

## Package leaflet: Information for the patient

### Cyproterone Acetate / Ethinylestradiol 2 mg / 0.035 mg Tablets (cyproterone acetate / ethinylestradiol)

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **What is in this leaflet:**

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

#### **1. What Cyproterone Acetate / Ethinylestradiol is and what it is used for**

Cyproterone Acetate / Ethinylestradiol is used to treat skin conditions such as acne, very oily skin and excessive hair growth in women of reproductive age. Due to its contraceptive properties it should only be prescribed for you if your doctor considers that treatment with a hormonal contraceptive is appropriate.

You should only take Cyproterone Acetate / Ethinylestradiol if your skin condition has not improved after use of other anti-acne treatments, including topical treatments and antibiotics.

#### **2. What you need to know before you take Cyproterone Acetate / Ethinylestradiol**

##### **Before you take Cyproterone Acetate / Ethinylestradiol**

It's important that you understand the benefits and risks of taking Cyproterone Acetate / Ethinylestradiol before you start taking it, or when deciding whether to carry on taking it. Although Cyproterone Acetate / Ethinylestradiol is suitable for most healthy women it isn't suitable for everyone.

##### **Warnings and precautions**

→ **Talk to your doctor or pharmacist** before taking Cyproterone Acetate / Ethinylestradiol **or** if you have any of the illnesses or risk factors mentioned in this leaflet.

##### **Before you start taking Cyproterone Acetate / Ethinylestradiol**

- Your doctor will ask about you and your family's medical problems and check your blood pressure and exclude the likelihood of you being pregnant. You may also need other checks, such as a breast examination, but only if these examinations are necessary for you or if you have any special concerns.
- Cyproterone Acetate / Ethinylestradiol also works as an oral contraceptive. You and your doctor will have to consider all the things that would normally apply to the safe use of oral hormonal contraceptives.

## When should you contact your doctor?

**Stop taking the tablets and contact your doctor immediately if you notice possible signs of a blood clot. These symptoms are described in section 2 ‘Cyproterone Acetate / Ethinylestradiol and blood clots’**

### While you’re on Cyproterone Acetate / Ethinylestradiol

- You will need **regular check-ups** with your doctor, usually when you need another prescription of Cyproterone Acetate / Ethinylestradiol.
- You should go for **regular cervical smear** tests.
- **Check your breasts** and nipples every month for changes – tell your doctor if you can see or feel anything odd, such as lumps or dimpling of the skin.
- **If you need a blood test** tell your doctor that you are taking Cyproterone Acetate / Ethinylestradiol, because this type of medicine can affect the results of some tests.
- **If you’re going to have an operation**, make sure your doctor knows about it. You may need to stop taking Cyproterone Acetate / Ethinylestradiol about 4–6 weeks before the operation. This is to reduce the risk of a blood clot (see section below). Your doctor will tell you when you can start taking Cyproterone Acetate / Ethinylestradiol again.
- **If you need to stop taking Cyproterone Acetate / Ethinylestradiol**, remember to use another contraceptive (e.g. condoms) if you are relying on Cyproterone Acetate / Ethinylestradiol for contraception.

## Cyproterone Acetate / Ethinylestradiol and blood clots

**Taking Cyproterone Acetate / Ethinylestradiol may slightly increase your risk of having a blood clot (called a *thrombosis*), especially in the first year of taking it.**

A clot in a leg vein – a *deep vein thrombosis* (or DVT) – is not always serious. However, if it moves up the veins and blocks an artery in the lungs, it can cause chest pain, breathlessness or collapse. A full recovery is not always made and in 1-2% of cases, can be fatal. This is called a *pulmonary embolism* and is very rare.

**Your chances of having a blood clot are only increased slightly by taking Cyproterone Acetate / Ethinylestradiol compared with women who do not take Cyproterone Acetate / Ethinylestradiol or any contraceptive pill.**

- Of 100,000 women who are **not taking Cyproterone Acetate / Ethinylestradiol, not on the Pill** and not pregnant, about **5 to 10** will have a blood clot in a year.
- Of 100,000 women who **take Cyproterone Acetate / Ethinylestradiol or the Pill**, up to **40** will have a blood clot in a year.
- Of 100,000 women who are **pregnant**, around **60** will have a blood clot in a year.

