

Yaz®

0.02 mg / 3 mg film-coated tablets
Ethinylestradiol / Drospirenone

1

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Seite 1

Bayer Pharma AG

Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Code-Nr.: **166**

Bezeichnung: **YAZ**

Aufmachung: **AME BPH**

Farben: **Black / PANT389C**

Version: **30.10.2012/01**

Freigabe:

This is a medicament

- ▶ A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- ▶ Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- ▶ The doctor and the pharmacist are experts in medicine, its benefits and risks.
- ▶ Do not by yourself interrupt the period of treatment prescribed.
- ▶ Do not repeat the same prescription without consulting your doctor.

2

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Mandant: **0021**

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Bayer Pharma AG

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Freigabe:

Keep medicament out
of reach of children

Council of Arab Health Ministers
Union of Arab Pharmacists

3

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Seite 3

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Mandant: **0021**

Stoff-Nr.: **81216835**

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Code-Nr.: **166**

Bezeichnung: **YAZ**

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Freigabe:

PACKAGE LEAFLET: INFORMATION FOR THE USER

Yaz® 0.02 mg / 3 mg film-coated tablets

Ethinylestradiol / Drospirenone

Read all of this leaflet carefully before you start taking this medicine.

- ▶ *Keep this leaflet, you may need to read it again.*
- ▶ *If you have any further questions, ask your doctor or pharmacist.*
- ▶ *This medicine has been prescribed for you, do not pass it on to others. It may harm them.*
- ▶ *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.*

4

Packaging Technology Berlin

Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Bayer Pharma AG

Code-Nr.: **166**

Bezeichnung: **YAZ**

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Version: **30.10.2012/01**

Freigabe:

In this leaflet

1. WHAT YAZ IS AND WHAT IT IS USED FOR	8
2. BEFORE YOU TAKE YAZ	9
When you should not use Yaz	11
When do you need to take special care with Yaz?	13
Yaz and venous and arterial blood clots	16
Yaz and cancer	21
Bleeding between periods	22
What you must do if no bleeding occurs during the placebo days	22
Yaz and using other medicines	23

5

Packaging Technology Berlin

Seite 5

Bayer Pharma AG

Mandant: 0021

Stoff-Nr.: 81216835

PZ: 2537A-4C

Code-Nr.: 166

Bezeichnung: YAZ

Aufmachung: AME BPH

Farben: Black / PANT389C

Version: 30.10.2012/01

Freigabe:

Taking Yaz with food and drink	25
Laboratory tests	25
Pregnancy	26
Breast-feeding	26
Driving and using machines	27
Important information about some of the ingredients of Yaz	27
3. HOW TO TAKE YAZ	28
Preparation of the strip	30
When can you start with the first strip?	32
If you take more Yaz than you should	36

6

Packaging Technology Berlin

Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Bayer Pharma AG

Code-Nr.: **166**

Bezeichnung: **YAZ**

Aufmachung: **AME BPH**

Farben: **Black / PANT389C**

Version: **30.10.2012/01**

Freigabe:

If you forget to take Yaz	36
What to do in the case of vomiting or severe diarrhoea	45
Delaying your period: what you need to know	46
Changing the first day of your period: what you need to know	47
If you want to stop taking Yaz	48
4. POSSIBLE SIDE EFFECTS	49
5. HOW TO STORE YAZ	55
6. FURTHER INFORMATION	56

7

1. WHAT YAZ IS AND WHAT IT IS USED FOR

- ▶ Yaz is a contraceptive pill and is used to prevent pregnancy.
- ▶ Each of the 24 light pink tablets contains a small amount of two different female hormones, namely drospirenone and ethinylestradiol.
- ▶ The 4 white tablets contain no active substances and are also called placebo tablets.
- ▶ Contraceptive pills that contain two hormones are called “combination” pills.

8

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Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Bayer Pharma AG

Code-Nr.: **166**

Bezeichnung: **YAZ**

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Version: **30.10.2012/01**

Freigabe:

2. BEFORE YOU TAKE YAZ

General notes

Before you can begin taking Yaz, your doctor will ask you some questions about your personal health history and that of your close relatives. The doctor will also measure your blood pressure and, depending upon your personal situation, may also carry out some other tests.

9

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Seite 9

Bayer Pharma AG

Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Code-Nr.: **166**

Bezeichnung: **YAZ**

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Version: **30.10.2012/01**

Freigabe:

In this leaflet, several situations are described where you should stop using Yaz, or where the reliability of Yaz may be decreased. In such situations you should either not have sex 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 alters the monthly changes of body temperature and of cervical mucus.

