

YAZ® Flex

drospirenone and ethinyloestradiol (as betadex clathrate)

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about YAZ Flex. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking YAZ Flex against the benefits they expect it will have for you.

If you have any concerns, or are unsure about taking this medicine, ask your doctor or pharmacist for more advice.

Keep this leaflet with the medicine. You may need to read it again.

WHAT YAZ FLEX IS USED FOR

YAZ Flex is a combined oral contraceptive, commonly known as a 'birth control pill' or 'the Pill'.

YAZ Flex is used to prevent pregnancy.

It is also used to treat moderate acne in women seeking oral contraception.

You may also experience the following benefits:

- improvement in symptoms like bloating, swelling or weight gain related to fluid retention
- fewer bleeding/spotting days
- a decrease in anaemia (iron deficiency)
- a decrease in period pain.

Some conditions such as pelvic inflammatory disease, ovarian cysts,

ectopic pregnancy (where the foetus is carried outside of your womb, lumpy breasts and cancer of the uterus (womb), and ovaries may be less common in women taking the Pill.

When taken correctly, it prevents you from becoming pregnant in various ways, including:

- inhibiting the egg release by stopping it maturing
- changing the cervical mucus consistency, making it more difficult for the sperm to reach the egg.

When the Pill is taken by women under close observation in clinical trials, it is more than 99% effective in preventing pregnancy. However, in real life the Pill is around 92% effective. This is because pills might be missed, or taken with medicines that may interfere with their effectiveness or may not be absorbed due to vomiting and diarrhoea.

Like all oral contraceptives, YAZ Flex is intended to prevent pregnancy. It does not protect against HIV infection (AIDS) and other sexually transmitted infections.

This means that with YAZ Flex, you may not have a menstrual period every month for up to 4 months. When you start to take YAZ Flex, you must take one tablet daily for 24 days without a tablet free break. This is called the fixed phase.

YAZ Flex allows you to schedule when you want to have your period. You can choose to take a 4 day tablet free break (have your period) during day 25 - 120. This is called the flexible phase.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

BEFORE YOU TAKE YAZ FLEX

When you must not take it

Do not take YAZ Flex if you have an allergy to

- drospirenone and/or ethinyloestradiol, the active ingredients in YAZ Flex
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty in breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take YAZ Flex if you are taking 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 hepatitis C virus).

Do not take YAZ Flex if you have or have had a blood clot in:

- the blood vessels of the legs (deep vein thrombosis - DVT)
- the lungs (pulmonary embolism - PE)
- the heart (heart attack)
- the brain (stroke)

- other parts of the body.

Do not take YAZ Flex if you have or are concerned about or have an increased risk of blood clots.

Blood clots are rare. Very occasionally blood clots may cause serious permanent disabilities, or may even be fatal.

You are more at risk of having a blood clot when you take the Pill. But the risk of having a blood clot when taking the Pill is less than the risk during pregnancy.

Do not take YAZ Flex if you are concerned about an increased risk of blood clots because of age or smoking.

The risk of having a heart attack or stroke increases as you get older. It also increases if you smoke. You should stop smoking when taking the Pill, especially if you are older than 35 years of age.

Do not take YAZ Flex if you have, or have had:

- any blood clotting disorders such as Protein C deficiency, Protein S deficiency, Leiden Factor V mutation, Antithrombin III deficiency or other inherited blood clotting conditions
- a confirmed blood test showing:
 - increased levels of homocysteine
 - antiphospholipid antibodies (APLAs) e.g. anticardiolipin-antibodies and lupus anticoagulant. These may increase your risk for blood clots or pregnancy losses (miscarriage)
- major surgery after which you have not been able to move around for a period of time
- angina (chest pain)
- mini-stroke (also known as TIA or transient ischaemic attack)
- severe kidney insufficiency or an acute failure of your kidney
- migraine, where you have also had problems with seeing, speaking or had weakness or numbness in any part of your body

- high risk of blood clots due to conditions such as diabetes with blood vessel damage, severe high blood pressure or severe high or low level of fats in your blood
- pancreatitis (an inflammation of the pancreas) associated with high levels of fatty substances in your blood
- severe liver disease and your liver function has not returned to normal
- cancer that may grow under the influence of sex hormones (e.g. of the breast or the genital organs)
- a benign or malignant liver tumour
- unexplained vaginal bleeding.

