

## CO-CYPRINDIOL 2000/35 COATED TABLETS

### Cyproterone acetate and ethinylestradiol

#### PACKAGE LEAFLET: INFORMATION FOR THE USER

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using 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 symptoms are the same as yours.
- If you get any of the side effects talk 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 Co-cyprindiol Tablets are and what they are used for
2. What you need to know before you use Co-cyprindiol Tablets
3. How to use Co-cyprindiol Tablets
4. Possible side effects
5. How to store Co-cyprindiol Tablets
6. Contents of the pack and other information

### 1 WHAT CO-CYPRINDIOL TABLETS ARE AND WHAT THEY ARE USED FOR

Cyproterone is an anti-androgen. Your ovaries make androgens (male sex hormones) to change into oestrogens (female sex hormones). Androgens can stimulate growth of hair on the face and body, and production of sebum (oil from your skin). If your skin produces too much oil the pores of your skin will become blocked, which can lead to spots. Cyproterone acts by reducing the amount of androgens released by your ovaries and by reducing the amount that can act in your body. Ethinylestradiol is an oestrogen (female sex hormone) which should be given in combination with Cyproterone.

Co-Cyprindiol Tablets also act like an oral contraceptive, by preventing the release of eggs, thickening the mucus in the neck of the womb to stop sperm passing through, and making the lining of the womb unsuitable for an egg to grow on. You should not take another oral contraceptive whilst taking these tablets.

Co-cyprindiol Tablets 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 Co-cyprindiol Tablets 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 USE CO-CYPRINDIOL TABLETS

Please take the time to read the following information carefully as this may stop you from being able to take Co-cyprindiol Tablets.

#### Do not use Co-cyprindiol Tablets

Tell your doctor if any of the following conditions applies to you before starting to use Co-cyprindiol Tablets. Your doctor may then advise you to use a different treatment:

- If you are allergic (hypersensitive) to cyproterone acetate, ethinylestradiol, or any of the other ingredients of Co-cyprindiol Tablets
- If you are pregnant or if there is a chance you may be pregnant
- If you are breast-feeding
- If you are using another hormonal contraceptive
- If you have (or have ever had) a blood clot in your leg (thrombosis), lung (pulmonary embolism) or other part of your body
- If you have (or have ever had) a disease that may be an indicator of a heart attack in the future (e.g. angina pectoris which causes severe pain in the chest) or 'mini-stroke' (transient ischaemic attack)
- If you have (or have ever had) a heart attack or stroke
- If you have a condition that may increase the risk of 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 problems with blood clotting (e.g. protein C deficiency)
- If you have (or have ever had) a migraine, with visual disturbances
- If you suffer from sickle cell anaemia (abnormal blood cells)
- If you have or have ever had breast cancer or endometrial (womb) cancer
- If you have vaginal bleeding of unknown cause
- If you have Dubin-Johnson or Rotor syndrome (types of jaundice)
- If you have or have ever had liver tumours
- If you have or have ever had liver disease
- If you have or have ever suffered from severe depression
- If you have or have ever had speech difficulties, arm or leg weakness and sensory abnormalities.

If you have had any of the following conditions when you were pregnant:

- itching of your whole body (pruritus)
- herpes rash (herpes gestationis)
- worsening of deafness (otosclerosis)
- yellowing of the skin or whites of the eyes (jaundice).

If any of the above apply to you and you have not already discussed this with your doctor or pharmacist, you should do so as soon as possible and before taking any tablets.

#### Warnings and precautions

Your doctor should check your medical history and that of your family before you start taking these tablets and on a regular basis whilst you are using Co-cyprindiol Tablets. He will also take your blood pressure and may check your breasts, abdomen and pelvic organs if considered necessary. You may also need to have a cervical smear. Your doctor will also make sure you are not pregnant.

