PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

YAZ® PLUS 3mg/0,02 mg/0,451 mg film-coated tablets
Drospirenone/Ethinylestradiol (as betadex clathrate)/Levomefolate calcium
Contains sugar (lactose)

Read all of this leaflet carefully before you start taking YAZ PLUS.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- YAZ PLUS has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1 What YAZ PLUS is and what it is used for
2 What you need to know before you take YAZ PLUS
3 How to take YAZ PLUS
4 Possible side effects
5 How to store YAZ PLUS
6 Contents of the pack and other information

1. What YAZ PLUS is what it is used for

- YAZ PLUS is used to prevent pregnancy and to improve the folate status in women who decide to use oral contraception.
- YAZ PLUS is used for the treatment of moderate acne vulgaris in women seeking oral contraception.
- YAZ PLUS is also used for the treatment of symptoms of premenstrual dysphoric disorder (PMDD) in women who have chosen oral contraceptive as their method of birth control. The efficacy of YAZ PLUS for PMDD was not assessed beyond 3 cycles.

Each of the 24 pink film-coated tablets contains a small amount of the female hormones ethinylestradiol and drospirenone and the vitamin levomefolate calcium (which is also contained in the 4 light orange hormone-free film-coated tablets).

Contraceptive pills that contain two hormones are called ‘combined pills’ or ‘combined oral contraceptives’.

2. What you need to know before you take YAZ PLUS

General notes

In this leaflet, several situations are described where you should stop using YAZ PLUS, or where the reliability of YAZ PLUS may be decreased. In such situations you should either not have sexual intercourse or you should take extra non-hormonal contraceptive precautions, e.g. use a condom or another barrier method. Do not use rhythm or temperature methods. These methods can be unreliable because YAZ PLUS alters the monthly changes of body temperature and cervical mucus.

YAZ PLUS does not protect against HIV infection (AIDS) or any other sexually transmitted infections (STI). Additional barrier contraceptive measures are needed to prevent transmission of

STIs and HIV.

Do not take YAZ PLUS

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

- if you are **allergic** (hypersensitive) to ethinylestradiol, drospirenone, levomefolate calcium or any of the other ingredients in YAZ PLUS (listed in section 6). This may cause, for example, itching, rash or swelling
- if you have (or have ever had) a **blood clot** in a blood vessel of the leg (thrombosis), of the lung (pulmonary embolism) or other parts of the body
- if you have (or have ever had) a **heart attack** or **stroke** (caused by a blood clot or a rupture of a blood vessel in the brain)
- if you have (or have ever had) a **disease that can be an indicator (i) of a future heart attack** (for example, angina pectoris which causes severe chest pain which may spread to the left arm) **or (ii) of a stroke** (for example, a minor stroke with no residual effects, a so-called transient ischaemic attack)
- if you have a high risk of venous or arterial blood clots (see "YAZ PLUS and blood clots" and consult your doctor who will decide whether you may use the Pill)
- if you have (or have ever had) a certain kind of **migraine** accompanied by e.g. visual symptoms, speech disability, or weakness or numbness in any part of your body
- if you have diabetes mellitus with damaged blood vessels
- if you have (or have ever had) **liver disease** (symptoms of which may be yellowing of the skin or itching over the whole body) and your liver is still not working normally
- if you are taking any antiviral medicines which contain ombitasvir, paritaprevir, or dasabuvir, and combinations of these. These antiviral medicines are used to treat chronic (long-term) hepatitis C (an infectious disease that affects the liver, caused by the hepatatis C virus).
- if you have (or have ever had) a **cancer** that may grow under the influence of sex hormones (e.g. **of the breast or the genital organs**)
- if you have a severe kidney insufficiency or acute kidney failure
- if you have (or have ever had) a benign or malignant **tumour of the liver**
- if you have any **unexplained bleeding from the vagina**
- if you are pregnant or think you might be pregnant

Warnings and precautions

In some situations you need to take special care while taking YAZ PLUS or any other combined pill, and your doctor may need to examine you regularly. Consult your doctor before starting to use YAZ PLUS if any of the following conditions apply to you or if any of them develop or worsen while you are taking YAZ PLUS**:**