If any of these conditions appear for the first time while using the Pill, stop taking it at once and tell your doctor. In the meantime use non-hormonal (barrier) methods of contraception (such as condoms or a diaphragm).

Do not take this medicine if you are pregnant or think you might be pregnant.

Do not give this medicine to a child.

Do not open the foil containing the cartridge of YAZ Flex tablets until you have a CLYK device and are ready to take your first Pill.

Once opened, the tablets last 40 days, so any unused tablets should be disposed of after this time.

Do not take this medicine after the expiry date printed on the pack and blister.

The expiry date is printed on the carton and on each blister after “EXP” (e.g. 11 18 refers to November 2018). The expiry date refers to the last day of that month. If it has expired return it to your pharmacist for disposal.

Do not take this medicine if the packaging is torn or shows signs of tampering.

If the packaging is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if:

- you smoke
- you or anyone in your immediate family has had blood clots in the legs (DVT) or lungs (PE), a heart attack, a stroke, breast cancer or high cholesterol.

Tell your doctor if you have, or have had any of the following medical conditions:

- depression
- diabetes
- high blood pressure
- heart valve disorders or certain heart rhythm disorders
- migraine
- an increased potassium blood level (e.g. due to problems with your kidney/s) and also use diuretics or other drugs that may increase the potassium in your blood
- cancer
- hyperhomocysteinaemia, a condition characterised by high levels of the amino acid homocysteine in the blood.

Ask your doctor to check if you:

- are overweight
- have any hereditary or acquired conditions that may make it more likely for you to get blood clots
- have high cholesterol or triglycerides
- have liver disease
- have high potassium in your blood
- have jaundice (yellowing of the skin) and/or pruritus (itching of the skin) related to cholestasis (condition in which the flow of bile from the liver stops or slows)
- have gall bladder disease
- have Crohn’s disease or ulcerative colitis (chronic inflammatory bowel disease)
- have systemic lupus erythematosus (SLE – a disease

affecting the skin all over the body)

- have haemolytic uraemic syndrome (HUS— a disorder of blood coagulation causing failure of the kidneys)
- have sickle cell disease
- 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*, a neurological disease called Sydenham's chorea)
- have chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face) - if so, avoid exposure to the sun or ultraviolet radiation
- have hereditary angioedema - you should see your doctor immediately if you experience symptoms of angio-oedema, such as swollen face, tongue and/or pharynx and/or difficulty swallowing, or hives together with difficulty in breathing.

If any of the above conditions appear for the first time, or recur or worsen while taking YAZ Flex, you should tell your doctor.

Tell your doctor if you are breastfeeding.

YAZ Flex is generally not recommended if you are breastfeeding.

YAZ Flex contains lactose.

If you have an intolerance to some sugars, tell your doctor before you start taking YAZ Flex.

If you have not told your doctor about any of the above, tell him/her before you start taking YAZ Flex.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and YAZ Flex may interfere with each other. These include:

- medicines used to treat tuberculosis such as rifampicin, rifabutin
- macrolide antibiotics (e.g. clarithromycin, erythromycin)
- medicines used to treat fungal infections, such as griseofulvin, ketoconazole, itraconazole, voriconazole, fluconazole
- medicines used to treat HIV, such as ritonavir or nevirapine
- some medicines used to treat Hepatitis C Virus (HCV) such as boceprevir, telaprevir
- medicines used to treat epilepsy such as phenytoin, primidone, barbiturates (e.g. phenobarbitone), carbamazepine, oxcarbazepine, topiramate, felbamate, lamotrigine
- cyclosporin, an immunosuppressant medicine
- some medicines used to treat high blood pressure, chest pain, or irregular heartbeats such as verapamil, diltiazem
- herbal medicines containing St John's Wort
- grapefruit juice.

These medicines may be affected by YAZ Flex, or may affect how well it works. Your doctor may need to alter the dose of these medicines, or prescribe a different medicine.