Yaz, like other hormonal contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

10

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Seite 10

Bayer Pharma AG

Mandant: 0021

Stoff-Nr.: 81216835

PZ: 2537A-4C

Code-Nr.: 166

Bezeichnung: **YAZ**

Aufmachung: **AME BPH**

Farben: **Black / PANT389C**

Version: **30.10.2012/01**

Freigabe:

When you should not use Yaz

- ▶ 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 organs
- ▶ if you have (or have ever had) a heart attack or stroke
- ▶ if you have (or have ever had) a disease that can be an indicator of a heart attack in the future (for example, angina pectoris, which causes severe pain in the chest) or of a stroke (for example, a passing slight stroke with no residual effects)
- ▶ if you have a disease that may increase the risk of a clot in the arteries. This applies to the following diseases:
 - ▷ diabetes with damaged blood vessels
 - ▷ very high blood pressure

11

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Seite 11

Bayer Pharma AG

Mandant: 0021

Stoff-Nr.: 81216835

PZ: 2537A-4C

Code-Nr.: 166

Bezeichnung: YAZ

Aufmachung: AME BPH

Farben: Black / PANT389C

Version: 30.10.2012/01

Freigabe:

- ▷ a very high level of fat in the blood (cholesterol or triglycerides)
- ▶ if you have a disturbance of blood clotting (for example, protein C deficiency)
- ▶ if you have (or have ever had) a certain form of migraine (with so-called focal neurological symptoms)
- ▶ if you have (or have ever had) an inflammation of the pancreas (pancreatitis)
- ▶ if you have (or have ever had) liver disease and your liver function is still not normal
- ▶ if your kidneys are not working well (renal failure)
- ▶ if you have (or have ever had) a tumour in the liver
- ▶ if you have (or have ever had) or if you are suspected of having breast cancer or cancer of the genital organs

12

- ▶ if you have any unexplained bleeding from the vagina
- ▶ if you are hypersensitive (allergic) to ethinylestradiol or drospirenone, or any of the other ingredients of Yaz
This may cause itching, rash or swelling.

When do you need to take special care with Yaz?

In some situations you need to take special care while using Yaz or any other combination pill, and your doctor may need to examine you regularly. If any of the following conditions applies to you, you must inform your doctor before starting to use Yaz. Also, if any of the following conditions develops or worsens while you are using Yaz you must consult your doctor:

- ▶ if a close relative has or has ever had breast cancer
- ▶ if you have a disease of the liver or the gallbladder

13

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Seite 13

Bayer Pharma AG

Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Code-Nr.: **166**

Bezeichnung: **YAZ**

Aufmachung: **AME BPH**

Farben: **Black / PANT389C**

Version: **30.10.2012/01**

Freigabe:

- ▶ if you have diabetes
- ▶ if you have depression
- ▶ if you have Crohn's disease or inflammatory bowel disease (ulcerative colitis)
- ▶ if you have a blood disease called HUS (haemolytic uraemic syndrome) that causes kidney damage
- ▶ if you have a blood disease called sickle cell anaemia
- ▶ if you have epilepsy (see page 23 "Yaz and using other medicines")
- ▶ if you have a disease of the immune system, called SLE (systemic lupus erythematosus)

14

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Seite 14

Bayer Pharma AG

Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Code-Nr.: **166**

Bezeichnung: **YAZ**

Aufmachung: **AME BPH**

Farben: **Black / PANT389C**


Version: **30.10.2012/01**

Freigabe:


- ▶ if you have a disease that first appeared during pregnancy or earlier use of sex hormones (for example, hearing loss, a blood disease called porphyria, skin rash with blisters during pregnancy (gestational herpes), a nerve disease causing sudden movements of the body (Sydenham's chorea)
- ▶ if you have or have ever had yellowish brown pigment patches (chloasma), so called "pregnancy patches", especially on the face. If this is the case, avoid direct exposure to sunlight or ultraviolet light.

15

Packaging Technology Berlin		Seite 15	Bayer Pharma AG
Mandant: 0021	Stoff-Nr.: 81216835	PZ: 2537A-4C	Code-Nr.: 166
Bezeichnung: YAZ		Aufmachung: AME BPH	
Farben: Black / PANT389C			
Version: 30.10.2012/01		Freigabe:	

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- ▶ If you have hereditary angioedema, products containing oestrogens may cause or worsen the symptoms. You should see your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue and/or pharynx and/or difficulty swallowing or hives together with difficulty breathing.

Yaz and venous and arterial blood clots



The use of any combination pill, including Yaz, increases a woman's risk of developing a **venous blood clot (venous thrombosis)** compared with women who do not take any contraceptive pill.

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

- ▶ with increasing age

16



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Seite 16

Bayer Pharma AG

Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Code-Nr.: **166**

Bezeichnung: **YAZ**

Aufmachung: **AME BPH**

Farben: **Black / PANT389C**

Version: **30.10.2012/01**

Freigabe:

- ▶ if you are overweight
 - ▶ if one of your close relatives had a blood clot in the leg, lung (pulmonary embolism), or other organ at a young age
 - ▶ if you must have surgery, if you have had a serious accident or if you are immobilized for a long time. It is important to tell your doctor in advance that you are using Yaz as the treatment may have to be stopped. Your doctor will tell you when to start Yaz again. This is usually about two weeks after you are back on your feet
- Your chances of having a blood clot are increased by taking the pill.
- ▶ Of 100,000 women who are not on the pill and not pregnant, about 5-10 may have a blood clot in a year.