Very rarely, blood clots can also form in the blood vessels of the heart (causing a **heart attack**) or the brain (causing a **stroke**). In healthy young women the chance of having a heart attack or stroke is extremely small.

### **Blood clots in a vein**

A blood clot in a vein (known as a ‘venous thrombosis’) can block the vein. This can happen in veins of the leg, the lung (a lung embolus), or any other organ.

Using a combined pill increases a woman’s risk of developing such clots compared with a woman not taking any combined pill. The risk of developing a blood clot in a vein is highest during the first year a woman uses the pill. The risk is not as high as the risk of developing a blood clot during pregnancy.

**The risk of blood clots in a vein in users of a combined pill increases further:**

- If you have **polycystic ovary syndrome**
- as you get **older**
- **if you smoke**

- **When using a hormonal contraceptive like Cyproterone Acetate / Ethinylestradiol you are strongly advised to stop smoking, especially if you are older than 35 years**
- if you or any of your close family have had **blood clots** in the leg, lung or other organ at a young age
- if you are **overweight**
- if you have **very rare blood disorders**
- if you have **recently had a baby**
- if you have **diabetes**
- if you have certain rare medical conditions such as **systemic lupus erythematosus, Crohn's disease** or **ulcerative colitis**
- if you have **sickle cell disease**
- if you must have an operation, or if you're **off your feet for a long time** because of an injury or illness, or have your leg in a plaster cast.

→ **If this applies to you**, it is important to tell your doctor that you are using Cyproterone Acetate / Ethinylestradiol, as the treatment may have to be stopped. Your doctor may tell you to stop using Cyproterone Acetate / Ethinylestradiol several weeks before surgery or while you are less mobile. Your doctor will also tell you when you can start using Cyproterone Acetate / Ethinylestradiol again after you are back on your feet.

### **Blood clots in an artery**

A blood clot in an artery can cause serious problems. For example, a blood clot in an artery in the heart may cause a heart attack, or in the brain may cause a stroke.

The use of a combined pill has been connected with an increased risk of clots in the arteries. This risk increases further:

- If you have **polycystic ovary syndrome**
- as you get **older**
- **if you smoke**
  - **When using a hormonal contraceptive like Cyproterone Acetate / Ethinylestradiol you are strongly advised to stop smoking, especially if you are older than 35 years**
- if you are **overweight**
- if you have **high blood pressure**
- if a close relative has had a heart attack or stroke at a young age
- if you have high levels or **a disorder of blood fat** (cholesterol or triglycerides) **metabolism**, or some other **very rare blood disorders**
- if you get **migraines**
- if you have a **heart valve disorder, disturbance of heart rhythm**, or a particular type of **irregular heartbeat** (atrial fibrillation)
- if you have **recently had a baby**
- if you have **diabetes**
- if you have certain rare medical conditions such as **systemic lupus erythematosus, Crohn's disease** or **ulcerative colitis**
- if you have **sickle cell disease**

### **Symptoms of blood clots**

**Stop taking the tablets and see your doctor immediately if you notice possible signs of a blood clot such as:**

- a **migraine** for the first time, a migraine that is worse than normal, unusual, or are frequent, or severe or long-lasting **headaches**
- any sudden **changes to your eyesight** (such as partial or complete loss of vision, double vision, or blurred vision)
- any sudden **changes to your hearing, speech** (such as slurring or speech disability), **sense of smell, taste or touch**
- **severe pain in your abdomen**
- **severe pain or swelling in either of your legs**
- **breathlessness or stabbing pain when you breathe**

- **unusual sudden coughing** for no apparent reason
- **severe pain and tightness in the chest which may reach the left arm**
- sudden **weakness** or **numbness** in one side or any part of your body
- **dizziness** or **fainting**.