The following situations require special care whilst taking Co-cyprindiol Tablets:

- If anyone in your family has suffered a heart attack, a stroke at a young age or an illness caused by blood clots
- If anyone in your family has had breast cancer
- If you have ever suffered or you are suffering from severe depression
- If you have varicose veins
- If you have diabetes (diabetes mellitus) or a tendency towards diabetes e.g. high levels of sugar in your urine
- If you have high blood pressure
- If you suffer from epilepsy (fits)
- If you have deafness (otosclerosis)
- If you have multiple sclerosis (disease of the nervous system)
- If you suffer from porphyria (a genetic disease)
- If you have calcium deficiency with cramps (tetany)
- If you have Sydenham's chorea (a movement disorder)
- If you have or have ever had breast disease
- If you suffer from disease of the heart and blood vessels
- If you have kidney problems
- If you have liver problems
- If you are obese (overweight)
- If you have an intolerance to contact lenses
- If you have Systemic lupus erythematosus (SLE – an inflammation of connective tissue)
- If you have asthma
- If you have uterine fibroids (benign tumour in the womb)
- If you have gallstones
- If you suffer from migraines
- If you have dark patches on your skin (chloasma)
- If you have any diseases which are known to worsen during pregnancy
- If you ever had or have phlebitis (inflamed veins).

If any of the above apply to you and you have not already discussed this with your doctor or pharmacist, you should do so as soon as possible and before taking any tablets.

If any of these conditions get worse, or if you experience them for the first time, you should not take any more tablets until you have discussed it with your doctor.

#### When should you contact your doctor

Stop taking tablets and contact your doctor immediately if you notice possible signs of a blood clot. The symptoms are described in section 2 'Blood clots (Thrombosis)'.

Co-cyprindiol Tablets 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.

If you stop taking your tablets, remember to use another form of contraception, like a condom or a cap with spermicide if you are using Co-cyprindiol Tablets for oral contraceptive purposes.

### Sunbeds/Sun-ray lamps (ultraviolet)/Sunbathing

You should avoid sunbeds and prolonged sunbathing if you are taking Co-cyprindiol Tablets, as this will increase the risk of developing chloasma (darkened patches of skin), as with ordinary oral contraceptives.

### Blood clots (thrombosis)

Taking Co-cyprindiol Tablets may slightly increase your risk of having a blood clot (called a thrombosis). Your chances of having a blood clot are only increased slightly by taking Co-cyprindiol Tablets compared with women who do not take Co-cyprindiol Tablets or any contraceptive pill. A full recovery is not always made and in 1-2% of cases, can be fatal.

### 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:

- with increasing age
- if you smoke. When using a hormonal contraceptive like Co-cyprindiol Tablets you are strongly advised to stop smoking, especially if you are older than 35 years
- if one of your close relatives has had a blood clot in the leg, lung or other organ at a young age
- if you are overweight
- if you must have an operation, or if you are off your feet for a long time because of an injury or illness, or you have your leg in a plaster cast.

If this applies to you, it is important to tell your doctor that you are using Co-cyprindiol Tablets as the treatment may have to be stopped. Your doctor may tell you to stop using Co-cyprindiol Tablets several weeks before surgery or while you are less mobile. Your doctor will also tell you when you can start using Co-cyprindiol Tablets 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:

- with increasing age
- if you smoke. When using a hormonal contraceptive like Co-cyprindiol Tablets 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 a high level of fat in your blood (cholesterol or triglycerides)
- if you get migraines
- if you have a problem with your heart (valve disorder, disturbance of the rhythm).

### Symptoms of blood clots

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

- an unusual sudden cough
- severe pain in the chest which may reach the left arm
- breathlessness
- any unusual, severe, or long-lasting headache or worsening of migraine
- partial or complete loss of vision, or double vision
- slurring or speech disability
- sudden changes to your hearing, sense of smell, or taste
- dizziness or fainting
- weakness or numbness in any part of your body
- severe pain in your abdomen
- severe pain or swelling in either of your legs.

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

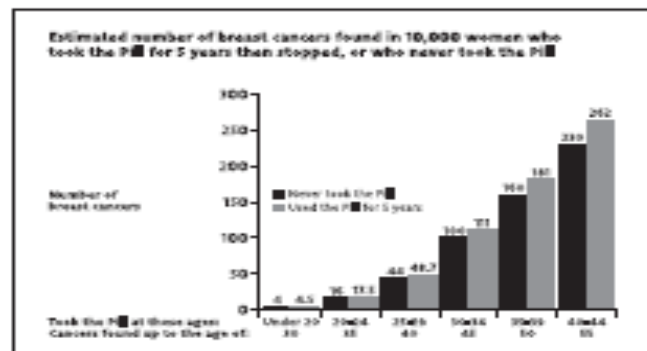
Directly after giving birth, women are at an increased risk of blood clots so you should ask your doctor how soon after delivery you can start taking Co-cyprindiol Tablets.