17

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Seite 17

Bayer Pharma AG

Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Code-Nr.: **166**

Bezeichnung: **YAZ**

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Version: **30.10.2012/01**

Freigabe:

- ▶ Of 100,000 women taking a pill like Yaz, 30-40 may have a blood clot in a year, the exact number is unknown.
- ▶ Of 100,000 women who are pregnant, around 60 may have a blood clot in a year.

A blood clot in the veins may travel to the lungs and may block blood vessels (called a lung embolus). Formation of blood clots in the veins may be fatal in 1-2% of cases. The level of risk may vary according to the type of pill you take. Discuss with your doctor the available options. The use of combination pills has been connected with an increase of the risk of an **arterial blood clot (arterial thrombosis)**, for example, in the blood vessels of the heart (heart attack) or the brain (stroke).

18

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Seite 18

Bayer Pharma AG

Mandant: 0021

Stoff-Nr.: 81216835

PZ: 2537A-4C

Code-Nr.: 166

Bezeichnung: YAZ

Aufmachung: AME BPH

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Version: 30.10.2012/01

Freigabe:

The risk of an arterial blood clot in users of combination pills increases:

- ▶ **if you smoke. You are strongly advised to stop smoking when you use Yaz, especially if you are older than 35 years.**
- ▶ if you have high levels of blood cholesterol or triglycerides
- ▶ if you are overweight
- ▶ if one of your close relatives had a heart attack or stroke at a young age
- ▶ if you have high blood pressure
- ▶ if you suffer from migraine
- ▶ if you have a problem with your heart (valve disorder, a disturbance of the cardiac rhythm)

19

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Seite 19

Bayer Pharma AG

Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Code-Nr.: **166**

Bezeichnung: **YAZ**

Aufmachung: **AME BPH**

Farben: **Black / PANT389C**

Version: **30.10.2012/01**

Freigabe:

Stop taking Yaz and contact your doctor immediately if you notice possible signs of a blood clot, such as:

- ▶ severe pain and/or swelling in one of your legs
- ▶ sudden severe pain in the chest which may reach the left arm
- ▶ sudden breathlessness
- ▶ sudden cough without an obvious cause
- ▶ any unusual, severe or long-lasting headache or worsening of migraine
- ▶ partial or complete blindness or double vision
- ▶ inarticulate language or difficulty in speaking
- ▶ giddiness or fainting
- ▶ weakness, strange feeling, or numbness in any part of the body

20

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Seite 20

Bayer Pharma AG

Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Code-Nr.: **166**

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Version: **30.10.2012/01**

Freigabe:

Yaz and cancer

Breast cancer has been observed slightly more often in women using combination pills, but it is not known whether this is caused by the treatment. For example it may be that more tumours are detected in women on combination pills because they are examined by their doctor more often. The occurrence of breast tumours becomes gradually less after stopping the combination hormonal contraceptives. It is important to regularly check your breasts and you should contact your doctor if you feel any lump.

In rare cases, benign liver tumours, and in even fewer cases malignant liver tumours have been reported in pill users. Contact your doctor if you have unusually severe abdominal pain.

21

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Seite 21

Bayer Pharma AG

Mandant: 0021

Stoff-Nr.: 81216835

PZ: 2537A-4C

Code-Nr.: 166

Bezeichnung: YAZ

Aufmachung: AME BPH

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Version: 30.10.2012/01

Freigabe:



Bleeding between periods

During the first few months that you are taking Yaz, you may have unexpected bleeding (bleeding outside the placebo days). If this bleeding occurs for more than a few months, or if it begins after some months, your doctor must find out what is wrong.

What you must do if no bleeding occurs during the placebo days

If you have taken all the light pink active tablets correctly, have not had vomiting or severe diarrhoea and you have not taken any other medicines, it is highly unlikely that you are pregnant.

22



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Seite 22

Bayer Pharma AG

Mandant: 0021

Stoff-Nr.: 81216835

PZ: 2537A-4C

Code-Nr.: 166

Bezeichnung: YAZ

Aufmachung: AME BPH

Farben: Black / PANT389C

Version: 30.10.2012/01

Freigabe:

If the bleeding does not happen twice in succession, you may be pregnant. Contact your doctor immediately. Only start the next strip if you are sure that you are not pregnant.

Yaz and using other medicines

Always tell your doctor which medicines or herbal products you are already using. Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist) that you use Yaz. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long.