You might have an increase in potassium in the blood if you are taking YAZ Flex with medicines that may increase potassium levels in the blood. These include:

- medicines used to treat high blood pressure, such as ACE inhibitors, angiotensin-II-receptor antagonists and diuretics
- certain anti-inflammatory medicines, such as indomethacin
- aldosterone antagonists, such as spironolactone and eplerenone.

In a study of women taking drospirenone together with an ACE inhibitor, no significant differences

were observed in the potassium levels when compared to the placebo.

You may need to use additional barrier methods of contraception (such as condoms or a diaphragm) while you are taking any of these medicines and for some time after stopping them.

Your doctor will be able to tell you about how long you will need to use additional contraceptive methods.

Your doctor and pharmacist have more information on medicines that you need to be careful with or avoid while taking this medicine.

HOW TO TAKE YAZ FLEX

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet. The information contained in this leaflet tells you how you should take the Pill.

A separate set of instructions is enclosed with the CLYK tablet dispenser. Please follow these instructions carefully on how to use the CLYK tablet dispenser.



The CLYK tablet dispenser is a dispensing system for YAZ Flex; it tells you when it is time to take your Pill and helps you keep track of your intake regimen.

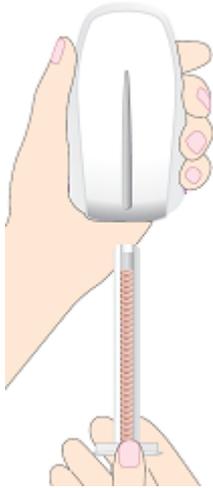
If you do not understand the instructions provided, ask your doctor or pharmacist for help.

How to take it

Take your first YAZ Flex tablet by dispensing the Pill from the CLYK tablet dispenser.

Insert the narrow end of the cartridge into the dispenser so that the tablets in the cartridge can be seen through the window of the dispenser (see Fig. 1).

Fig. 1: Preparing the CLYK tablet dispenser for use



Note: There is a grey coloured disc on top of the pink YAZ Flex tablets in the cartridge. This is not a tablet. It is a plastic stopper that is part of the cartridge unit.

Unpack and insert the cartridge on the day you want to start taking your Pill.

Make sure the day and time you release your first Pill is convenient for you.

The dispenser will automatically record when the first tablet is released by setting this time as the reference time.

Slowly press the two soft sides of the dispenser, firmly and completely (at the Bayer logo), at the same time to release the tablet.

Take one tablet daily at about the same time every day. You must take YAZ Flex every day regardless of how often you have sex. This will also help you remember when to take it. Take the tablets for the first 24 days (fixed phase) without a tablet free break.

A 4 day tablet free break can be taken between the flexible phase - days 25 - 120. A tablet free break should not be longer than 4 days.

A 4 day tablet free interval must be taken after taking the Pill for 120 consecutive days.

After each 4 day tablet free interval, a new cycle of Pill taking starts with a minimum of 24 days and a maximum of 120 days.

Swallow the tablet whole with a full glass of water.

It does not matter if you take it before or after food.

If you see an exclamation mark symbol (!) on the CLYK tablet dispenser screen, this means you must use additional barrier contraceptive precautions (e.g. condoms, diaphragm) until this symbol (!) disappears.

If you do not understand the instructions ask your doctor or pharmacist for help.

When to take it

If you are starting YAZ Flex after a natural cycle, and you have not used a hormonal contraceptive in the past month, start on the first day of your period, i.e. on the first day of your menstrual bleeding.

You may also start on days 2-5 of your period, but in that case make sure you also use additional barrier contraceptive precautions (e.g. condom) for the first 7 days of tablet-taking.

Your doctor will advise you when to start if you

- are taking YAZ Flex after having a baby
- have had a miscarriage or an abortion.

Changing from a combined oral contraceptive:

Start taking YAZ Flex on the day after taking the last placebo tablet in your previous Pill pack.

Changing from a vaginal ring:

Start taking YAZ Flex on the day after the removal is due.

Changing from a progestogen-only pill:

Stop taking the minipill on any day and start taking YAZ Flex at the same time the day after you took your last minipill.

You must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm) for the first 7 days of tablet-taking when having intercourse.

Changing from a progestogen-only injection, implant or-intrauterine system (IUS):

Start YAZ Flex when your next injection is due, or on the day that your implant or IUS is removed.