→ **See a doctor as soon as possible. Do not take any more Cyproterone Acetate / Ethinylestradiol** until your doctor says you can. If needed, use another method of contraception, such as condoms, in the meantime.

Following a blood clot, recovery is not always complete. Rarely serious permanent disabilities may occur or the blood clot may even be fatal.

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

### **Cyproterone Acetate / Ethinylestradiol and cancer**

While high dose COCs reduce your risk of cancer of the ovary and womb if used in the long term, it is not clear whether lower dose oestrogen-progestogen containing Pills like Cyproterone Acetate / Ethinylestradiol also provide the same protective effects. However, it also seems that taking Cyproterone Acetate / Ethinylestradiol slightly increases your risk of **cancer of the cervix** – although this may be due to having sex without a condom, rather than Cyproterone Acetate / Ethinylestradiol. All women should have regular **smear tests**.

If you have **breast cancer**, or have had it in the past, you should not take Cyproterone Acetate / Ethinylestradiol or other oral contraceptives, as they slightly increase your risk of breast cancer. This risk goes up the longer you're on Cyproterone Acetate / Ethinylestradiol, but returns to normal within about 10 years of stopping it. Because breast cancer is rare in women under the age of 40, the extra cases of breast cancer in current and recent Cyproterone Acetate / Ethinylestradiol users is small. For example:

- Of 10,000 women who have **never taken Cyproterone Acetate / Ethinylestradiol or the Pill**, about **16** may have breast cancer by the time they are 35 years old.
- Of 10,000 women who **take Cyproterone Acetate / Ethinylestradiol or the Pill for 5 years in their early twenties**, about **17–18** may have breast cancer by the time they are 35 years old.
- Of 10,000 women who have **never taken Cyproterone Acetate / Ethinylestradiol or the Pill**, about **100** may have breast cancer by the time they are 45 years old.
- Of 10,000 women who **take Cyproterone Acetate / Ethinylestradiol or the Pill for 5 years in their early thirties**, about **110** may have breast cancer by the time they are 45 years old.

### **Your risk of breast cancer is higher:**

- if you have a close relative (mother, sister or grandmother) who has had breast cancer
- if you are seriously overweight

→ **See a doctor as soon as possible if you notice any changes in your breasts**, such as dimpling of the skin, changes in the nipple or any lumps you can see or feel.

- Taking Cyproterone Acetate / Ethinylestradiol has also been linked to liver diseases, such as jaundice and noncancer liver tumours, but this is rare. Very rarely, Cyproterone Acetate / Ethinylestradiol has also been linked with some forms of liver cancer in women who have taken it for a long time.

→ **See a doctor as soon as possible if you get severe pain in your stomach, or yellow skin or eyes (jaundice)**. You may need to stop taking Cyproterone Acetate / Ethinylestradiol.

### **Make sure Cyproterone Acetate / Ethinylestradiol is OK for you**

### **Cyproterone Acetate / Ethinylestradiol should not be taken by some women**

→ **Tell your doctor** if you have any medical problems or illnesses.

### **Do not take Cyproterone Acetate / Ethinylestradiol**

Tell your doctor if any of the following conditions applies to you before starting to use Cyproterone Acetate / Ethinylestradiol. Taking Cyproterone Acetate / Ethinylestradiol would put your health at risk. Your doctor may then advise you to use a different treatment:

- If you are using another hormonal **contraceptive**
- If you are **pregnant** or might be pregnant
- If you are **breast-feeding**
- If you have or have ever had **breast cancer**
- If you have (or have ever had) a problem with your blood circulation. This includes a **blood clot** in the legs (*deep vein thrombosis*) or the lungs (*pulmonary embolism*) or any other part of the body
- If you have (or have ever had), or your close family have ever had, a **heart attack** or **stroke**.
- If you have any condition which makes you **more at risk of a blood clot** (*thrombosis* – see section above, *Cyproterone Acetate / Ethinylestradiol and blood clots*) or a **blood clot in your arteries**. This applies to the following conditions:
  - **diabetes affecting your blood vessels**
  - very high **blood pressure**
  - a very high level of **fat in your blood** (cholesterol or triglycerides)
- If you have (or have ever had) any **symptoms of a blood clot or of a disease that may be an indicator of a heart attack in the future**, such as **severe chest pain** (*angina pectoris*) or **‘mini-stroke’** (*transient ischaemic attack*)
- If you have problems with **blood clotting** (e.g. protein C deficiency)
- If you have **uncontrolled blood pressure**
- If you have (or have ever) suffered from **migraine, with visual disturbances**
- If you have ever had a **severe liver disease**, and you have been told by your doctor that your liver test results are not yet back to normal
- If you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir (see also in section Other medicines and Cyproterone Acetate/Ethinylestradiol).
- If you have ever had **liver tumours**
- If you are **allergic** to cyproterone acetate, ethinylestradiol or any of the other ingredients of this medicine (listed in section 6).

→ **If you suffer from any of these**, or get them for the first time while taking Cyproterone Acetate / Ethinylestradiol, contact your doctor as soon as possible. Do not take Cyproterone Acetate / Ethinylestradiol. If needed, use another form of contraception.

### **Cyproterone Acetate / Ethinylestradiol can make some illnesses worse**

Some of the conditions listed below can be made worse by taking Cyproterone Acetate / Ethinylestradiol. Or they may mean it is less suitable for you. You may still be able to take Cyproterone Acetate / Ethinylestradiol but you need to take special care and have check-ups more often.

- If you or your close family have ever had problems with your heart or circulation, such as **high blood pressure**
- If you or your close family have ever had problems with **blood clotting**
- If you have had **migraines**
- If you are currently suffering from **depression** or have done so in the past
- If you are **overweight** (*obese*)
- If you have the inherited disease called **porphyria**
- If you have **diabetes** with blood disorders or disorder of the eye, kidneys or nerves
- If you have **inflammation of the pancreas** (*pancreatitis*), or a history or family history of **high levels of fat in your blood** (*hypertriglyceridemia*), as you may be at risk of developing pancreatitis
- If you have **brown patches on your face or body** (*chloasma*) (see below ‘Cyproterone Acetate / Ethinylestradiol and sun-beds or sun-lamps’)
- If you have **any illness that worsened during pregnancy or previous use of the Pill or**

### **Cyproterone Acetate / Ethinylestradiol** (see section 4)

- If you have **hereditary angioedema**. Consult your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue or throat, and/or difficulty swallowing, or hives, together with difficulty breathing. Products containing oestrogens may induce or worsen symptoms of angioedema.

→ **Tell your doctor if any apply to you.** Also tell them if you get any of these for the first time while taking Cyproterone Acetate / Ethinylestradiol, or if any get worse or come back, because you may need to stop taking it.

Cyproterone Acetate / Ethinylestradiol will not protect you against sexually transmitted infections, such as Chlamydia or HIV. Only condoms can help to do this.

### **Other medicines and Cyproterone Acetate / Ethinylestradiol**

Also check the leaflets that come with all your medicines to see if they can be taken with hormonal contraceptives. Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If you are taking Cyproterone Acetate / Ethinylestradiol for skin treatment, you must not take any other hormonal contraceptive at the same time.

Some medicines can stop Cyproterone Acetate / Ethinylestradiol from working properly – for example:

- **some medicines used to treat epilepsy** (such as primidone, phenytoin, carbamazepine, oxcarbazepine, topiramate, felbamate)
- **some medicines used to treat HIV and Hepatitis C Virus infection** (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors such as ritonavir, nelfinavir and nevirapine)
- **griseofulvin and rifampicin** (anti-fungal medicines)
- **certain sedatives** (called *barbiturates*)
- **St. John's wort** (a herbal remedy).

If you do need to take one of these medicines, Cyproterone Acetate / Ethinylestradiol may not be suitable for you or you may need to use extra contraception for a while. Your doctor, pharmacist or dentist can tell you if this is necessary and for how long.

