Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using YAZ?

YAZ contains the active ingredients drospirenone and ethinylestradiol (as betadex clathrate). YAZ is a combined oral contraceptive used to prevent pregnancy, treat moderate acne and treat symptoms of premenstrual dysphoric disorder (PMDD) in women seeking oral contraception. For more information, see Section <u>1</u>. Why am I using YAZ? in the full CMI.

2. What should I know before I use YAZ?

Do not use if you have ever had an allergic reaction to YAZ or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions especially if it increases your risk of blood clots, if you have or had blood clots, certain cancers or migraines. Tell your doctor if you take any other medicines, are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use YAZ? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with YAZ and affect how it works. The main types of medicines that affect how well YAZ works include certain antibiotics, antifungal medicines, HIV treatments, hepatitis C virus treatments, epilepsy medicines, medicines for high blood pressure and the heart.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use YAZ?

- Take one tablet daily at about the same time each day. Swallow the tablet whole with a full glass of water.
- If you vomit within 3-4 hours or have severe diarrhoea after taking a light pink active tablet, the active ingredients may not have been completely absorbed. This is like missing a tablet. Follow the advice for missed tablets.

More instructions can be found in Section <u>4. How do I use YAZ ?</u> in the full CMI.

5. What should I know while using YAZ?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using YAZ. Use additional barrier contraceptives (e.g. condoms) to protect yourself from STIs. Tell your doctor if you are going to have surgery or if you plan to travel by air for greater than 4 hours. Stop taking YAZ and call your doctor immediately if you notice signs of a possible blood clot e.g. chest pains, breathlessness or difficulty breathing, swelling, pain or tenderness of one leg, sudden dizziness, loss of balance, trouble speaking or seeing.
Things you should not do	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, or do not take a tablet every day.
Looking after your medicine	Store it in a cool dry place away from moisture, heat or sunlight where the temperature says below 30°C.

For more information, see Section 5. What should I know while using YAZ? in the full CMI.

6. Are there any side effects?

Less serious side effects can include irregular periods or bleeding between periods, breast pain, mood changes, nausea, headaches (including migraines). Serious side effects include signs of a blood clot (e.g. breathlessness, sudden weakness/pins and needles, sudden stomach pains, fainting, unusual headaches or migraines that are worse than usual, sudden problems speaking, sudden trouble walking, pain in chest, arms or below breast bone); jaundice (yellowing skin or eyes); coughing up blood; unexplained vaginal bleeding; breast lumps.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Active ingredients: drospirenone and ethinylestradiol (as betadex clathrate)

Consumer Medicine Information (CMI)

This leaflet provides important information about using YAZ. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using YAZ.

Where to find information in this leaflet:

- 1. Why am I using YAZ?
- 2. What should I know before I use YAZ?
- 3. What if I am taking other medicines?
- 4. How do I use YAZ?
- 5. What should I know while using YAZ?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using YAZ?

YAZ contains the active ingredients drospirenone and ethinylestradiol (as betadex clathrate). YAZ is a combined oral contraceptive, commonly known as a 'birth control pill' or 'the Pill'.

YAZ has 24 active (hormone) tablets and 4 inactive tablets, rather than the traditional 21 active tablets and 7 inactive tablets. This means that with YAZ, you take the active (hormone) tablets for three more days. This helps your hormone levels to stay even.

YAZ is used to:

- prevent pregnancy
- treat moderate acne
- treat symptoms of premenstrual dysphoric disorder (PMDD) in women seeking oral contraception.

While taking YAZ you may also experience more regular and lighter periods – which may also help to improve iron deficiency (anaemia). YAZ can also help to decrease period pain as well as improve symptoms such as bloating, swelling or weight gain related to fluid retention.

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

- inhibiting the egg release by stopping it from 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.

2. What should I know before I use YAZ?

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

Warnings

Do not use YAZ if:

 you have an allergy to drospirenone, ethinylestradiol, or any of the ingredients listed at the end of this leaflet.

Always check the ingredients to make sure you can use this medicine.

- you are taking antiviral medicines which contain: glecaprevir, pibrentasvir, sofosbuvir, velpatasvir, voxilaprevir, ombitasvir, paritaprevir, or dasabuvir, and combinations of these. These antiviral medicines are used to treat long term hepatitis C (an infectious disease that affects the liver, caused by the hepatitis C virus).
- 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) or other parts of the body.
 - 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 miscarriages
 - 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
 - migraines, 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)
- o a benign or malignant liver tumour
- o unexplained vaginal bleeding
- you have or are concerned about an increased risk of blood clots.