- ▶ Some medicines can make Yaz less effective in preventing pregnancy, or can cause unexpected bleeding. These include medicines used for the treatment of

23

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Seite 23

Bayer Pharma AG

Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Code-Nr.: **166**

Bezeichnung: **YAZ**

Aufmachung: **AME BPH**

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Version: **30.10.2012/01**

Freigabe:

- ▷ epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine)
- ▷ tuberculosis (e.g. rifampicin)
- ▷ HIV infections (ritonavir, nevirapine) or other infections (antibiotics such as griseofulvin, penicillin, tetracycline)
- ▷ high blood pressure in the blood vessels in the lungs (bosentan)
- ▷ the herbal remedy St. John's wort
- ▶ Yaz may influence the effect of other medicines, e.g.
 - ▷ medicines containing ciclosporin
 - ▷ the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures)

24

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Seite 24

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Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Code-Nr.: **166**


Bezeichnung: **YAZ**

Aufmachung: **AME BPH**

Farben: **Black / PANT389C**

Version: **30.10.2012/01**

Freigabe:




Ask your doctor or pharmacist for advice before taking any medicine.

Taking Yaz with food and drink

Yaz may be taken with or without food, if necessary with a small amount of water.

Laboratory tests

If you need a blood test, tell your doctor or the laboratory staff that you are taking the pill, because hormonal contraceptives can affect the results of some tests.



25



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Seite 25

Bayer Pharma AG

Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Code-Nr.: **166**

Bezeichnung: **YAZ**

Aufmachung: **AME BPH**

Farben: **Black / PANT389C**

Version: **30.10.2012/01**

Freigabe:



Pregnancy

If you are pregnant, you must not take Yaz. If you become pregnant while taking Yaz you must stop immediately and contact your doctor. If you want to become pregnant, you can stop taking Yaz at any time (see also page 48 “If you want to stop taking Yaz”).

Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding

Use of Yaz is generally not advisable when a woman is breast-feeding. If you want to take the pill while you are breast-feeding you should contact your doctor.

Ask your doctor or pharmacist for advice before taking any medicine.

26



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Seite 26

Bayer Pharma AG

Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Code-Nr.: **166**

Bezeichnung: **YAZ**

Aufmachung: **AME BPH**

Farben: **Black / PANT389C**

Version: **30.10.2012/01**

Freigabe:




Driving and using machines

There is no information suggesting that use of Yaz affects driving or use of machines.

Important information about some of the ingredients of Yaz

Yaz contains lactose.

If you cannot tolerate certain sugars, contact your doctor before you take Yaz.



27



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Seite 27

Bayer Pharma AG

Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Code-Nr.: **166**

Bezeichnung: **YAZ**

Aufmachung: **AME BPH**

Farben: **Black / PANT389C**

Version: **30.10.2012/01**

Freigabe:

3. HOW TO TAKE YAZ

Each blister contains 24 active light pink tablets and 4 white placebo tablets.

The two differently coloured tablets of Yaz are arranged in order. A strip contains 28 tablets.

Take one tablet of Yaz every day, if necessary with a small amount of water. You may take the tablets with or without food, but you should take the tablets every day around the same time.

28

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Seite 28

Bayer Pharma AG

Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Code-Nr.: **166**

Bezeichnung: **YAZ**

Aufmachung: **AME BPH**

Farben: **Black / PANT389C**

Version: **30.10.2012/01**

Freigabe:

Do not confuse the tablets: take a light pink tablet for the first 24 days and then a white tablet for the last 4 days. You must then start a new strip straightaway (24 light pink and then 4 white tablets). There is therefore no gap between two strips.

Because of the different composition of the tablets it is necessary to begin with the first tablet on the upper left and that you take the tablets every day. For the correct order, follow the direction of the arrows on the strip.

29

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Seite 29

Bayer Pharma AG

Mandant: **0021**

Stoff-Nr.: **81216835**

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Code-Nr.: **166**

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Farben: **Black / PANT389C**

Version: **30.10.2012/01**

Freigabe:

Preparation of the strip

To help you keep track, there are 7 stickers each with the 7 days of the week for each strip of Yaz. Choose the week sticker that starts with the day you begin taking the tablets. For example, if you start on a Wednesday, use the week sticker that starts with “WED”.

Stick the week sticker along the top of the Yaz strip where it reads “Place week sticker here”, so that the first day is above the tablet marked “START”.

There is now a day indicated above every tablet and you can see whether you have taken a certain pill. The arrows show the order you are to take the pills.

30

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Seite 30

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Mandant: 0021

Stoff-Nr.: 81216835

PZ: 2537A-4C

Code-Nr.: 166

Bezeichnung: YAZ

Aufmachung: AME BPH

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Version: 30.10.2012/01

Freigabe:

During the 4 days when you are taking the white placebo tablets (the placebo days), bleeding should begin (so-called withdrawal bleeding). This usually starts on the 2nd or 3rd day after the last light pink active tablet of Yaz. Once you have taken the last white tablet, you should start with the following strip, whether your bleeding has stopped or not. This means that you should start every strip on the same day of the week, and that the withdrawal bleed should occur on the same days each month.

If you use Yaz in this manner, you are protected against pregnancy also during the 4 days when you are taking a placebo tablet.

31

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Seite 31

Bayer Pharma AG

Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Code-Nr.: **166**

Bezeichnung: **YAZ**

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Farben: **Black / PANT389C**

Version: **30.10.2012/01**

Freigabe:

When can you start with the first strip?

