been observed slightly more often in women using combined 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 you must 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.

TAKING OTHER MEDICINES

Elevin Tablets and taking other medicines

Always tell your doctor which medicines or herbal products you are already using. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long.

Some medicines can make Elevin Tablets 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**).
- Tuberculosis (e.g., **rifampicin**).
- HIV infections (**ritonavir, nevirapine**) or other infections (**antibiotics** such as **griseofulvin, penicillin, tetracycline**).
- 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).

Ask your doctor or pharmacist for advice before taking any medicine

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

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.

Ask your doctor or pharmacist for advice before taking any medicine

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.

Ask your doctor or pharmacist for advice before taking any medicine

Driving and using machines

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

Important information about some of the ingredients of Elevin Tablets

Elevin Tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, you should talk to your doctor before taking Elevin Tablets.

3. HOW TO TAKE ELEVIN TABLETS

Take one 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. **Take all 21 tablets.**

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 the gap week.

On the 8th day after the last Elevin Tablet (that is, after the 7 day gap week), start the following strip, even if the bleeding has not stopped. This means that you should start the following 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 during the 7 days that you are not taking a tablet.

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.

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 menstruation). If you start Elevin Tablets on the first day of your menstruation 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 combined oral contraceptive, or combined contraceptive vaginal ring or patch.

You can start Elevin tablets preferably on the day after the last active tablet (the last tablet containing the active substances) of your previous pill, but at the latest on the day after the tablet-free days of your previous pill finish (or after the last inactive tablet of your previous pill). When changing from a combined 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-releasing IUD)

You may switch any day from the progestogen-only pill (from an implant or the IUD on the day of its removal, from an injectable when the next injection would be due) but in all of

these cases you must 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.

After having a baby

After having a baby, you can start Elevation Tablets between 21 and 28 days later. If you start later than day 28, you must use a so-called barrier method (for example a condom) during the first 7 days of Elevation tablets use. If, after having a baby, you have had intercourse before starting Elevation tablets (again), you must first be sure that you are not pregnant or you must wait until the next menstrual bleed.

Let your doctor advise you if you are not sure when to start

If you are breastfeeding and want to start Elevation Tablets (again) after having a baby

Read the section on "Breast feeding"

If you take more Elevation Tablets than you should

There are no reports of serious harmful effects of taking too many Elevation Tablets.

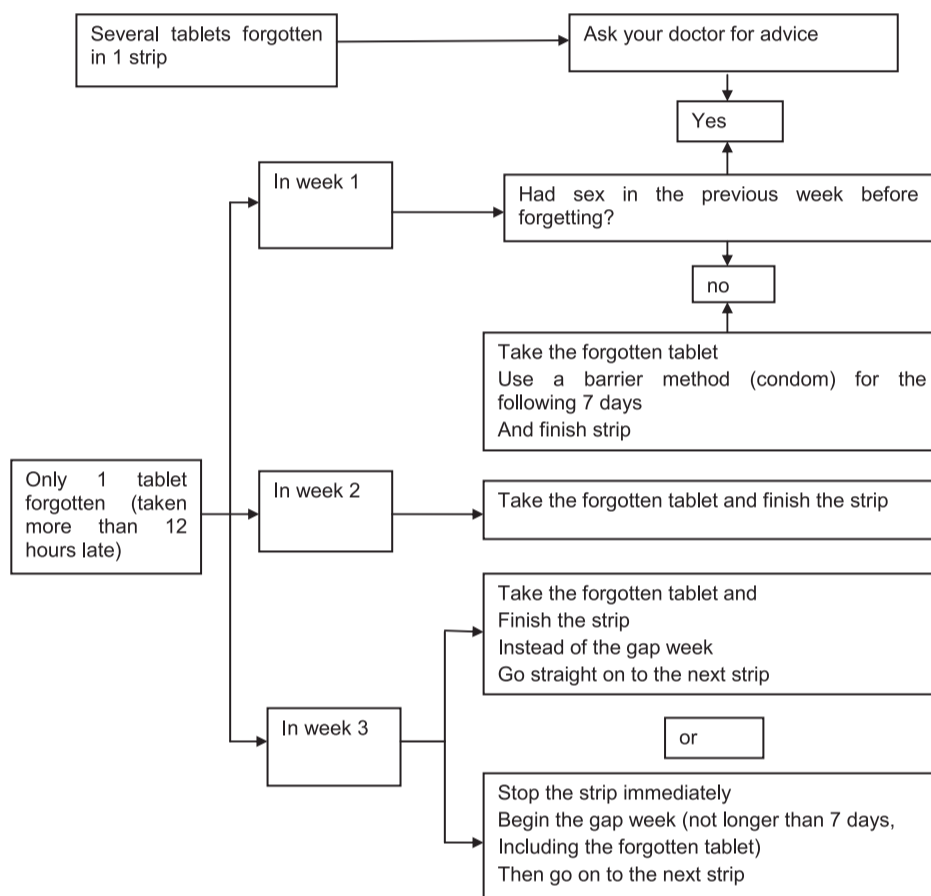
If you take several tablets at once then you may have symptoms of nausea or vomiting. Young girls may have bleeding from the vagina