Do not use Cyproterone Acetate/Ethinylestradiol if you have Hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir as this may cause increases in liver function blood test results (increase in ALT liver enzyme).

Your doctor will prescribe another type of contraceptive prior to start of the treatment with these medicinal products.

Cyproterone Acetate/Ethinylestradiol can be restarted approximately 2 weeks after completion of this treatment. See section “Do not take Cyproterone Acetate/Ethinylestradiol”.

### **Cyproterone Acetate / Ethinylestradiol can also affect how well other medicines work.**

Cyproterone Acetate / Ethinylestradiol may increase or decrease the amount of certain medicines (such as ciclosporin and lamotrigine) in your blood. Your doctor may need to adjust the dose of your other medicine.

In addition, Cyproterone Acetate / Ethinylestradiol can also interfere with the results of some blood tests, so always tell your doctor that you are taking Cyproterone Acetate / Ethinylestradiol if you have a blood test.

### **Pregnancy and breast-feeding**

#### **Do not use Cyproterone Acetate / Ethinylestradiol if you are pregnant or are breast-feeding.**

If you think you might be pregnant, do a pregnancy test to confirm that you are before you stop taking Cyproterone Acetate / Ethinylestradiol.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### **Driving and using machines**

Cyproterone Acetate / Ethinylestradiol has no known effect on the ability to drive or use machines.

### **Cyproterone Acetate / Ethinylestradiol and sun-beds or sun-lamps**

Sun-lamps are used by some women for acne as well as to tan the skin. This is not a very useful treatment for acne. **Do not use sun-beds** or sun-lamps and avoid prolonged sunbathing if you are taking Cyproterone Acetate / Ethinylestradiol. Their use increases the chance of chloasma, a patchy discolouration of the skin (as it does with ordinary oral contraceptives).

### **Cyproterone Acetate / Ethinylestradiol contains lactose and sucrose**

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

## **3. How to take Cyproterone Acetate / Ethinylestradiol**

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

Your doctor has chosen Cyproterone Acetate / Ethinylestradiol as a treatment for your severe acne or excessive hair growth on your face and body. However, Cyproterone Acetate / Ethinylestradiol also has a contraceptive effect, so it is important to follow the advice below if you are relying on Cyproterone Acetate / Ethinylestradiol for contraception.

If you are only using Cyproterone Acetate / Ethinylestradiol for your acne or excessive hair growth, you can still follow this advice, but ask your doctor if you are unsure.

### **Duration of use**

Your doctor will tell you how long you need to keep taking Cyproterone Acetate / Ethinylestradiol.

### **How to take it**

#### **Take Cyproterone Acetate / Ethinylestradiol every day for 21 days**

Cyproterone Acetate / Ethinylestradiol comes in strips of 21 pills, each marked with a day of the week.

- Take your pill at the same time every day.
- Start by taking a pill marked with the correct day of the week.
- Follow the direction of the arrows on the strip. Take one pill each day, until you have finished all 21 pills.
- Swallow each pill whole, with water if necessary. Do not chew the pill.

#### **Then have seven pill-free days**

After you have taken all 21 pills in the strip, you have seven days when you take no pills. Within a few days of taking the last pill from the strip, you should have a withdrawal bleed like a period. This bleed may not have finished when it is time to start your next strip of pills. If you are relying on this medicine to prevent pregnancy, always take Cyproterone Acetate / Ethinylestradiol as described here. You don't need to use extra contraception during the seven pill-free days – as long as you have taken your pills correctly and start the next strip of pills on time. Check with your doctor if you are not sure.

#### **Start your next strip on day eight**

Start taking your next strip of Cyproterone Acetate / Ethinylestradiol after the seven pill-free days (**on day eight**) – even if you are still bleeding. So if you take the last pill of one pack on a Friday, you will

take the first pill of your next pack on the Saturday of the following week. Always start the new strip on time.

As long as you take Cyproterone Acetate / Ethinylestradiol correctly, you will always start each new strip on the same day of the week.