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.

Check with your doctor if you:

- smoke
- 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.
- have, or have had any of the following medical conditions:
 - diabetes
 - high blood pressure
 - heart valve disorders or certain heart rhythm disorders
 - 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.
- 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 kidney disease
- 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 angio-oedema 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 these conditions appear for the first time, recur or worsen 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).

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6. Are there any side effects?</u>

Pregnancy and breastfeeding

- Check with your doctor if you are pregnant or intend to become pregnant. Do not take this medicine if you are pregnant or think you might be pregnant.
- Tell your doctor immediately if you think you are pregnant.
- Talk to your doctor if you are breastfeeding or intend to breastfeed. YAZ is generally not recommended if you are breastfeeding.

3. What if I am taking other medicines?

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

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

Medicine class	Examples		
Antibiotics	rifampicin, rifabutin, macrolide antibiotics (e.g. Clarithromycin, erythromycin)		
Antifungal medicines	griseofluvin, ketoconazole		
HIV medicines	ritonavir, nevirapine		
Hepatitis C Virus (HCV) medicines	boceprevir, telaprevir, glecaprevir, pibrentasvir, ombitasvir, paritaprevir, or dasabuvir, and combinations of these.		
Epilepsy medicines	phenytoin, primidone, barbiturates (e.g. phenobarbitone), carbamazepine, oxcarbazepine, topiramate, felbamate, lamotrigine		
Immunosuppressants	cyclosporin		
Medicines for high blood pressure, chest pain and or irregular heart beats	diltiazem, verapamil, spironolactone, eplerenone ACE inhibitors (e.g. lisinopril, perindopril), angiotensin II receptor blockers (e.g. candesartan, irbesartan), diuretics (e.g. hydrochlorothiazide, furosemide), aldosterone		

	antagonists (e.g. spironolactone, eplerenone)
Anti-inflammatory medicines	etoricoxib, indomethacin
Other	melatonin midazolam theophylline
	St John's Wort grapefruit juice

These medicines may be affected by YAZ or may affect how well it works. They can:

- have an influence on the blood levels of YAZ
- make it less effective in preventing pregnancy
- cause unexpected bleeding.

Your doctor may need to alter the dose of these medicines, or prescribe a different medicine.

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 how long you will need to use additional contraceptive methods.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect YAZ.

4. How do I use YAZ?

How much to take

Take one tablet daily at about the same time each day. You must take YAZ every day regardless of how often you have sex. This will also help you remember when to take it.

How to take YAZ

- Swallow the tablet whole with a full glass of water. It does not matter if you take it before or after food.
- If you vomit within 3-4 hours or have severe diarrhoea after taking a light pink active tablet, the active ingredients may not have been completely absorbed. This is like missing a tablet. Follow the advice for missed tablets.
- Each blister pack is marked with the day of the week.
- Take your first tablet from the green area on the blister pack corresponding to the day of the week.
- Follow the direction of the arrows on the blister pack until all the tablets have been taken.
- Your period should begin 2-3 days after starting to take the white inactive tablets and may not have finished before the next pack is started.
- Always start a new blister pack on the same day of the week as your previous pack.

Taking YAZ for the first time

If you are starting YAZ 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 after having a baby
- have had a miscarriage or an abortion.

Changing from another contraceptive

Type of	How do I change	Will I need	
Type of	over to YAZ?	additional	
contraceptive	over to TAZ!		
Cambinad		contraception?	
Combined	Start taking YAZ on	No	
oral	the day after taking		
contraceptive	the last active tablet		
	in your previous pill		
	pack. Bleeding may		
	not occur until the		
	end of the first pack		
	of YAZ.		
	You can also switch		
	to YAZ after taking		
	one or more inactive		
	tablets in your		
	previous pack, but		
	no later than the day		
	after taking the last		
	inactive tablet		
Vaginal ring	Start YAZ on the day	No	
	of removal of the		
	vaginal ring or, at the		
	latest, when the next		
	application would		
	have been due		
Progesterone	Stop taking the	You must also	
only pill	minipill on any day	use additional	
(minipill)	and start taking YAZ	barrier	
	at the same time the	contraceptive	
	day after you took	precautions	
	your last minipill	(e.g. condoms	
Progestogen- Start taking YAZ		or a	
only	when your next	diaphragm) for	
injection,	injection is due, or	the first 7 days	
implant or	on the day that your	of tablet-taking	
intrauterine	implant or IUS is	when having	
system (IUS)	removed	intercourse	