- if you smoke
- if you have diabetes
- if you are overweight
- if you have high blood pressure
- if you have a heart valve disorder or a certain heart rhythm disorder
- if you have an inflammation of your veins (superficial phlebitis)
- if you have varicose veins
- if anyone in your immediate family has ever had a blood clot (thrombosis in the leg, lung 'pulmonary embolism', or elsewhere), a heart attack or a stroke at a young age
- if you suffer from migraine
- if you have epilepsy
- if you have an increased potassium blood level (e.g. due to problems with your kidneys) and also use diuretics that may increase the potassium in your blood (ask your doctor if you're not sure)

- if you or someone in your immediate family has ever had high blood levels of cholesterol or triglycerides (fatty substances)
- if a close relative has or has ever had breast cancer
- if you have a disease of the liver or gall bladder
- if you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- if you have systemic lupus erythematosus (or SLE, a disease of the immune system)
- if you have haemolytic uremic syndrome (or 'HUS', a disorder of blood coagulation causing failure of the kidneys)
- if you have sickle cell disease
- if you have a condition that occurred for the first time or worsened during pregnancy or previous use of sex hormones (e.g. hearing loss, a metabolic disease called porphyria, a skin disease called herpes gestationis, or a neurological disease called Sydenham's chorea)
- if you have (or have ever had) golden brown pigment patches so-called 'pregnancy patches' especially on the face (chloasma). If this is the case, avoid direct exposure to sunlight or ultraviolet light
- if you suffer from vitamin B12 deficiency (for example due to a reduced B12 diet such as a strict vegetarian diet, due to a history of gastrointestinal surgery or certain types of gastritis) tell your doctor that you use YAZ PLUS because folates may hide vitamin B12 deficiency
- if you have hereditary angioedema. Consult your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue or throat, and/or difficulty swallowing, or hives, together with difficulty breathing. Products containing estrogens may induce or worsen symptoms of angioedema

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

<u>YAZ PLUS and depression</u>
Some women using hormonal contraceptives including YAZ PLUS have reported depression or 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.

YAZ PLUS and blood clots (thrombosis)

A thrombosis is the formation of a blood clot which may block a blood vessel.

A thrombosis sometimes occurs in the deep veins of the legs (deep venous thrombosis). If a blood clot breaks away from the vein where it has formed, it may reach and block the arteries of the lungs, causing a so-called 'pulmonary embolism'. Blood clots can also occur very rarely in the blood vessels of the heart (causing a heart attack). Blood clots or a ruptured blood vessel in the brain may cause a stroke.

The risk of venous thromboembolism is highest during the first year of use. This increased risk is present after initially starting the combined pill or restarting (following a 4 week or greater pill free interval) the same or a different combined pill. Data from a large study suggest that this increased risk is mainly present during the first 3 months.

Overall the risk for venous thromboembolism in users of low estrogen dose pills is two to threefold higher than for non-users of combined oral contraceptives (COCs) who are not pregnant. Venous or arterial thromboembolic events may cause serious permanent disabilities, may be life-threatening, or may even be fatal. Blood clots can occur in other parts of the body including the liver, gut, kidney, brain or eye.

Stop taking the pill and contact a doctor immediately if you notice signs of:

Deep venous thrombosis, such as: swelling of one leg or along a vein in the leg, pain or tenderness in the leg *which may be felt only when standing or walking,* increased *warmth in the affected leg, red or discoloured skin on the leg.*

Pulmonary embolism, such as: sudden onset of unexplained shortness of breath or rapid breathing, sudden coughing *which may bring up blood,* sharp chest pain *which may increase with deep breathing, sense of anxiety,* severe light-headedness or dizziness, *rapid or irregular heartbeat.* Some of these symptoms (e.g. "shortness of breath", "coughing") are non-specific and be misinterpreted as more common or less severe events (e.g. respiratory tract infection).

Arterial thromboembolism (arterial blood vessels blocked by blood clots and such blood clots which have broken away)

- **Stroke** such as: sudden numbness or weakness 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.
- **Blood clots blocking other arterial blood vessels,** such as: *sudden pain, swelling and slight blue discolouration of an extremity,* "acute" abdomen.
- **Heart attack** such as pain, *discomfort, pressure, heaviness, sensation of squeezing or fullness* in the chest, arm, or below the breastbone; discomfort radiating to the back, *jaw, throat, arm, stomach, fullness, indigestion or choking feeling; sweating, nausea, vomiting* or dizziness; extreme weakness, *anxiety,* or shortness of breath; *rapid or irregular heartbeats.*

Your doctor will check, e.g. whether you have a higher risk of getting a thrombosis due to a combination of risk factors or perhaps one very strong risk factor. In the case of a combination of factors the risk may be higher than simply adding two individual risks. If the risk is too high, your doctor will not prescribe the Pill. (see also 'Do not take YAZ PLUS').