The skin problems treated by Co-cyprindiol Tablets may sometimes be caused by conditions such as polycystic ovarian syndrome, which may also increase the risk of disease of the heart and blood vessels.

### The pill and cancer

The pill does give a substantial degree of protection against cancers of the ovary and the lining of the womb. An increased risk of cervical cancer in long-term users of the pill has been reported in some studies. It is uncertain whether this increased risk is caused by the pill as it could be due to the effects of sexual behaviour and other factors.

- Every woman is at risk of breast cancer whether or not she takes the Pill. Breast cancer is rare under the age of 40 years, but the risk increases as a woman gets older. Breast cancer has been found slightly more often in women who take the Pill than in women of the same age who do not take the Pill. If women stop taking the Pill this reduces the risk so that 10 years after stopping the Pill, the risk of finding breast cancer is the same as for women who have never taken the Pill. Breast cancer seems less likely to have spread when found in women who take the Pill than in women who do not take the Pill.
- It is not certain whether the Pill causes the increased risk of breast cancer. It may be that women taking the Pill are examined more often, so that breast cancer is noticed earlier. The risk of finding breast cancer is not affected by how long a woman takes the Pill but by the age at which she stops. This is because the risk of breast cancer strongly increases as a woman gets older.
- The chart below shows the background chances of breast cancer at various ages for 10,000 women who have never taken the Pill (black bars) and for 10,000 women whilst taking the Pill and during the 10 years after stopping it (grey bars). The small extra risk of finding breast cancer can be seen for each age group. This small possible additional risk in women who take the Pill has to be balanced against the fact that the Pill is a very effective contraceptive and it may also help prevent cancer of the womb or ovary.



- On rare occasions, the use of the pill has led to liver diseases such as jaundice and benign liver tumours, and, very rarely, it has been associated with some forms of malignant liver tumours (cancer) in long-term users. Liver tumours may lead to life-threatening intra-abdominal haemorrhage (bleeding in the abdomen). Therefore, if you have pain in the upper abdomen that does not soon clear up, tell your doctor. Also, if your skin becomes yellow (jaundice) you must tell your doctor.
- Certain conditions may sometimes get worse during use of the pill. The diseases are those listed under 'Before you use Co-cyprindiol Tablets'.

### When you should stop taking Co-cyprindiol Tablets immediately

You must stop taking the tablets immediately if you experience any of the following conditions, and report them to your doctor as soon as possible. Remember to use another form of contraception, like a condom or cap with spermicide if you are using Co-cyprindiol Tablets for contraceptive purposes.

- Yellowing of the skin or whites of the eyes (jaundice), inflammation of the liver (hepatitis) or itching all over your body
- Increased frequency of fits (epilepsy)
- A large increase in your blood pressure
- Severe depression
- Worsening of any conditions which had got worse during a previous pregnancy or whilst taking the pill or other hormonal contraception (injection, implant, intrauterine system) in the past
- Pregnancy or if you think you might be pregnant
- Surgery or extended rest periods – for a planned major operation (e.g. stomach surgery, surgery on your legs or treatment for varicose veins) you must stop taking the tablets 6 weeks before. If you have to have an extended rest period, either after surgery, an accident or illness, you must also stop taking Co-cyprindiol Tablets. Your doctor will advise you when to start taking the tablets again.

### Other medicines and Co-cyprindiol Tablets

Some medicines can stop Co-cyprindiol Tablets working properly. If a doctor prescribes you another medicine, you should tell them you are taking Co-cyprindiol Tablets. If you are taking Co-cyprindiol Tablets for contraception your doctor will advise you whether you should use another form of contraception and for how long. Medicines which may stop Co-cyprindiol Tablets from working properly include:

- Antibiotics (e.g. ampicillin and rifampicin). For further information on rifampicin please see below)
- Griseofulvin (an antifungal)
- Phenylbutazone (an anti-inflammatory drug for joint diseases)
- Phenytoin, Primidone, Phenobarbital, Carbamazepine and other medicines used for epilepsy
- Barbiturates (anaesthetics, sleeping tablets or sedatives) e.g. amobarbital, butobarbital or secobarbital
- Oral tetracyclines.

