

[illegible]

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

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

### What is the risk of developing a blood clot?

- 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 Elevein 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

- if you are very overweight (body mass index or BMI over 30kg/m<sup>2</sup>);
- if one of your immediate family had a blood clot in the leg, lung or other organ at a young age (e.g. before the age of about 50);
- if you 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.
- if you get older (particularly above about 35 years);
- if you have birth less than a few weeks ago

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.

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

## Factors that increase your risk of a blood clot in an artery

- **if you smoke.** When using a combined hormonal contraceptive like **Ellevin 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.

## **Elin 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.

### What to do if no bleeding occurs in the gap week


## Psychiatric disorders

## Other medicines and Elevin Tablets

Do not use Evrin 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 products.

Evin Tablets can be restarted approximately 2 weeks after completion of this treatment. See section "Do not take Evin Tablets".



<div><div><div><div><div><div></div><div>Artwerk</div></div></div><div><div>creative designs</div><div>Artwerk at apolito</div></div></div><div><div>e-mail: <a href="mailto:artwerkcd@gmail.com">artwerkcd@gmail.com</a></div><div><a href="mailto:press@cd@gmail.com">press@cd@gmail.com</a></div><div>Ph: +49-864515616</div></div></div></div>		Colours Used	<div><div><div></div></div><div>Black</div></div>
			<div><div><div></div></div><div>Keyline</div></div>
Artwork No.	1502017/1		
Customer	Calisto		
Description	Elevin 30 micrograms /150 micrograms Leaflet		
Market	UK		
Language	English		
Dimensions	500 x 460 mm		
Min. Font Size	8 pt		
Version No.	11		
Date	10-10-22		



AUßENSEITE



AUßENSEITE

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

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

If you have been told by your doctor that you have an intolerance 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 pharmacist if you are not sure.

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 the gap week.

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 patch*  
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-releasing IUD)*  
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.

- *After having a baby*  
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 pharmacist for advice.

#### 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

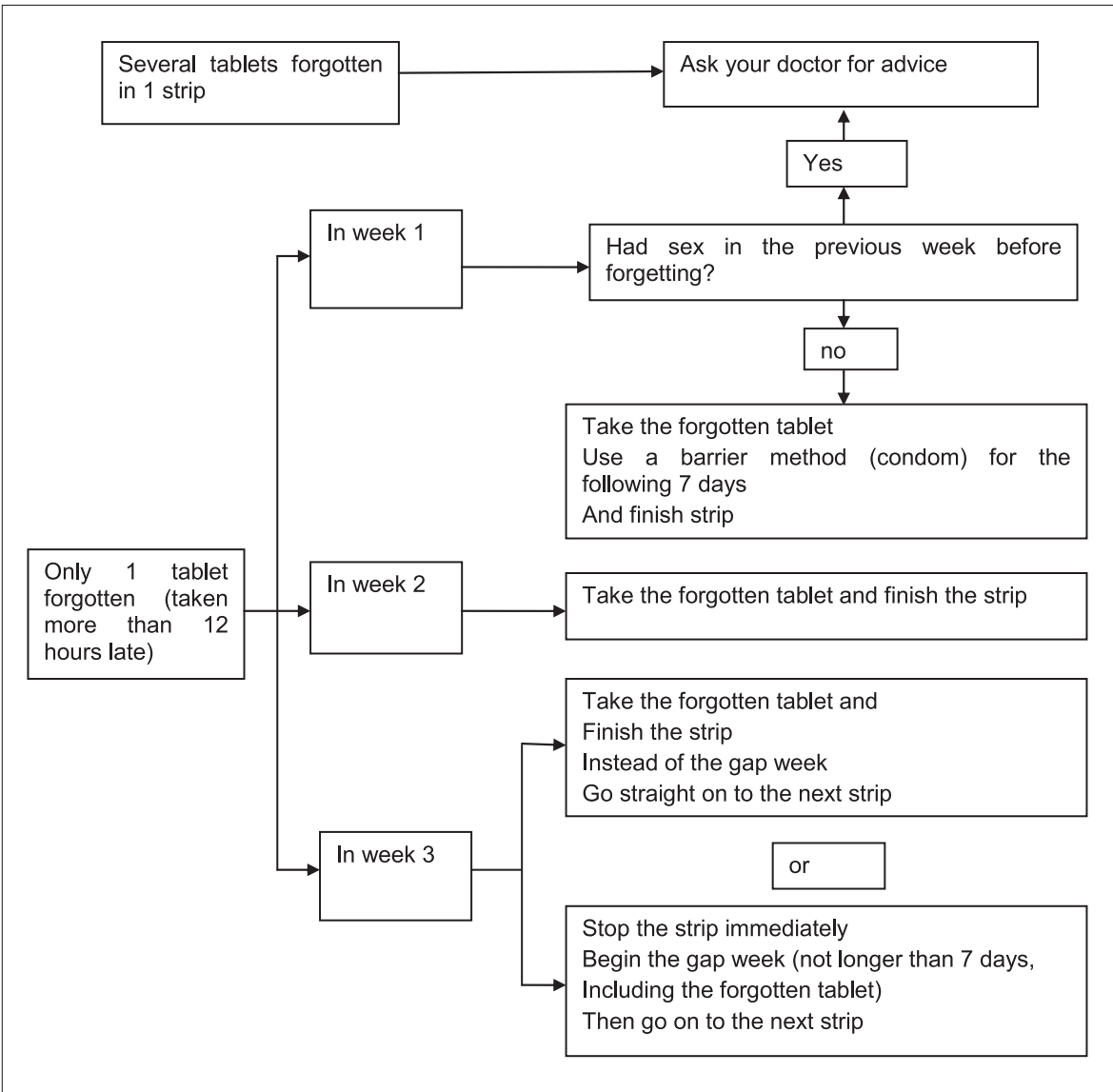
You can choose between two possibilities:

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. 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)
- acne
- 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

#### Uncommon (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:

#### 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 (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 occur)
- 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)
- 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](http://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 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. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

### 6. 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 3 x 21 film-coated tablets

Calendar pack with 12 x 21 film-coated tablets

100 x 21 film-coated tablets (hospital pack)

Not all pack sizes may be marketed.

#### Marketing Authorisation holder

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

#### Manufacturer

Pharbit Walthrop GmbH, Im Wirrigen 25, 45731 Walthrop, Germany, Telefon: +49(2309) 93750 Telefax: +49(2309) 9375313

This leaflet was last revised in 10/2022.