- ▶ *If you have not used a contraceptive with hormones in the previous month*

Begin with Yaz on the first day of the cycle (that is, the first day of your period). If you start Yaz on the first day of your menstruation you are immediately protected against pregnancy. You may also begin on day 2-5 of the cycle, but then you must use extra protective measures (for example, a condom) for the first 7 days.

32

Packaging Technology Berlin

Seite 32

Bayer Pharma AG

Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Code-Nr.: **166**

Bezeichnung: **YAZ**

Aufmachung: **AME BPH**

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Version: **30.10.2012/01**

Freigabe:

- *Changing from a combined hormonal contraceptive (“pill” containing two hormones), or combined contraceptive vaginal ring or patch*

You can start Yaz preferably on the day after the last active tablet (the last tablet containing the active substances) of your previous pill, but at the latest on the day after the tablet-free days of your previous pill (or after the last inactive tablet of your previous pill). When changing from a combined contraceptive vaginal ring or patch, follow the advice of your doctor.

- ▶ *Changing from a progestogen-only-method (progestogen-only pill, injection, implant or a progestogen-releasing IUD)*
You may switch any day from the progestogen-only pill to Yaz (from an implant or an IUD on the day of its removal, from an injectable when the next injection would be due) but in all of these cases you must use extra protective measures (for example, a condom) for the first 7 days of tablet-taking.
- ▶ *After a miscarriage*
Follow the advice of your doctor.

34

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Seite 34

Bayer Pharma AG

Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Code-Nr.: **166**

Bezeichnung: **YAZ**

Aufmachung: **AME BPH**

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Version: **30.10.2012/01**

Freigabe:

► *After having a baby*

You can start Yaz between 21 and 28 days after having a baby. If you start later than day 28, you must use a so-called barrier method (for example, a condom) during the first seven days of Yaz use.

If, after having a baby, you have had sex before starting Yaz (again), you must first be sure that you are not pregnant or you must wait until your next period.

► *If you are breast-feeding and want to start Yaz (again) after having a baby*

Read the section on “Breast-feeding”, page 26.

35

Packaging Technology Berlin

Seite 35

Bayer Pharma AG

Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Code-Nr.: **166**

Bezeichnung: **YAZ**

Aufmachung: **AME BPH**

Farben: **Black / PANT389C**

Version: **30.10.2012/01**

Freigabe:



Ask your doctor what to do if you are not sure when to start.

If you take more Yaz than you should

There are no reports of serious harmful results of taking too many Yaz tablets.

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

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

If you forget to take Yaz

The last 4 tablets in the 4th row of the strip are the placebo tablets. If you forget one of these tablets, this has no effect on the reliability of Yaz. Throw away the forgotten placebo tablet.

36



Packaging Technology Berlin

Seite 36

Bayer Pharma AG

Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Code-Nr.: **166**

Bezeichnung: **YAZ**

Aufmachung: **AME BPH**

Farben: **Black / PANT389C**

Version: **30.10.2012/01**

Freigabe:



If you miss a light pink, active tablet (tablets 1-24 of your blister-strip), you must do the following:

- ▶ If you are **less than 12 hours** late taking a tablet, the protection against pregnancy is still guaranteed. Take the tablet as soon as you remember and then take the following tablets again at the usual time.
- ▶ If you are **more than 12 hours** late taking a tablet, the protection against pregnancy cannot be guaranteed. The greater the number of tablets that you have forgotten, the greater is the risk of becoming pregnant.

The risk of an unintentional pregnancy is greatest if you forget a light pink tablet at the beginning or at the end of the strip. Therefore, you should keep to the following rules (see also the diagram on page 42, 43 and 44)

37



Packaging Technology Berlin		Seite 37	Bayer Pharma AG
Mandant: 0021	Stoff-Nr.: 81216835	PZ: 2537A-4C	Code-Nr.: 166
Bezeichnung: YAZ		Aufmachung: AME BPH	
Farben: Black / PANT389C			
Version: 30.10.2012/01		Freigabe:	

- ▶ **More than one tablet forgotten in this strip**
Contact your doctor.
- ▶ **One tablet forgotten between days 1 - 7 (first row)**

Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time and use extra precautions for the next 7 days, for example, a condom. If you have had sex in the week before forgetting the tablet you must realize that there is a risk of pregnancy. In that case, contact your doctor.

38

Packaging Technology Berlin

Seite 38

Bayer Pharma AG

Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Code-Nr.: **166**

Bezeichnung: **YAZ**

Aufmachung: **AME BPH**

Farben: **Black / PANT389C**

Version: **30.10.2012/01**

Freigabe:

- ▶ **One tablet forgotten between days 8 - 14 (second row)**

Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time. The protection against pregnancy is not reduced, and you do not need to take extra precautions.

- ▶ **One tablet forgotten between days 15 - 24 (third or fourth row)**

You can choose between two possibilities:

1. Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time. Instead of taking the white placebo tablets on this strip, throw them away, and start the next strip (the starting day will be different).