If you are given any of the above medicines and are relying on Co-cyprindiol Tablets for contraception, you will need to use another form of contraception, like a condom or a cap with spermicide, from when you start taking the medicine, and for 7 days after you finish taking it. If your current pack of tablets runs out before these 7 days, carry on into the next pack without taking a break. This may mean you do not have a period until after the end of the second pack but this is not harmful. If you do not have a period at the end of the second pack, you must talk to your doctor before starting another pack.

A doctor may give you other oral antibiotics for your acne as well as this medicine. If so, you must make sure they are aware that you wish to use Co-cyprindiol Tablets as a form of contraception. Medication to be applied to the skin, including antibiotics, will not affect the contraceptive effects of these tablets.

If you are given rifampicin and you are using Co-cyprindiol Tablets for contraception, you must use a different form of contraception from when you start taking it and for 4 weeks after you finish taking it.

If you are diabetic your doctor may alter the dose of your diabetes medicine.

The herbal remedy St John's wort (*Hypericum perforatum*) should not be taken at the same time as Co-cyprindiol Tablets. If you already take a St John's wort preparation, stop taking the St John's wort and mention it to your doctor at your next visit.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. If you are not sure whether another medicine you are taking may be one of the types listed, check with your doctor or pharmacist.

### Pregnancy and breast-feeding

You must not take Co-cyprindiol Tablets if you are pregnant or breast-feeding.

Androgens (male sex hormones) are necessary for the development of the sexual organs in males, and the strong action of cyproterone acetate (contained in Co-cyprindiol Tablets) against androgens has been found to prevent the normal development of these organs during pregnancy in experimental animals. The degree of risk in humans of such an effect (known as "feminisation") is uncertain and for this reason it is absolutely essential that you should not be pregnant while taking Co-cyprindiol Tablets. If you think you might be pregnant, stop taking Co-cyprindiol Tablets and consult your doctor immediately. Use another method of contraception such as a condom until you see your doctor.

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

### Driving and using machines

It is unlikely that you will experience any side effects which will affect your ability to drive or operate machinery.

### Co-cyprindiol Tablets contain sucrose and lactose

Co-cyprindiol Tablets contain sucrose and lactose which are types of sugars. 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 CO-CYPRINDIOL TABLETS

Always take Co-cyprindiol Tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. If you are relying on this medicine for contraception it is important to follow these instructions carefully.

### When to start taking Co-cyprindiol Tablets

If you are new to taking Co-cyprindiol Tablets, or are restarting after a break, take your first tablet on the first day of your period. Start with a tablet labelled with the correct day of the week (Other users should see sections 'Changing from another type of oral contraceptive', 'Starting Co-cyprindiol Tablets after having a baby' and 'Starting Co-cyprindiol Tablets after having a miscarriage or an abortion').

### Taking your first pack of Co-cyprindiol Tablets

After taking your first pill, take one each day, following the direction of the arrows, until you have taken all 21 pills in the pack. You should try to take the pill at the same time every day, for example, after breakfast, and swallow whole, with water if required. You will have contraceptive cover straight away if you start in this way.

### Your 7 pill-free days

After taking all 21 pills, you have 7 days when you do not take a pill. A few days after taking the last pill in the pack, you will have your period. Your periods will be regular, probably lighter than before, and almost always painless. You are less likely to experience PMS (pre-menstrual syndrome), and can continue without any contraceptive protection during these 7 days, provided you have taken your previous pack correctly, and start the next pack on time.

### Taking your next pack of Co-cyprindiol Tablets

Start taking your next pack of pills after you have had 7 pill-free days. Each new pack will begin on the same day of the week as the one before. You should take the pill on this day even if you still have your period.

### Changing from another type of oral contraceptive 21 day pill

If you are taking another 21 day pill, finish your current pack, and then take your first Co-cyprindiol tablet the next day, and do not have a break between packs. Start with a pill labelled with the correct day of the week. Follow the instructions above under the section 'Taking your first pack of Co-cyprindiol Tablets'. You will have contraceptive cover straight away if you start in this way. You may not have your period until the end of your first Co-cyprindiol tablet pack, and may have some bleeding on pill-taking days, but this is normal.