You must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm) for the first 7 days of tablet-taking when having intercourse.

Stopping YAZ Flex

You can stop taking YAZ Flex at any time. If you are considering becoming pregnant, it is recommended that you begin taking a vitamin supplement containing folic acid. It is best that you start taking folic acid tablets before you stop taking YAZ Flex and not stop until your doctor advises this. Ask your doctor or pharmacist about suitable supplements. It is both safe and recommended that you take folic acid during pregnancy.

If you forget to take it

If you are late taking a tablet but still take it within 24 hours, contraception is maintained. If you are more than 24 hours late, this is called a missed Pill. The CLYK tablet dispenser will guide you through what to do in this situation. If you want further information follow these instructions:

For YAZ Flex to be effective, the tablets need to be taken uninterrupted for 7 days.

FIXED PHASE: Days 1 – 7

If you miss one or more YAZ Flex tablets during the first 7 days of tablet taking, take the last missed

tablet as soon as you remember, even if this means taking two YAZ Flex tablets at the same time. Then, take the next tablet at the usual time when the CLYK prompts you. Use extra contraceptive precautions (barrier method such as a condom) for the next 7 days. If you had sexual intercourse in the week before missing the tablets, there is a possibility of becoming pregnant. Tell your doctor immediately.

The chance of pregnancy after missing a YAZ Flex tablet depends on when you missed the tablet. There is a higher risk of becoming pregnant if you miss a tablet at the beginning of a cycle or directly before or directly after a 4 day tablet free break.

FIXED PHASE: Days 8 – 24

If you miss one or more YAZ Flex tablets during days 8 – 24 of tablet taking, take the last missed YAZ Flex tablet as soon as you remember, even if this means taking two YAZ Flex tablets at the same time. Then, take the next tablet at the usual time when the CLYK prompts you. Use additional contraceptive precautions if the CLYK prompts you.

FLEXIBLE PHASE: Days 25 - 120

If you have missed one or more YAZ Flex tablets during days 25 – 120, you can choose either option:

1. Take the last missed tablet as soon as you remember, even if it means taking two YAZ Flex tablets at the same time. Then, take the next tablet at the usual time when the CLYK prompts you **until you have taken at least 7 YAZ Flex tablets in a row without interruption.**
2. You can stop taking your Pill, take a 4 day tablet free break, including the days where tablets were missed, and then continue with a new cycle of YAZ Flex. The total tablet free break should be no longer than 4 days. **The CLYK may prompt you to use additional contraceptive**

precautions. It is important that you follow this advice.

If you have forgotten to take your tablets and you do not have your expected menstrual bleed (that should start while having a 4 day Pill free break), you may be pregnant. Contact your doctor before you continue tablet-taking.

Please see the end of this leaflet for “Summary of advice if you missed a tablet more than 24 hours ago”.

Ask your doctor or pharmacist to answer any questions you may have.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Australia: 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much YAZ Flex.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take several light pink active tablets at once, you may feel sick or vomit or may bleed from the vagina. Even girls who have not yet started to menstruate but have accidentally taken this medicine may experience such bleeding.

WHILE YOU ARE TAKING YAZ FLEX

Things you must do

Tell any doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Have regular check-ups with your doctor.

When you are taking the Pill, your doctor will tell you to return for

regular check-ups, including getting a Cervical Screening Test. Your doctor will advise how often you need a Cervical Screening Test. A Cervical Screening Test can detect abnormal cells lining the cervix. Sometimes abnormal cells can progress to cancer.

If you are about to start on any new medicine, remind your doctor and pharmacist that you are taking YAZ Flex.

Stop taking YAZ Flex and see your doctor immediately if you notice the following signs:

- one-sided swelling of the leg and/or foot 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
- sudden onset of unexplained shortness of breath or rapid breathing
- sudden coughing or coughing up of blood
- sharp chest pain or sudden severe pain in the chest which may increase with deep breathing
- severe light headedness or dizziness
- rapid or irregular heartbeat
- sudden pain, swelling and slight blue discoloration of an extremity
- sudden numbness or weakness of the face, arm or leg, especially on one side of the body
- sudden trouble walking, dizziness, loss of balance or coordination
- sudden confusion, slurred speech or aphasia; sudden partial or complete loss of vision, double vision, painless blurring of vision which can progress to loss of vision
- sudden, severe or prolonged headache with no known cause
- loss of consciousness or fainting with or without seizure

- 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
- feeling of being full, having indigestion or choking
- sweating, nausea, vomiting
- extreme weakness and anxiety.