Most likely, you will have a period at the end of the second strip - while taking the white placebo tablets - but you may have light or menstruation-like bleeding during the second strip.

40

Packaging Technology Berlin



Seite 40

Bayer Pharma AG

Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Code-Nr.: **166**

Bezeichnung: **YAZ**

Aufmachung: **AME BPH**

Farben: **Black / PANT389C**

Version: **30.10.2012/01**

Freigabe:

2. You can also stop the active light pink tablets and go directly to the 4 white placebo tablets (**before taking the placebo tablets, record the day on which you forgot your tablet**). If you want to start a new strip on the day you always start, take the placebo tablets for *less than 4 days*.

If you follow one of these two recommendations, you will remain protected against pregnancy.

- ▶ If you have forgotten any of the tablets in a strip, and you do not have a bleeding during the placebo days, this may mean that you are pregnant. You must contact your doctor before you start the next strip.

41

Packaging Technology Berlin



Seite 41

Bayer Pharma AG

Mandant: 0021

Stoff-Nr.: 81216835

PZ: 2537A-4C

Code-Nr.: 166

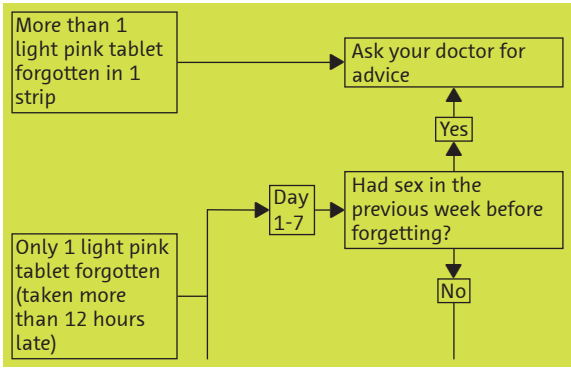
Bezeichnung: YAZ

Aufmachung: AME BPH

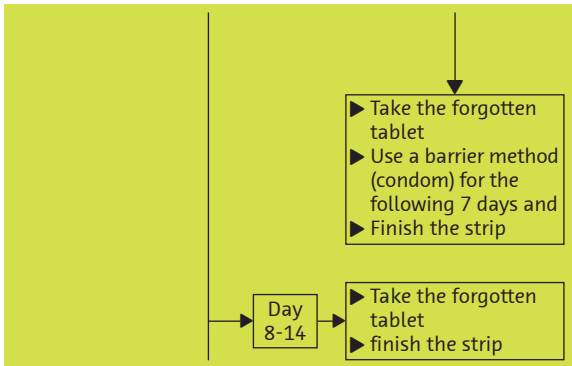
Farben: Black / PANT389C

Version: 30.10.2012/01

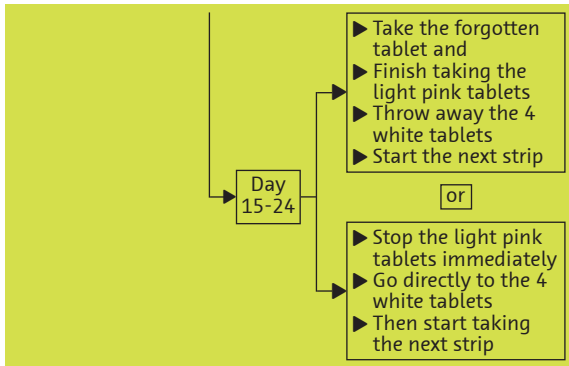
Freigabe:



42



43



44



What to do in the case of vomiting or severe diarrhoea

If you vomit within 3-4 hours of taking an active light pink tablet or you have severe diarrhoea, there is a risk that the active substances in the pill will not be fully taken up by your body. The situation is almost the same as forgetting a tablet. After vomiting or diarrhoea, you must take another light pink tablet from a reserve strip as soon as possible. If possible take it within 12 hours of when you normally take your pill. If this is not possible or 12 hours have passed, you should follow the advice given under “If you forget to take Yaz”, page 36.

45

Packaging Technology Berlin



Seite 45

Bayer Pharma AG

Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Code-Nr.: **166**

Bezeichnung: **YAZ**

Aufmachung: **AME BPH**

Farben: **Black / PANT389C**

Version: **30.10.2012/01**

Freigabe:

Delaying your period: what you need to know

Even if it is not recommended, you can delay your period by not taking the white placebo tablets from the 4th row and going straight to a new strip of Yaz and finishing it. You may experience light or menstruation-like bleeding while using this second strip. Finish this second strip by taking the 4 white tablets from the 4th row. Then start your next strip.