The risk of venous or arterial blood clots (e.g. deep venous thrombosis, pulmonary embolism, heart attack) or stroke increases:

- with <u>older</u> age
- if you are overweight
- if anyone in your immediate family has ever had a blood clot (thrombosis in the leg, lung 'pulmonary embolism', or elsewhere), a heart attack or a stroke at a young age, or if you or any of your relatives are known or suspected of having a hereditary blood clotting disorder increasing your risk for developing blood clots
- with prolonged immobilisation (for example, when you have your leg or legs in plaster or splints), major surgery, any surgery to the legs, or major trauma. In these situations it is better to stop taking the YAZ PLUS (if the surgery is planned you should stop at least four weeks beforehand) and not to start again until two weeks after you are fully on your feet again
- if you smoke (the risk increases the more you smoke and the older you get, especially in women over 35 years of age). **When using YAZ PLUS you should stop smoking, especially if you are older than about 35 years of age.**
- if you or someone in your immediate family has or has ever had high blood levels of cholesterol or triglycerides (fatty substances)
- if you have high blood pressure . **If you develop high blood pressure while using YAZ PLUS, you may be told to stop using it.**
- if you suffer from migraine
- if you have a heart valve disorder or a certain heart rhythm disorder

Directly after giving birth, women are at an increased risk of blood clots so you should ask your doctor how soon after delivery you can start taking YAZ PLUS.

YAZ PLUS and cancer

Breast cancer has been observed slightly more often in women using combined contraceptive pills. The risk of breast tumours becomes gradually less after stopping the combined hormonal contraceptive. It is important to regularly check your breasts and you should contact your doctor if you feel any lump.

Benign liver tumours, and **malignant liver tumours** have been reported. These tumours have led to life-threatening internal bleeding. Contact your doctor if you have unusually severe abdominal pain.

The most important risk factor for cervical cancer is persistent Human Papilloma Virus (HPV) infection. Studies suggest that long-term use of the pill increases a woman's risk of developing **cervical cancer**.

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

Bleeding between periods

For the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding) between your periods. Continue to take your tablets as normal. Irregular vaginal bleeding usually stops once your body has adjusted to YAZ PLUS (usually after about 3 tablet-taking cycles). If it continues, becomes heavy or starts again, tell your doctor.

What to do if no bleeding occurs

If you have taken all the tablets correctly, have not had any vomiting or severe diarrhoea and you have not taken any other medicines, it is highly unlikely that you are pregnant. Continue to take YAZ PLUS as usual.

If you have taken the tablets incorrectly, or, if you have taken the tablets correctly but the expected bleeding does not happen twice in a row, you may be pregnant. Contact your doctor immediately. Do not start the next pack until you are sure that you are not pregnant.

Other medicines and YAZ PLUS

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of YAZ PLUS with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

Some medicines can have an influence on the blood levels of YAZ PLUS and can make it **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, topiramate, felbamate);
  - tuberculosis (e.g. rifampicin);
  - HIV and Hepatitis C Virus infections (so called protease inhibitors and non-nucleoside reverse transcriptase inhibitors) (e.g. ritonavir, nevirapine);
  - fungal infections (griseofulvin, azole antifungals, e.g. itraconazole, voriconazole, fluconazole, ketoconazole);
  - bacterial infections (macrolide antibiotics, e.g. clarithromycin, erythromycin);
  - certain heart diseases, high blood pressure (calcium channel blockers, e.g. verapamil, diltiazem;
  - arthritis, arthrosis (etoricoxib)
- the herbal remedy St. John's wort
- grapefruit juice

The efficacy of levomefolate calcium in YAZ PLUS **can be diminished** by:

- medicines containing methotrexate, trimethoprim, sulphasalazine, triamterene, cholestyramine, or by antiepileptics such as carbamazepine, phenytoin, phenobarbital, primidone or valproic acid.

YAZ PLUS may **influence the effect** of other medicines, e.g.

- anti-epileptics such as lamotrigine and phenytoin;
- ciclosporin;
- melatonin
- midazolam
- theophylline
- tizanidine
- methotrexate or pyrimethamine.

In theory your potassium levels may increase if you are taking YAZ PLUS with other medicines that can also increase potassium levels.