## **Starting Cyproterone Acetate / Ethinylestradiol**

### **New users or starting Cyproterone Acetate / Ethinylestradiol after a break**

It is best to take your first Cyproterone Acetate / Ethinylestradiol pill on the first day of your next period. By starting in this way, you will have contraceptive protection with your first pill.

### **Changing to Cyproterone Acetate / Ethinylestradiol from another contraceptive Pill**

- **If you are currently taking a 21-day Pill:** start Cyproterone Acetate / Ethinylestradiol the next day after the end of the previous strip. You will have contraceptive protection with your first pill. You will not have a bleed until after your first strip of Cyproterone Acetate / Ethinylestradiol.
- **If you are taking a 28-day Pill:** start taking Cyproterone Acetate / Ethinylestradiol the day after your last active pill. You will have contraceptive protection with your first pill. You will not have a bleed until after your first strip of Cyproterone Acetate / Ethinylestradiol.
- **If you are taking a progestogen-only Pill (POP or 'mini Pill'):** start Cyproterone Acetate / Ethinylestradiol on the first day of bleeding, even if you have already taken the progestogen-only Pill for that day. You will have contraceptive protection straight away.

### **Starting Cyproterone Acetate / Ethinylestradiol after a miscarriage or abortion**

If you have had a miscarriage or an abortion **during the first three months** of pregnancy, your doctor

may tell you to start taking Cyproterone Acetate / Ethinylestradiol straight away. This means that you will have contraceptive protection with your first pill.

If you have had a miscarriage or an abortion **after the third month** of pregnancy, ask your doctor for

advice. You may need to use extra contraception, such as condoms, for a short time.

### **Contraception after having a baby**

If you have just had a baby, your doctor may advise you that Cyproterone Acetate / Ethinylestradiol should be started 21 days after delivery provided that you are fully mobile. You do not have to wait for a period. You will need to use another method of contraception, such as a condom, until you start Cyproterone Acetate / Ethinylestradiol and for the first 7 days of pill taking.

### **A missed pill**

**If you are less than 12 hours late with a pill,** take it straight away. Keep taking your pills at the usual time. This may mean taking two pills in one day. Don't worry – your contraceptive protection should not be reduced.

**If you are more than 12 hours late with a pill,** or you have missed more than one pill, your contraceptive protection may be reduced.

- **Take the most recently missed pill** as soon as you remember, even if it means taking two at once. Leave any earlier missed pills in the pack.
- **Continue to take a pill every day for the next seven days** at your usual time.
- **If you come to the end of a strip of pills** during these seven days, start the next strip without taking the usual seven day break. You probably won't have a bleed until after you finish the second strip of pills, but don't worry. If you finish the second strip of pills and don't have a bleed, do a pregnancy test before starting another strip.
- **Use extra contraception for seven days after missing a pill,** such as condoms.
- If you have missed one or more pills from the first week of your strip (days 1 to 7) and



had sex in that week, you could become pregnant. Contact your doctor or pharmacist for advice as soon as possible. They may recommend you use emergency contraception.

**If you have missed any of the pills in a strip, and you do not bleed in the first pill free break, you may be pregnant. Contact your doctor or do a pregnancy test yourself.**

**If you start a new strip of pills late**, or make your ‘week off’ longer than seven days, you may not be

protected from pregnancy. If you had sex in the last seven days, ask your doctor or pharmacist for advice. You may need to consider emergency contraception.

You should also use extra contraception, such as a condom, for seven days.

### **A lost pill**

If you lose a pill,

**Either** take the last pill of the strip in place of the lost pill. Then take all the other pills on their proper days. Your cycle will be one day shorter than normal, but your contraceptive protection won’t be affected. After your seven pill-free days you will have a new starting day, one day earlier than before.

**Or** if you do not want to change the starting day of your cycle, take a pill from a spare strip if you have one. Then take all the other pills from your current strip as usual. You can then keep the opened spare strip in case you lose any more pills.