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

46

Packaging Technology Berlin

Seite 46

Bayer Pharma AG

Mandant: 0021

Stoff-Nr.: 81216835

PZ: 2537A-4C

Code-Nr.: 166

Bezeichnung: **YAZ**

Aufmachung: **AME BPH**

Farben: **Black / PANT389C**

Version: 30.10.2012/01

Freigabe:



Changing the first day of your period: what you need to know

If you take the tablets according to the instructions, then your period will begin during the placebo days. If you have to change this day, reduce the number of placebo days – when you take the white placebo tablets – (but never increase them – 4 is the maximum!). For example, if you start taking the placebo tablets on a Friday, and you want to change this to a Tuesday (3 days earlier) you must start a new strip 3 days earlier than usual. You may not have any bleeding during this time. You may then experience light or menstruation-like bleeding.

If you are not sure what to do, consult your doctor.

47



Packaging Technology Berlin		Seite 47	Bayer Pharma AG
Mandant: 0021	Stoff-Nr.: 81216835	PZ: 2537A-4C	Code-Nr.: 166
Bezeichnung: YAZ			Aufmachung: AME BPH
Farben: Black / PANT389C			
Version: 30.10.2012/01		Freigabe:	

If you want to stop taking Yaz

You can stop taking Yaz whenever you want. If you do not want to become pregnant, ask your doctor for advice about other reliable methods of birth control. If you want to become pregnant, stop taking Yaz and wait for a menstrual period before trying to become pregnant. You will be able to calculate the expected delivery date more easily.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

48

Packaging Technology Berlin



Seite 48

Bayer Pharma AG

Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Code-Nr.: **166**

Bezeichnung: **YAZ**

Aufmachung: **AME BPH**

Farben: **Black / PANT389C**

Version: **30.10.2012/01**

Freigabe:

4. POSSIBLE SIDE EFFECTS

Like all medicines, Yaz can cause side effects although not everybody gets them.

The following is a list of the side effects that have been linked with the use of Yaz:

Common side effects (between 1 and 10 in every 100 users may be affected):

- ▶ mood swings
- ▶ headache
- ▶ nausea
- ▶ breast pain, problems with your periods, such as irregular periods, absence of periods

49

Packaging Technology Berlin

Seite 49

Bayer Pharma AG

Mandant: 0021

Stoff-Nr.: 81216835

PZ: 2537A-4C

Code-Nr.: 166

Bezeichnung: YAZ

Aufmachung: AME BPH

Farben: Black / PANT389C

Version: 30.10.2012/01

Freigabe:

Uncommon side effects (between 1 and 10 in every 1,000 users may be affected):

- ▶ depression, decreased interest in sex, nervousness, sleepiness
- ▶ dizziness, 'pins and needles'
- ▶ migraine, varicose veins, increased blood pressure
- ▶ stomach ache, vomiting, indigestion, intestinal gas, inflammation of the stomach, diarrhoea
- ▶ acne, itching, rash
- ▶ aches and pains, e.g. back pain, limb pain, muscle cramps

50

Packaging Technology Berlin

Seite 50

Bayer Pharma AG

Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Code-Nr.: **166**

Bezeichnung: **YAZ**

Aufmachung: **AME BPH**

Farben: **Black / PANT389C**

Version: **30.10.2012/01**

Freigabe:

- ▶ vaginal fungal infection, pelvic pain, breast enlargement, benign breast lumps, uterine/vaginal bleeding (which usually subsides during continued treatment), genital discharge, hot flushes, inflammation of the vagina (vaginitis), problems with your periods, painful periods, reduced periods, very heavy periods, vaginal dryness, abnormal cervical smear
- ▶ lack of energy, increased sweating, fluid retention
- ▶ weight increase

Rare side effects (between 1 and 10 in every 10,000 users may be affected):

- ▶ candida (fungal infection)
- ▶ anemia, increase in the number of platelets in the blood
- ▶ allergic reaction

51

Packaging Technology Berlin



Seite 51

Bayer Pharma AG

Mandant: 0021

Stoff-Nr.: 81216835

PZ: 2537A-4C

Code-Nr.: 166

Bezeichnung: YAZ

Aufmachung: AME BPH

Farben: Black / PANT389C

Version: 30.10.2012/01

Freigabe:

- ▶ hormonal (endocrine) disorder
- ▶ increased appetite, loss of appetite, abnormally high concentration of potassium in the blood, abnormally low concentration of sodium in the blood
- ▶ failure to experience an orgasm, insomnia
- ▶ giddiness, tremor
- ▶ eye disorders, e.g. inflammation of the eyelid, dry eyes
- ▶ abnormally rapid heartbeat
- ▶ inflammation of a vein, nosebleed, fainting
- ▶ enlarged abdomen, bowel disorder, feeling bloated, stomach hernia, fungal infection of the mouth, constipation, dry mouth
- ▶ pain of bile ducts or the gallbladder, inflammation of the gallbladder

52

Packaging Technology Berlin

Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Bayer Pharma AG

Code-Nr.: **166**

Bezeichnung: **YAZ**

Aufmachung: **AME BPH**

Farben: **Black / PANT389C**

Version: **30.10.2012/01**

Freigabe:

- ▶ yellow brown patches on the skin, eczema, hair loss, acne-like inflammation of the skin, dry skin, lumpy inflammation of the skin, excessive hair growth, skin disorder, stretch marks on the skin, skin inflammation, light-sensitive skin inflammation, skin nodules
- ▶ difficult or painful sex, inflammation of the vagina (vulvovaginitis), bleeding following intercourse, withdrawal bleeding, breast cyst, increased number of breast cells (hyperplasia), malignant lumps in the breast, abnormal growth on the mucosal surface of the neck of the womb, shrinkage or wasting of the lining of the womb, ovarian cysts, enlargement of the womb
- ▶ feeling generally unwell
- ▶ weight loss

53

Packaging Technology Berlin



Seite 53

Bayer Pharma AG

Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Code-Nr.: **166**

Bezeichnung: **YAZ**

Aufmachung: **AME BPH**

Farben: **Black / PANT389C**

Version: **30.10.2012/01**

Freigabe:

The following side effects have also been reported, but their frequency cannot be estimated from the available data: hypersensitivity, erythema multiforme (rash with target-shaped reddening or sores).

If any of the side effects gets serious or if you notice any side effects not listed in this leaflet or if you think that this may be the case, please tell your doctor or pharmacist.

54

Packaging Technology Berlin



Seite 54

Bayer Pharma AG

Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Code-Nr.: **166**

Bezeichnung: **YAZ**

Aufmachung: **AME BPH**

Farben: **Black / PANT389C**

Version: **30.10.2012/01**

Freigabe:

5. HOW TO STORE YAZ

Keep Yaz out of the reach and sight of children.

Store below 30°C.

Expiry date

Do not take Yaz after the date on the packaging after” Do not use after:” or “EXP:.”

This medicine should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose this medicine if no longer required. These measures will help to protect the environment.

55

Packaging Technology Berlin

Seite 55

Bayer Pharma AG

Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Code-Nr.: **166**

Bezeichnung: **YAZ**

Aufmachung: **AME BPH**

Farben: **Black / PANT389C**

Version: **30.10.2012/01**

Freigabe:

6. FURTHER INFORMATION

What Yaz contains

- ▶ The active substances are ethinylestradiol (as betadex clathrate) and drospirenone.
Each light pink active film-coated tablet contains 0.020 milligram ethinylestradiol (as betadex clathrate) and 3 milligram drospirenone.
- ▶ The white film-coated tablets do not contain active substances.
- ▶ The other ingredients are:
- ▶ Light pink active film-coated tablets:
 - ▷ Tablet core: lactose monohydrate, maize starch, magnesium stearate (Ph.Eur.) [herbal] (E470b)

56

Packaging Technology Berlin

Seite 56

Bayer Pharma AG

Mandant: 0021

Stoff-Nr.: 81216835

PZ: 2537A-4C

Code-Nr.: 166

Bezeichnung: YAZ

Aufmachung: AME BPH

Farben: Black / PANT389C

Version: 30.10.2012/01

Freigabe:

- ▶ Tablet film-coating: hypromellose (E464), talc (E553b), titanium dioxide (E171) and iron oxide red (E172).
- ▶ White inactive film-coated tablets:
 - ▶ Tablet core: lactose monohydrate, maize starch, povidone K25, magnesium stearate (Ph.Eur.) [herbal] (E470b)
 - ▶ Tablet film-coating: hypromellose (E464), talc (E553b) and titanium dioxide (E171).

What Yaz looks like and content of the pack

- ▶ Each blister of Yaz contains 24 light pink, active film-coated tablets in the 1st, 2nd, 3rd and 4th rows of the strip and 4 white placebo film-coated tablets in row 4.

57

Packaging Technology Berlin



Seite 57

Bayer Pharma AG

Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Code-Nr.: **166**

Bezeichnung: **YAZ**

Aufmachung: **AME BPH**

Farben: **Black / PANT389C**

Version: **30.10.2012/01**

Freigabe:

- ▶ Yaz tablets, both the light pink and the white, are film-coated tablets; the core of the tablet is coated.
- ▶ The active tablet is light pink, round with convex surfaces; one side is embossed with the letters “DS” in a regular hexagon.
- ▶ The placebo tablet is white, round with convex surfaces; one side is embossed with the letters “DP” in a regular hexagon.
- ▶ Yaz is available in packs of 1, 3, 6 and 13 blisters each with 28 tablets.

Not all pack sizes may be marketed.

58

Packaging Technology Berlin

Seite 58

Bayer Pharma AG

Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Code-Nr.: **166**

Bezeichnung: **YAZ**

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Version: **30.10.2012/01**

Freigabe:

Manufacturer

Bulk manufacturer

Bayer Weimar GmbH & Co. KG

D – 99427 Weimar, Germany

Packaging and final release

Bayer Pharma AG

D – 13342 Berlin, Germany

This leaflet was last approved in May 2011.

59

Packaging Technology Berlin

Seite 59

Bayer Pharma AG

Mandant: **0021**

Stoff-Nr.: **81216835**

PZ: **2537A-4C**

Code-Nr.: **166**

Bezeichnung: **YAZ**

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