Laboratory tests

If you need a blood test or other laboratory tests 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 breastfeeding

Do not take YAZ PLUS if you are pregnant, or, if you think you may be pregnant. If you become pregnant while taking YAZ PLUS, stop taking it immediately and contact your doctor. If you want to become pregnant, you can stop taking YAZ PLUS at any time (see also "If you stop taking YAZ PLUS"). If you stop YAZ PLUS in order to become pregnant you should consider to continue to take folate supplements.

YAZ PLUS should not be used during breastfeeding or before the breastfeeding mother has completely weaned her child.

If you are pregnant or breastfeeding, think you may be pregnant or planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machinery

No studies on the effects of the ability to drive and use machines have been performed.

YAZ PLUS contains lactose

Each pink film-coated tablet of YAz PLUS contains 45 mg lactose per tablet and each light orange film-coated tablet contains 48 mg lactose per tablet. If you are intolerant to some types of sugar contact your doctor before taking YAZ PLUS.

3. How to take YAZ PLUS

Do not share medicines prescribed for you with others.

Always take YAZ PLUS exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The YAZ PLUS pack contains 28 tablets. Take your tablet at about the same time each day, with some liquid if necessary. Follow the direction of the arrows until all 28 tablets have been taken. Usually a period will start on day 2 to 3 after the last hormone-containing pink YAZ PLUS tablet (i.e. while you are taking the last 4 hormone-free light orange tablets). Do not leave a gap between packs,

i.e. start taking your next pack on the day after you have finished the current one, even if your period continues. This means that you will always start new packs on the same day of the week, and also that you have your withdrawal bleed on about the same days every month.

When taken correctly, combined oral contraceptives, have a failure rate of approximately 1 % per year. The failure rate may increase when pills are missed or taken incorrectly.

When can you start with the first pack?

If you have not used a contraceptive with hormones during the previous month:

Start taking YAZ PLUS on the first day of the cycle (that is, the first day of your period). Then follow the days in order. YAZ PLUS will work immediately, it is not necessary to use an additional contraceptive method.

If you take more YAZ PLUS than you should

There are no reports of serious harmful effects of taking too many YAZ PLUS tablets.
If you take several hormone-containing tablets at once, you may feel sick or vomit or may bleed from the vagina. Even girls who have not yet started to menstruate may experience such bleeding.

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

If you forget to take YAZ PLUS

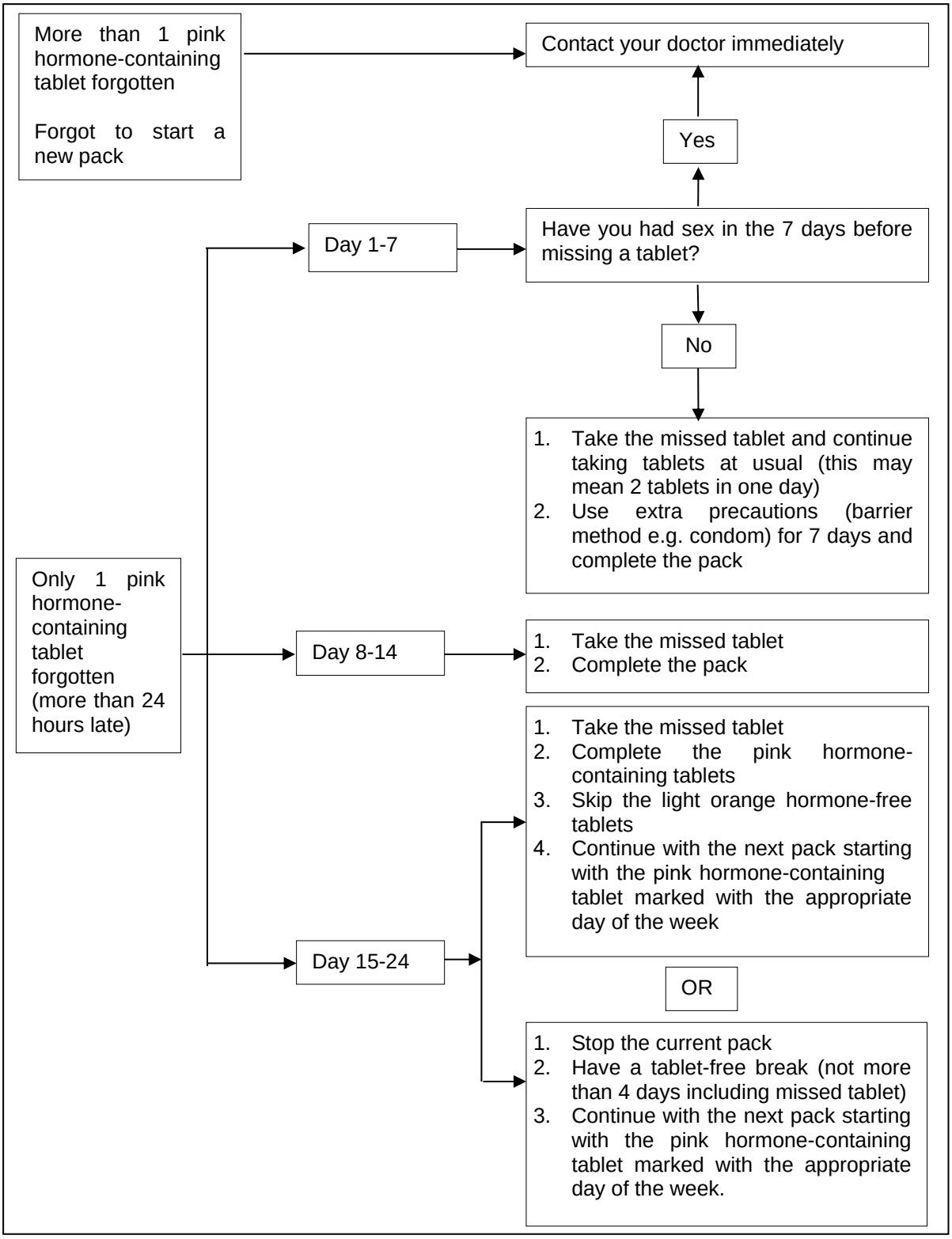
Depending on the day of the cycle on which **one** tablet has been missed, you may need to take **additional contraceptive precautions,** for example a barrier method such as a condom. **Take the tablets according to the following principles**. **See also the 'missed pill chart' for details. In case of doubt, contact your doctor.**