### Every day (ED) combined pill (28 day pill)

Co-cyprindiol Tablets should be started after taking the last active pill from the everyday pill pack. If you are not sure which pills are the active ones, ask your doctor or pharmacist. Take the first Co-cyprindiol tablet the next day, without a break between packs. Start with a pill labelled with the correct day of the week. You will have contraceptive cover straight away if you start in this way. Take the remaining inactive tablets from your old pill to your pharmacist for disposal. Follow the instructions above under the section 'Taking your first pack of Co-cyprindiol Tablets'. You may not have your period until the end of your first Co-cyprindiol Tablet pack, and may have some bleeding on pill-taking days, but this is normal.

### Mini pill (progesterone-only pill / POP)

The first Co-cyprindiol tablet should be taken on the first day of your period, even if you have already taken a mini pill on that day. Start with a pill labelled with the correct day of the week. Follow the instructions above under the section 'Taking your first pack of Co-cyprindiol Tablets'. You will have contraceptive cover straight away if you start in this way. Take the remainder of your mini pills to your pharmacist for disposal.

### Starting Co-cyprindiol Tablets after having a baby

Your doctor may advise you to start taking Co-cyprindiol tablets 21 days after delivery. You do not have to wait for your period. You will need to use an additional method of contraception until you start Co-cyprindiol Tablets, and for the first 7 days of the pack. Follow the instructions above under the section 'Taking your first pack of Co-cyprindiol Tablets'. You must not breast-feed if you take this medicine.

### Starting Co-cyprindiol Tablets after having a miscarriage or an abortion

Your doctor may advise you to start taking Co-cyprindiol Tablets straight away. Follow the instructions above under the section 'Taking your first pack of Co-cyprindiol Tablets'.

### While you are taking Co-cyprindiol Tablets

You should expect to find your skin is less greasy after a few weeks, and see a clear improvement in your acne after about 3 months. If you are taking this medicine to treat excessive hair growth on your face and body, it may take several months before you can see a clear improvement. The delay is because this medicine treats the underlying cause of the acne and hair growth, and not the actual spots or hair you have at the time.

### How long can you take Co-cyprindiol Tablets?

Your doctor will stop treating you with this medicine when your skin is completely clear or your hair growth has decreased. If the problem comes back, you can take further courses for as long as necessary.

### What to do if you miss a period

If you do not have your period in the 7 pill-free days, whether you have missed any pills or not, you should tell your doctor as soon as possible and do not start another pack until your doctor tells you to. In the meantime you must use another form of contraception.

### **If you bleed between periods**

Some women experience a little breakthrough bleeding or spotting while they are taking this medicine, but this is normal and will stop in a day or two. If you continue to take your pills as usual, the problem should disappear after the first few packs. However, if the bleeding keeps returning, is annoying or long lasting, talk to your doctor. It can also be a sign that you are not taking your pill regularly enough, so try to take it at the same time every day.

### **What to do if you want to have a baby**

The bleeding you have during your 7 pill-free days, and after the last pack you take, is not a true period. Your doctor will use the date of your last true period before you get pregnant to predict when your baby is due. Therefore, if you stop taking Co-cyprindiol Tablets so you can have a baby, you should use another method of contraception until you have had a true period, but it is not harmful to you or your baby if you get pregnant straight away.

### **Duration of use**

Your doctor will tell you how long you need to keep taking Co-cyprindiol Tablets.

### **Stomach upsets**

If you are sick or have severe diarrhoea, it may stop your medicine from working properly. If you are ill in this way, carry on taking your pills as normal, but you must also use another form of contraception, like a condom or a cap with spermicide. You must do this from when you become ill and for 7 days after you get better. If your current pack runs out before these 7 days, start the next pack without taking a break. This may mean you do not have a period until after the end of the second pack. If you do not have a period at the end of the second pack, you must talk to your doctor before starting another pack. If your sickness or diarrhoea continues for a long time, see your doctor who may consider another form of contraception for you.

### **If you take more Co-cyprindiol Tablets than you should**

If you take more tablets than you should, you must talk to a doctor or pharmacist immediately. Overdose may make you sick or feel sick, and may cause withdrawal bleeding. You should discuss with your doctor any action to take, if necessary.

### **If you forget to take Co-cyprindiol Tablets:**

Do not take a double dose to make up for a forgotten tablet.