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

If you forget to take Elevation Tablets

If you are less than 12 hours late taking a tablet, the protection from pregnancy is not reduced. Take the tablet as soon as you remember and then take the following tablets at the usual time.

If you are more than 12 hours late taking a tablet, the protection from pregnancy may be reduced. The greater the number of tablets that you have forgotten, the greater is the risk that the protection from pregnancy is reduced. The risk of incomplete protection against pregnancy is greatest if you forget a tablet at the beginning or the end of



What you must do in the case of vomiting or severe diarrhoea

If you vomit within 3-4 hours of taking a tablet or you have severe diarrhoea, there is a risk that the active substances in the pill are not fully absorbed into your body. The situation is similar to if you forget a tablet. After vomiting or diarrhoea, you must 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 this is not possible or 12 hours have passed, you should follow the advice given under "if you forget to take Elevation Tablets".

Delay of menstrual period:

Even if not recommended, delay of your menstrual period (withdrawal bleed) is possible by going straight on to a new strip of Elevation Tablets instead of the tablet-free period, to the end of the second strip. You may experience spotting (drops or flecks of blood) or breakthrough bleeding while using the second strip. After the usual tablet-free period of 7 days, continue with the following strip.

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

Change of the first day of your menstrual period:

If you take the tablets according to the instructions, then your menstrual period/withdrawal bleed will begin in the tablet-free week. If you have to change this day, you do this by making the tablet-free period shorter (but never longer!) For example, if your tablet-free period begins on a Friday, and you want to change this to a Tuesday (3 days earlier) you must start a new strip 3 days earlier than usual. If you make the tablet-free period very short (for example 3 days or less) then it may be that you do not have any bleeding during this tablet-free period. You may then experience spotting (droplets or flecks of blood) or breakthrough bleeding.

If you are not sure what to do, contact your doctor for advice

If you want to stop taking Elevation Tablets

You can stop taking Elevation 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 have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE-EFFECTS

Like all medicines, Elevation Tablets can cause side-effects although not everybody gets them.

The following frequency information is used for evaluating side-effects:

very common: affects more than 1 user in 10
common: affects 1 to 10 users in 100
uncommon: affects 1 to 10 users in 1,000
rare: affects 1 to 10 users in 10,000
very rare: affects less than 1 user in 10,000
not known: frequency cannot be estimated from the available data

Contact your doctor immediately if you experience any of the following symptoms as they may be signs of an allergic reaction:

- Swelling of the face, lips, mouth, tongue or throat
- Difficulty breathing
- Severe skin rashes