If you want to delay a period

To delay your period:

- continue taking the light pink active tablets in the current blister
- skip the white inactive tablets in the last row of the same blister, and
- start a new blister by taking the light pink active tablet from the green area corresponding to the day of the week (to ensure that you take your tablets on the corresponding day of the week as marked on the

pack, you may have some extra tablets left over in your current blister which you can discard).

You can continue to delay your period by skipping the white inactive tablet in the second blister. The delay can be extended until the last light pink active tablet in the third blister is taken.

If you wish for your period to begin at any time during the extension, stop taking the light pink active tablets and start taking the white inactive tablets instead.

You should get your period approximately 2 - 3 days after you start taking the white inactive tablet. After taking the last white inactive tablet, start a new blister by taking the light pink active tablet.

During the extension, you may have some breakthrough bleeding or spotting on active tablet-taking days.

If you forget to use YAZ

For YAZ to be most effective, light pink active tablets need to be taken uninterrupted for 7 days.

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. Follow these detailed instructions:

- If you have been taking the light pink active tablets for 7 uninterrupted days and miss a light pink active tablet, take the missed tablet as soon as you remember, then go back to taking your medicine as you would normally, even if this means taking two tablets in one day. You will not need to use additional barrier contraceptive precautions.
- The chance of pregnancy after missing a light pink active tablet depends on when you missed the tablet. There is a higher risk of becoming pregnant if you miss a tablet at the beginning or end of a pack.
 - If after taking your missed tablet you have less than 7 days of light pink active tablets left in a row, you should finish the active tablets in your pack but skip the white inactive tablets and start a new pack.
 - This is the best way to maintain contraceptive protection. However, you may not have a period until the end of the light pink active tablets of the second pack. You may have spotting or breakthrough bleeding on tablet-taking days.
- If you have been taking the light pink active tablets for less than 7 days and miss a light pink active tablet, take the missed tablet as soon as you remember, then go back to taking your medicine as you would normally, even if this means taking two tablets in one day. In addition, you must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm) for the next 7 days.
 - If you have had sexual intercourse during that time, there is a possibility of pregnancy and you may need emergency contraception.

- If you forget to take more than one light pink active tablet, seek advice from your doctor or pharmacist about what to do.
 - If you have had sexual intercourse in the week before missing your tablets, there is a possibility of becoming pregnant.
- If you miss a white inactive tablet, you do not need to take them later because they do not contain any active ingredients. However, it is important that you discard the missed white tablet(s) to make sure that the number of days between taking active tablets is not increased as this would increase the risk of pregnancy. Continue with the next tablet at the usual time.

Please see the diagram at the end of this leaflet for "Summary of advice if you missed a light pink active tablet more than 24 hours ago".

Stopping YAZ

You can stop taking YAZ 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 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 take too much YAZ

If you think that you have used too much YAZ, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 in Australia or 0800 764 766 in New Zealand), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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.

5. What should I know while using YAZ?

Things you should 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.
- Use additional barrier contraceptives (e.g. condoms) to protect yourself from STIs. YAZ 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

- If you are going to have surgery, tell your doctor beforehand that you are taking YAZ. 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 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 has not been discontinued in advance.
- Tell your doctor if you plan to air travel for greater than 4 hours. There may be an increased risk of blood clots due to lack of movement, particularly in women with other risk factors.
- 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.
- Tell your doctor if you develop high blood pressure while taking YAZ you may be told to stop taking it.
- If you are about to start on any new medicine, remind your doctor and pharmacist that you are taking YAZ.

Call your doctor straight away 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
- unexpected bleeding and it continues, becomes heavy, or occurs again
- pregnancy

Things you should not do

- Do not take YAZ 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, or do not take a tablet every day.

Bleeding and Missed Periods

When taking these tablets for the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding) between your periods. 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 light pink active tablets at the right time
- you have not been taking medicine(s) that may interfere with YAZ
- you have not vomited or had severe diarrhoea during this cycle.