- If you forgot to take any of the 4 hormone-free light orange film-coated tablets **(the last 4 tablets in the blister)**, you are still protected against pregnancy because they do not contain any hormones. However, to make sure that you do not change your pill taking rhythm, which is important for the contraceptive reliability of your Pill, you should proceed with your next tablet at the normal time and discard the forgotten hormone-free light orange film-coated tablet(s) to avoid any confusion. If you forgot the last hormone-free light orange tablet of your current pack it is important that you still take the first tablet from the next pack at the correct time.

The following advice refers to the pink tablets (those containing hormones) **(tablets 1-24 of your blister)**:

- If you are **less than 24 hours** late when taking a tablet, the protection against pregnancy is not reduced. Take the tablet as soon as you remember and then continue taking the tablets again at the usual time.
- If you are **more than 24 hours** late in taking any of pink tablets your protection against pregnancy may be reduced. The more pink tablets you have forgotten, the greater the risk that the protection from pregnancy is reduced. There is a particularly high risk of becoming pregnant if you miss tablets at the beginning of the pack or at the end (the last of the 24 pink tablets). Therefore, you should follow the rules given below (see also the diagram below).
- **More than one tablet forgotten in a pack** Contact your doctor.

Missed pill chart



What to do if you vomit or have severe diarrhoea

If you vomit or have severe diarrhoea after taking any of the pink tablets, the active ingredients in that tablet may not have been completely absorbed. If you vomit within 3 to 4 hours after taking your tablet, this is like missing a tablet. Therefore, follow the advice under ‘If you forget to take YAZ PLUS‘. If you have severe diarrhoea, please contact your doctor. Vomiting or diarrhoea while taking the 4 hormone-free light orange film-coated tablets at the end of your blister does not have an influence on the contraceptive reliability.

If you stop taking YAZ PLUS

You can stop taking YAZ PLUS at any time. 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 YAZ PLUS and wait for a menstrual period before starting to try to become pregnant.

4. Possible side effects

YAZ PLUS can have side effects.

Not all side effects reported for YAZ PLUS are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Tell your doctor if you notice any side effect, especially if severe or persistent, or if there is a change in your health that you think might be caused by the Pill.

Serious side effects

See also section "Warnings and precautions", "YAZ PLUS and blood clots" and "YAZ PLUS and cancer" for side effects, including serious reactions, associated with the use of YAZ PLUS. Please read these sections carefully and consult your doctor at once where appropriate.