### **If you are sick or have diarrhoea**

If you are sick (*vomit*) or have very bad diarrhoea, your body may not get its usual dose of hormones from that pill. **If you are better within 12 hours of taking Cyproterone Acetate /**

**Ethinylestradiol**, follow the instructions in section above, *A lost pill*, which describes how to take another pill.

If you are still sick or have diarrhoea **more than 12 hours after taking Cyproterone Acetate / Ethinylestradiol**, see section above, *A missed pill*.

→ **Talk to your doctor if your stomach upset carries on or gets worse.** He or she may recommend another form of contraception.

### **Missed a period – could you be pregnant?**

Occasionally, you may miss a withdrawal bleed. This could mean that you are pregnant, but that is very unlikely if you have taken your pills correctly. Start your next strip at the normal time. If you think that you might have put yourself at risk of pregnancy (for example, by missing pills or taking other medicines), or if you miss a second bleed, you should do a pregnancy test. You can buy these

from the chemist or get a free test at your doctors surgery. If you are pregnant, stop taking Cyproterone Acetate / Ethinylestradiol and see your doctor.

### **Taking more than one pill should not cause harm**

It is unlikely that taking more than one pill will do you any harm, but you may feel sick, vomit or have some vaginal bleeding. Talk to your doctor if you have any of these symptoms.

### **When you want to get pregnant**

If you are planning a baby, it’s best to use another method of contraception after stopping Cyproterone Acetate / Ethinylestradiol until you have had a proper period. Your doctor or midwife relies on the date of your last natural period to tell you when your baby is due. However, it will not cause you or the baby any harm if you get pregnant straight away.

## **4. Possible side effects**

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

**If any of the following side effects happen, you may need urgent medical attention. Stop**

**taking Cyproterone Acetate / Ethinylestradiol and contact a doctor or go to the nearest hospital immediately.**

**Uncommon** (may affect up to 1 in 100 people)

- if you get migraines or if you get more frequent headaches

**Rare** (may affect up to 1 in 1,000 people)

**Signs of a severe allergic reaction or worsening of hereditary angioedema:**

- a red bumpy rash (*hives*) and itching, swelling of the hands, face, lips, mouth, tongue or throat. A swollen tongue/throat may lead to difficulty swallowing and breathing

**Venous or arterial blood clot which include signs such as:**

- a migraine for the first time, a migraine that is worse than normal or unusually frequent or severe headaches
- any sudden changes to your eyesight (such as loss of vision or blurred vision)
- any sudden changes to your hearing, speech, sense of smell, taste or touch
- pain or swelling in your leg
- stabbing pain when you breathe
- coughing for no apparent reason
- pain and tightness in the chest
- sudden weakness or numbness in one side or part of your body
- dizziness or fainting.

**Not known** (frequency cannot be estimated from the available data)

**Severe depression:**

Although, it is not considered a direct side effect of Cyproterone Acetate / Ethinylestradiol, some women have reported feeling depressed whilst taking Cyproterone Acetate / Ethinylestradiol. In very rare cases this has been associated with thoughts of ending their lives. If you develop severe depression, you should stop Cyproterone Acetate / Ethinylestradiol as a precaution, and see your doctor straight away.

- **inflammation of the colon or other parts of the intestine (*Crohn's disease or ulcerative colitis*)**
- **severe increase in blood pressure**

**breast cancer, which include signs such as:**

- dimpling of the skin
- changes in the nipple
- any lumps you can see or feel.

**cancer of the cervix, which include signs such as:**

- vaginal discharge that smells and/or contains blood
- unusual vaginal bleeding
- pelvic pain
- painful sex.

**severe liver problems, which include signs such as:**

- severe pain in your stomach
- yellow skin or eyes (*jaundice*)
- inflammation of the liver (*hepatitis*)
- your whole body starts itching.