### **If you forget to take your pill and are relying on it for contraceptive cover**

#### **1. If you are more than 12 hours late in taking your pill, or if you have missed more than one**

Your contraceptive protection will be lower, so you must use extra protection. Follow the instructions for the 7 day rule:

Take the most recent 'late' pill and continue to take your next pills at the normal time and use extra contraception, like a condom or a cap with spermicide for the next 7 days and if your current pack runs out before these 7 days, carry on into the next pack without taking a break. This may mean you do not have period until after the end of the second pack, and may have some bleeding on pill-taking days, but this is normal. If you do not have a period at the end of the second pack, you must talk to your doctor before starting another pack.

#### **2. If you have missed one pill by 12 hours or less**

If you have only missed one pill, and you were due to have taken it 12 hours ago or less, take it straight away, take the rest of your pills as normal, and your contraceptive cover will not be affected.

### **What to do if you lose a pill**

The easiest thing to do if this happens is to take the last pill of the pack in place of the lost one. Then continue to take the rest of the pills on the correct days. Your cycle will then finish a day earlier, but you will still have contraceptive cover. You will then start your next pack one day earlier than before. If you lose the entire pack halfway through, ask your doctor or pharmacist what you should do.

### **If you stop taking Co-cyprindiol Tablets**

When you stop taking Co-cyprindiol Tablets it may take some time for your regular periods to return to normal, particularly if you experienced problems before taking Co-cyprindiol Tablets.

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

## **4 POSSIBLE SIDE EFFECTS**

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

Serious reactions have been associated with contraceptive pills that contain oestrogen and progestogen. Although Co-cyprindiol Tablets are not actually a contraceptive pill, some of the actions mean it should be considered as one. These serious reactions include venous blood clot (a clot that forms in blood vessels) or liver disease. These serious reactions are explained in more detail in Section 2 'Before you use Co-cyprindiol Tablets'.

The following side effects may also occur with Co-cyprindiol Tablets:

- Effects on the Blood – taking this medicine may affect the results of some blood tests. Tell the doctor or nurse taking the test that you take Co-cyprindiol Tablets.
- Effects on the Nervous System – headaches, depressive moods, increased or decreased interest in sex. Severe depression has sometimes been associated with contraceptive pills that contain oestrogen and progestogen (see "When you should stop taking Co-cyprindiol Tablets immediately").
- Effects on the Stomach – stomach upsets, feeling or being sick
- Effects on the Liver – liver disease
- Effects on the Skin – dark patches of skin (chloasma). This can be reduced by avoiding prolonged sunbathing and sunbeds.
- Effects on the Reproductive System – breast tenderness, reduction in flow of periods, missed periods, bleeding/spotting between periods (especially during the first few months)
- General Effects – weight changes, poor tolerance to contact lenses.

If you think that you have had a serious adverse reaction to these tablets, stop taking them and consult your doctor immediately.

Although severe depression is not considered a direct side effect of Co-cyprindiol Tablets, if you develop severe depression you should stop taking Co-cyprindiol Tablets as a precaution.

### **Reporting of side effects:**

If you get any side effects, talk to your doctor, pharmacist or nurse. 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.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

## **5 HOW TO STORE CO-CYPRINDIOL TABLETS**

### **Keep out of the sight and reach of children.**

Store below 30°C in the original package. Do not use this medicine after the expiry date which is stated on the carton after 'Expiry date'. The expiry date refers to the last day of that month.

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 Co-cyprindiol Tablets contain**

- The active substances are cyproterone acetate and ethinylestradiol. Each tablet contains 2000 micrograms of cyproterone acetate and 35 micrograms of ethinylestradiol.
- The other ingredients are lactose monohydrate, maize starch, povidone K25, talcum, magnesium stearate (E572). The tablet coating contains sucrose, calcium carbonate (E170), macrogol 6000, povidone K90, titanium dioxide (E171), glycerol 85 % (E 422), montan glycol wax, iron oxide pigment (E 172).

### **What Co-cyprindiol Tablets look like and contents of the pack**

Co-cyprindiol Tablets are round, biconvex, yellow sugar-coated tablets. The tablets are available in blister packs containing 3 x 21 or 1 x 21 calendar packs. Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### **Marketing Authorisation Holder:**

TEVA UK Limited,  
Eastbourne, BN22 9AG.

#### **Manufacturer:**

Teva Operations Poland Sp. z o.o.  
80, Mogilska Str., 31-546 Krakow, Poland

### **This medicinal product is authorised in the Member States of the EEA under the following names:**

United Kingdom Co-cyprindiol 2000/35 Coated Tablets

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