The following side effects were reported in studies with Yaz or with Yaz Plus:

Frequent side effects
- Emotional lability (mood swings), depression/depressive mood
- Migraine
- Nausea
- Breast pain, unscheduled uterine bleeding (bleeding between periods), genital tract bleeding (vaginal bleeding) not further specified

Less frequent side effects
- Decrease and loss of libido (reduced or loss of sex drive)
- Venous and arterial thromboembolic events*

* Estimated frequency, from epidemiological studies encompassing a group of combined oral contraceptives. Frequency was borderline to Very Rare. The term venous and arterial thromboembolic events covers the following: any blockage or clot in a deep peripheral vein, clots which travel through the venous blood system (e.g. to the lung known as pulmonary embolism or as pulmonary infarction), heart attack caused by blood clots, stroke caused by blockage of the blood supply to or in the brain

Side effects that have been reported with the use of the Pill, without knowing their precise frequency: erythema multiforme (a skin condition characterised by itchy red blotches or swollen patches of skin).

Description of selected side effects

Side effects with very low frequency or with delayed onset of symptoms which are considered to be related to the group of combined oral contraceptives are listed below (see also sections 'Do not take YAZ PLUS', 'Warnings and precautions'):

Tumours
- The frequency of diagnosis of breast cancer is very slightly increased among users of oral contraceptives. As breast cancer is rare in women under 40 years of age the excess number is small in relation to the overall risk of breast cancer. It is not known whether there is a direct link to users of combined oral contraceptives.

- liver tumours (benign and malignant)

Other conditions

- erythema nodosum (a skin condition characterised by tender red nodules)
- women with hypertriglyceridaemia (increased blood fats resulting in an increased risk of pancreatitis when using combined oral contraceptives)
- high blood pressure
- occurrence or worsening of conditions for which a link to combined oral contraceptives is not definite: jaundice and/or itching related to cholestasis (blocked bile flow); gallstone formation; a metabolic condition called porphyria; systemic lupus erythematosus (a chronic autoimmune disease); haemolytic uraemic syndrome (a blood clotting disease); a neurological condition called Sydenham's chorea; herpes gestationis (a type of skin condition that occurs during pregnancy); otosclerosis-related hearing loss
- In women with hereditary angioedema (characterised by sudden swelling of e.g. the lips, tongue, eyes, mouth, throat etc.) external estrogens may induce or worsen symptoms of angioedema
- disturbed liver function
- changes in glucose tolerance or effect on peripheral insulin resistance
- Crohn's disease, ulcerative colitis
- chloasma
- hypersensitivity (including symptoms such as rash, urticaria)

Interactions
Unexpected bleeding and/or contraceptive failure may result from interactions of other medicines with YAZ PLUS (e.g. the herbal remedy St. John's wort, or medicines for epilepsy, tuberculosis, HIV and Hepatitis C Virus infections and other infections). See section 'Other medicines and YAZ PLUS'.

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.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of YAZ PLUS.

5. How to store YAZ PLUS

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
Store at or below 30 °C.
Keep the blister strip in the pouch, in the original carton until required for use.
Do not use after expiry date stated on the carton.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What YAZ PLUS contains

24 pink film-coated tablets containing the hormones ethinylestradiol (0,02 mg), drospirenone (3 mg) and the vitamin levomefolate calcium (0,451 mg).
4 light orange hormone free film-coated tablets containing the vitamin levomefolate calcium (0,451 mg).

The other ingredients are: croscarmellose sodium, hydroxypropylcellulose, hypromellose , iron oxide red, iron oxide yellow, lactose monohydrate, macrogol 6000, magnesium stearate, microcrystalline cellulose, talc, titanium dioxide.

What YAZ PLUS looks like and contents of the pack

YAZ PLUS is packed in colourless transparent high barrier PVC/PE.EVOH.PE/PCTFE/aluminium blisters containing 24 pink film-coated hormonal tablets plus 4 light orange hormone-free film-coated tablets per blister strip packed in a hermetic pouch (PET/Al/PE). The pouch is packed into an outer cardboard carton..
Pack sizes: 28 tablets: 1 x (24 + 4) tablets.

The film-coated tablet containing hormones is pink, round, biconvex with one side marked with “Z+” in a regular hexagon, while the other side is blank.
The hormone-free tablet is light orange, round, biconvex with one side marked with “M+” in a regular hexagon, while the other side is blank.

Holder of Certificate of Registration

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