**Other conditions that may happen or worsen during pregnancy or use of the Pill such as:**

- **yellowing of the skin (*jaundice*)**
- **persistent itching (*pruritus*)**
- **kidney or liver problems**
- **gall stones**
- certain rare medical conditions such as **systemic lupus erythematosus**
- **blister-like rash (*herpes gestationis*)** whilst pregnant

- an inherited form of **deafness** (*otosclerosis*)
- a personal or family history or a form of **sickle cell disease**
- an inherited disease called **porphyria**
- **cancer of the cervix**
- movement disorder **chorea**

If you have hereditary angioedema medicines containing certain female sex hormones (oestrogens) may induce or worsen the symptoms of angioedema (see section 2 “Cyproterone Acetate / Ethinylestradiol can make some illnesses worse”).

### Other possible side effects:

#### Common (may affect up to 1 in 10 people)

- feeling sick
- stomach ache
- putting on weight
- headaches
- depressive moods or mood swings
- sore or tender breasts

#### Uncommon (may affect up to 1 in 100 people)

- being sick, diarrhoea
- fluid retention
- reduced sex drive
- breast enlargement
- skin rash, which may be itchy

#### Rare (may affect up to 1 in 1,000 people)

- poor tolerance of contact lenses
- losing weight
- increased sex drive
- vaginal or breast discharge
- painful reddish nodules in the skin ( *erythema nodosum* ), skin rash with irregular red patches  
( *erythema multiforme* )

#### Not known (frequency cannot be estimated from the available data)

- changes in the amount of fat in the blood or in liver function which may be seen in blood tests
- change in menstrual periods including absence of menstruation. elevated blood glucose (glucose intolerance)
- bleeding and spotting between your periods can sometimes occur for the first few months but this usually stops once your body has adjusted to Cyproterone Acetate / Ethinylestradiol. If it continues, becomes heavy or starts again, contact your doctor  
chloasma (yellow brown patches on the skin). This may happen even if you have been using Cyproterone Acetate / Ethinylestradiol for a number of months. Chloasma may be reduced by avoiding too much sunlight and/or UV lamps
- increase in blood pressure

### Bleeding between periods should not last long

A few women have a little unexpected bleeding or spotting while they are taking Cyproterone Acetate / Ethinylestradiol, especially during the first few months. Normally, this bleeding is nothing to worry about and will stop after a day or two. Keep taking Cyproterone Acetate / Ethinylestradiol as usual. The problem should disappear after the first few strips.

You may also have unexpected bleeding if you are not taking your pills regularly, so try to take your pill at the same time every day. Also, unexpected bleeding can sometimes be caused by other medicines.

→ **Make an appointment to see your doctor** if you get breakthrough bleeding or spotting that:

- carries on for more than the first few months
- starts after you've been taking Cyproterone Acetate / Ethinylestradiol for a while
- carries on even after you've stopped taking Cyproterone Acetate / Ethinylestradiol.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: [www.yellow.gov.uk/yellowcard](http://www.yellow.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Cyproterone/Ethinylestradiol**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton/strip after EXP. The expiry date refers to the last day of that month.

Keep the blister strips in the outer carton in order to protect from light. Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Cyproterone Acetate and Ethinylestradiol contains**

The active substances are cyproterone acetate and ethinylestradiol. Each coated tablet contains cyproterone acetate 2 mg and ethinylestradiol 35 micrograms.

The tablet also contains: Lactose monohydrate, Maize starch, Povidone, Talc, Magnesium stearate, Sucrose, Macrogol, Calcium carbonate, Glycerol 85%, Titanium dioxide, Iron oxide yellow, Montanglycol wax.

### **What Cyproterone Acetate and Ethinylestradiol looks like and contents of the pack**

Cyproterone Acetate / Ethinylestradiol tablets are round, beige, coated tablets with no markings.

These tablets are available in blister packs of 21, 42, 63, 84, 105, 126, 147, 168, 189, 210, 231, 252 tablets\*. Your pharmacist will dispense the number of tablets prescribed by your doctor.

*\*Not all pack sizes may be marketed.*

### **Marketing Authorisation Holder:**

Mylan, Potters Bar, Herts EN6 1TL

### **Manufacturer:**

Bayer Weimar GmbH und Co. KG, Dobereinerstrasse 20, 99427 Weimar, Germany

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