Other side effects

Very common: affects more than 1 user in 10

- Headaches (including migraine)
- Spotting and intra-cyclic menstrual bleeding

Common: affects 1 to 10 users in 100

- Inflammation of the vagina including fungal infection (candidiasis)
- Mood shifts including depression, changes in sex drive (libido)
- Nervousness
- Dizziness
- Nausea
- Vomiting
- Abdominal pain
- Acne
- Breast pain
- Sensitivity of the breasts, enlargement of the breasts
- Mammary gland secretion
- Period pain (Dysmenorrhoea)
- Changes in menstrual blood flow, this may mean no menstrual bleeding (Amenorrhoea)
- Changes on the cervix and cervical secretion
- Changes in weight (increase or decrease)
- Fluid retention

the strip. Therefore, you should follow the rules given below:

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. If you have had intercourse in the week before you forgot to take the tablet or you have forgotten to start a new strip after the tablet-free period, you must realise that there is a risk of pregnancy. In that case, contact your doctor.

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. Take the tablets again at the usual time. The protection from pregnancy is not reduced, and you do not need to take extra precautions.

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. Take the tablets again at the usual time. Instead of the tablet-free period go straight on to the next strip. Most likely, you will have a period (withdrawal bleed) at the end of the second strip but you may also have spotting or breakthrough bleeding during the second strip.
- 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 your fixed start day, 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, this may mean that you are pregnant. **You must contact your doctor before you go on to the next strip.**

Uncommon: affects 1 to 10 users in 1,000

- Changes in appetite (increase or decrease)
- Abdominal cramps and bloating
- Rash
- Skin discolouration (Chloasma)
- Excessive growth of body hair (Hirsutism)
- Hair loss (Alopecia)
- Increased blood pressure
- Changes in blood lipid levels (hyper-triglyceridaemia)

Rare: affects 1 to 10 users in 10,000

- Glucose intolerance
- Incompatibility with contact lenses
- Yellowing of the skin and eyes (Cholestatic jaundice)
- Tender red nodules or lumps on the skin (Erythema nodosum)

Very rare: affects less than 1 user in 10,000

- Urticaria
- Severe skin reaction with multiple skin lesions, including blisters, often with fever, itching and joint pain (Erythema multiforme)
- Hepatocellular carcinoma
- Benign liver tumours

Not known: frequency cannot be estimated from the available data

- Worsening of Systemic lupus erythematosus (a severe skin condition with joint pain, fever and tiredness)
- Herpes gestationis blistering skin disorder seen during pregnancy
- Worsening of chorea minor a movement disorder
- Optic nerve inflammation
- Abdominal pain with blood in the stools (Ischemic colitis)
- Worsening of Crohn's disease and ulcerative colitis
- Pancreatitis with simultaneous serious hypertriglyceridaemia
- Gall bladder disease including gall stones
- Worsening of varicose veins
- Haemolytic-uremic syndrome a syndrome of haemolytic anaemia, thrombocytopenia and acute renal failure
- Otosclerosis abnormal bone growth in the middle ear
- Worsening of porphyria

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.

5. HOW TO STORE ELEVATION TABLETS

Keep all medicines out of the reach and sight of children.

The expiry date is printed on the pack. Do not use Elevation Tablets after the expiry date which is stated on the outer packaging and on the foil strip/blister pack "after "Exp". The expiry date refers to the last day of that month. Do not store above 25°C

6. FURTHER INFORMATION

What Elevation Tablets contain:

Active substances are:

Each (a "Pill") contains 30 microgram ethinylestradiol and 150 microgram levonorgestrel.

Other ingredients (excipients) are:

Tablet core: lactose monohydrate, maize starch, gelatine, magnesium stearate
Tablet coating: hypromellose (3 cps), Macrogol 4000, titanium dioxide (E171), iron oxide yellow (E172)

What Elevation Tablets looks like and contents of the pack
Elevation Tablets are brownish, round convex, film-coated tablets

Elevation Tablets are available in packages 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

Marketing Authorisation holder

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Manufacturer

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