If this is so, continue to take YAZ 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 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.

If you choose to delay your period while taking YAZ, your regular bleeding is not expected to occur during the

extension period when the intake of the light pink active tablet is uninterrupted. Therefore, the absence of regular bleeding cannot be used as a sign of an unexpected pregnancy and as such, unexpected pregnancy may be difficult to recognise. Although pregnancy is unlikely if YAZ is taken as directed, if for any reason you think you might be pregnant, contact your doctor and do a pregnancy test. This may be of particular importance if you are also using other medications, since some medications are known to be harmful to the foetus.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how YAZ affects you.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight where the temperature stays below 30°C.

Do NOT store it in the bathroom or near a sink, or in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
 Reproductive system-related unscheduled vaginal bleeding abnormal periods irregular bleeding between periods breast tenderness or pain Mood related mood changes, including depression 	Speak to your doctor if you have any of these less serious side effects and they worry you.
 General nausea headache, including migraines 	

Serious side effects

 Signs of blood clot, such as: 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 ended 	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious
 one side of the body sudden trouble walking, dizziness, loss of balance or coordination severe, sudden stomach pains a fainting attack, or you collapse unusual headaches or migraines that are worse than usual sudden problems with speech, understanding or eyesight 	side effects.
 Liver-related jaundice (yellowing skin or yellowing eyes) 	
Blood-relatedcoughing up blood	

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

Other side effects not listed here may occur in some people.

Blood clots and the Pill

Blood clots are rare. Very occasionally blood clots may cause serious permanent disability and may even be fatal.

Blood clots can form, travel and block different blood vessels in the body. They can occur in the deep veins of the legs (causing deep vein thrombosis), the clot can travel and cause a blockage in the lungs (called pulmonary embolism). Blood clots can occur in the blood vessels of the heart (causing a heart attack) or the brain (causing a stroke).

All combined oral contraceptive pills, including YAZ, increase the risk of having a blood clot. However, blood clots can form whether or not you are taking the pill, including in pregnancy. The risk of having a blood clot when taking YAZ is less than the risk of having a blood clot 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.

Stop taking YAZ and call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice signs of a possible blood clot.

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

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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <u>www.tga.gov.au/reporting-problems</u> or in New Zealand at <u>https://pophealth.my.site.com/carmreportnz/s/</u>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What YAZ contains

Active ingredients (main ingredients in the light pink tablets)	 3 milligram drospirenone 20 microgram ethinylestradiol (as betadex clathrate)
Other ingredients	Light pink tablet
(inactive ingredients)	lactose monohydratemaize starch

	 hypromellose magnesium stearate purified talc titanium dioxide iron oxide red 	
	White tablet	
	 lactose monohydrate microcrystalline cellulose magnesium stearate hypromellose purified talc titanium dioxide 	
Potential allergens	Lactose monohydrate	

Do not take this medicine if you are allergic to any of these ingredients.

What YAZ looks like

YAZ active tablets are light pink round tablets marked on one side with the letters "DS" in a regular hexagon. YAZ inactive tablets are white round tablets marked on one side with the letters "DP" in a regular hexagon.

YAZ comes in a box containing either 1 or 3 blister packs. Each blister pack contains 24 light pink active tablets and 4 white inactive tablets. (AUST R 226241)

Who distributes YAZ

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

Bayer New Zealand Hillcrest North Shore Auckland 0627 New Zealand

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

See MEDSAFE website (<u>www.medsafe.govt.nz</u>) for latest New Zealand Consumer Medicine Information.

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Summary of advice if you missed a light pink active tablet more than 24 hours ago

Before missing your tablet, did you take light	No	Did you have sex in the 7 days before missing the tablet?	→	No Take the tablet missed AND use extra barrier precaution for 7 days. If there are fewer than 7 light pink active tablets left in the pack, finish the active tablets and go straight to the light pink active tablets of the next pack. This means you skip the white inactive tablets. Yes See your Doctor or Pharmacist for advice
pink active tablets for the previous 7 days?	Yes	Does your pack still have 7 active light pink tablets in a row to follow?	→	No Take the tablet missed AND complete taking the light pink active tablets. Skip the white inactive tablets. Start your next pack with the light pink active tablets Yes Take the tablet missed AND complete the pack as normal