If you are going to have surgery, tell the surgeon or anaesthetist beforehand that you are taking this medicine.

The risk of having blood clots is temporarily increased as a result of major surgery, any surgery to the legs or pelvis, neurosurgery or major trauma. In women who take YAZ Flex, the risk may be higher.

In women at risk of prolonged immobilisation (including major surgery, any surgery to the legs or pelvis, neurosurgery, or major trauma), your doctor may tell you to stop taking (in the case of elective surgery at least four weeks in advance) and not resume until two weeks after complete remobilisation. Another method of contraception should be used to avoid unintentional pregnancy. Your doctor may prescribe other treatment (e.g. treatment for blood clots) if YAZ Flex has not been discontinued in advance.

Other risk factors for blood clotting include temporary immobilisation including air travel of greater than 4 hours, particularly in women with other risk factors.

Consult your doctor if you plan to air travel for greater than 4 hours.

Consult your doctor if you develop high blood pressure while taking YAZ Flex – you may be told to stop taking it.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you vomit within 3-4 hours or have severe diarrhoea after taking a YAZ Flex tablet, the active ingredients may not have been

completely absorbed. This is like missing a tablet. Follow the advice for missed tablets.

In the event of spotting and/or bleeding on three consecutive days during the flexible phase (days 25 – 120), it is recommended to take the 4 day tablet free interval.

This will reduce the total number of days with bleeding.

If you have unexpected bleeding and it continues, becomes heavy, or occurs again, tell your doctor.

When taking these tablets for the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding), even during the fixed phase of the cycle between days 1 – 24. You may need to use sanitary products, but continue to take your tablets as normal. Irregular vaginal bleeding usually stops once your body has adjusted to the Pill, usually after about 3 months.

If you have missed a period, but you have taken all your tablets, it is very unlikely that you are pregnant, as long as:

- you have taken the tablets at the right time
- you have not been taking medicine(s) that may interfere with YAZ Flex
- you have not vomited or had severe diarrhoea during this cycle.

If this is so, continue to take YAZ Flex as usual. If you have any concerns consult your doctor or pharmacist.

If you miss your period twice in a row, you may be pregnant even if you have taken the Pill correctly. Stop taking YAZ Flex and seek advice from your doctor. You must use a non-hormonal method of contraception (such as condoms or a diaphragm) until your doctor rules out pregnancy.

YAZ Flex will not protect you from HIV-AIDS or any other Sexually Transmitted Infections (STIs), such as chlamydia, genital herpes, genital warts, gonorrhoea, hepatitis B, human papilloma virus and syphilis.

To protect yourself from STIs, you will need to use additional barrier contraceptives (e.g. condoms).

Things you must not do

Do not take YAZ Flex to treat any other conditions, unless your doctor tells you to.

Do not give your medicine to anyone else.

Do not stop taking your medicine or change the dosage without checking with your doctor.

You may become pregnant if you are not using any other contraceptive and you stop taking YAZ Flex, or do not take a tablet every day.

SIDE EFFECTS

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking YAZ Flex.

This medicine helps most people, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

The following list includes the more common side effects of your Pill. These are usually mild and lessen with time.

If you notice any of the following side effects and they worry you, tell your doctor or pharmacist:

- nausea
- headache, including migraines
- mood changes, including depression
- unscheduled vaginal bleeding
- abnormal periods
- irregular bleeding between periods

- decrease and loss of libido
- breast tenderness or pain.

The following list includes very serious but rare side effects. You may need urgent medical attention or hospitalisation.

If you experience any of the following, tell your doctor immediately, or go to the Emergency Department at your nearest hospital:

- pain in the chest, arm or below the breastbone
- pain or discomfort that goes to your back
- breathlessness and/or difficulty breathing
- swelling, pain or tenderness of one leg
- sudden weakness, numbness or bad ‘pins and needles’ of the face, arm or leg, especially on one side of the body
- sudden trouble walking, dizziness, loss of balance or coordination
- severe, sudden stomach pains
- a bad fainting attack, or you collapse
- unusual headaches or migraines that are worse than usual
- sudden problems with your speech or eyesight

The side effects listed above are possible signs of a blood clot (thrombosis).

- jaundice (yellowing skin or yellowing eyes)
- you cough up blood
- breast lumps
- unexplained vaginal bleeding.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

Other side effects not listed on the following pages may also occur in some people.

Blood clots and the Pill

Blood clots may block blood vessels in your body. This type of blood clot is also called thrombosis.

Blood clots sometimes occur in the deep veins of the legs (DVT). If a blood clot breaks away from the veins where it has formed, it may reach and block the blood vessels of the lungs, causing pulmonary embolism (PE).

Blood clots can also occur in the blood vessels of the heart (causing a heart attack) or the brain (causing a stroke).

Blood clots are a rare occurrence and can develop whether or not you are taking the Pill. They can also happen during pregnancy. The risk of having blood clots is higher in Pill users than in non users, but not as high as during pregnancy.

The risk of a blood clot is highest during the first year of taking the Pill for the first time, or when re-starting after having a break from the Pill for 4 weeks or more.

If you notice possible signs of a blood clot, stop taking YAZ Flex and consult your doctor immediately.

To prevent pregnancy, you must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm).

If you are concerned about an increased risk of blood clots while on YAZ Flex, speak to your doctor.

Cancer and the Pill

Breast cancer has been diagnosed slightly more often in women who take the Pill than in women of the same age who do not take the Pill.

This slight increase in the numbers of breast cancer diagnoses gradually disappears during the course of the 10 years after women stop taking the Pill.

It is not known whether the difference is caused by the Pill. It may be that these women were examined more often, so that the breast cancer was noticed earlier.

It is important that you check your breasts regularly and contact your doctor if you feel any lumps.

In rare cases benign liver tumours and, even more rarely, malignant liver tumours have been reported in users of the Pill. These tumours may lead to internal bleeding.

Contact your doctor immediately if you have severe pain in your abdomen.

Cervical cancer has been reported to occur more often in women who have been taking the Pill for a long time. This finding may not be caused by the Pill, but may be related to sexual behaviour and other factors.

AFTER TAKING YAZ FLEX

Storage

Keep the YAZ Flex cartridge in the blister foil until you have a CLYK device and are ready to start taking your Pill.

Once the cartridge is taken out of the foil, YAZ Flex tablets only keep for 40 days, including the time they are in the CLYK device.

Any unused tablets must be disposed of after this time.

Keep your tablets and the CLYK device in a cool dry place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a window-sill. Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep YAZ Flex where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Return any unused medicine to your pharmacist.

PRODUCT DESCRIPTION

What it looks like

YAZ Flex is available in dispenser packs containing either 1, 3 or 4 refills. Each dispenser pack contains 30 light pink tablets.

Ingredients

Each YAZ Flex light pink tablet contains:

Active ingredients:

- 3 milligram of drospirenone
- 20 microgram of ethinylloestradiol (as betadex clathrate)

Inactive ingredients:

- lactose
- maize starch
- hypromellose
- magnesium stearate
- purified talc
- titanium dioxide
- iron oxide red

YAZ Flex tablets do not contain gluten. Tablets also do not contain tartrazine or any other azo dyes.

Supplier

Made in Germany for:

Bayer Australia Ltd.
ABN 22 000 138 714
875 Pacific Highway
Pymble NSW 2073

Australian Registration Number

YAZ Flex - AUST R 179878

Date of Preparation

February 2018

See TGA website
(www.ebs.tga.gov.au) for latest Australian Consumer Medicine Information.

Missed a pill?

See the end of this leaflet

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Summary of advice if you missed a tablet more than 24 hours ago.

Always follow the instructions given on the screen of your CLYK tablet dispenser.

If you see an exclamation mark symbol (!) on the CLYK tablet dispenser screen, this means you must use additional barrier contraceptive precautions (e.g. condoms, diaphragm) until this symbol (!) disappears.

If you are concerned, contact your doctor or pharmacist for advice. In addition, you may contact Bayer Medical Information on 1800 673 270.