

## Package Leaflet: Information for Co-cyprindiol 2000/35 Tablets Co-cyprindiol 2000/35 Tablets (cyproterone acetate and 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. Do not pass it on to others. It may harm them, even if their symptoms 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 Co-cyprindiol Tablets are and what they are used for
2. What you need to know before you take Co-cyprindiol Tablets
3. How to take Co-cyprindiol Tablets
4. Possible side effects
5. How to store Co-cyprindiol Tablets
6. Contents of this pack and other information

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

Co-cyprindiol Tablets contain a combination of two active substances. Ethinylestradiol is an oestrogen and cyproterone acetate is an anti-androgen. Co-cyprindiol is used to treat skin conditions such as acne, very oily skin and excessive hair growth in a woman 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 conditions have not improved after use of other anti-acne treatments, including topical treatments and antibiotics.

## 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CO-CYPRINDIOL TABLETS

### Do not take Co-cyprindiol Tablets:

- if you are using another hormonal contraceptive
- if you have hepatitis C and are taking the medicinal products containing ombitasvir / paritaprevir / ritonavir, neflavinir, nevirapine and dasabuvir (see also in section Other medicines and Co-cyprindiol Tablets).
- if you are **allergic** (hypersensitive) to ethinylestradiol or cyproterone acetate or any other ingredients of **Co-cyprindiol Tablets** (listed in section 6).
- if you are (or think you are) **pregnant or breast-feeding**
- have (or have ever had) a **blood clot** in your leg (thrombosis), lung (pulmonary embolism) or other part of your body.
- if you have problems with blood clotting (e.g. protein C deficiency)
- if you or any close family members have any medical condition which makes you more **at risk of a thrombosis** (see Oral contraceptives and blood clots (thrombosis))
- if you have (or have ever had) a disease that may be an indicator of 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 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 (or have ever had) a **migraine, with visual disturbances**
- if you suffer from **sickle cell anaemia** (abnormal red blood cells)
- if you have disorders of **lipid metabolism** (high blood cholesterol or triglycerides)
- if you have cancer of the breast or of the **lining of the womb** (mammary or endometrial carcinoma) or a history of these conditions
- if you suffer from **abnormal vaginal bleeding** of unknown cause
- if you have certain types of **jaundice** (Dubin-Johnson or Rotor syndromes)
- if you have **liver tumours** or have ever had these
- if you have any other short or long term **liver disease**
- if you have meningioma or have ever been diagnosed with a meningioma (a generally benign tumour of the tissue layer between the brain and the skull)
- **if you have had any of the following conditions whilst pregnant:**
  - itching of your whole body (pruritus of pregnancy)
  - a blister-like rash, often on the soles of your feet or palms of your hands
  - a hearing problem
  - jaundice which was not caused by infection (jaundice of pregnancy).

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.

### Warnings and precautions

Before you start taking Co-cyprindiol Tablets, your doctor will have given you a check-up to see if it is suitable for you to take.

For high doses (25 mg and above) of cyproterone acetate an increased risk of a benign brain tumour (meningioma) has been reported. If you are diagnosed with meningioma, your doctor will stop all cyproterone containing products, including Co-cyprindiol as a precautionary measure (see section 'Do not take Co-cyprindiol').

### While you are on Co-cyprindiol

You will need to have regular check-ups with your doctor while taking Co-cyprindiol. You should have regular cervical smear tests. You should check your breasts and nipples every month for changes and tell your doctor if you can see or feel anything different, such as lumps or dimpling of the skin.

If you need a blood test, tell your doctor you are taking Co-cyprindiol, because this type of medicine can affect the results of some tests. If you are going to have an operation, make sure your doctor knows about it. You may need to stop taking Co-cyprindiol 4-6 weeks before the operation. This is to reduce the risk of a blood clot. Your doctor will tell you when you can start taking Co-cyprindiol again. If you need to stop taking Co-cyprindiol, remember to use another contraceptive (e.g. condoms) if you are relying on Co-cyprindiol for contraception. A number of medical conditions need watching carefully while you are taking Co-cyprindiol Tablets.

**Tell your doctor if you have any of the following conditions now, or have had them in the past before taking Co-cyprindiol Tablets:**

- depression, or have suffered from depression in the past
- varicose veins or inflamed veins (phlebitis)
- diabetes
- high blood pressure (hypertension)
- fits (epilepsy)
- an inherited form of deafness known as otosclerosis
- a disease of the nervous system called multiple sclerosis
- an inherited metabolic disease called porphyria
- cramps caused by calcium deficiency (tetany)
- a movement disorder called Sydenham's chorea
- breast problems, past or present or if anyone in your immediate family has had breast cancer
- any heart or circulation problems or if anyone in your family has had any illness caused by blood clots, or a heart attack or stroke at a young age
- kidney diseases
- problems with the way your liver works
- you are overweight (obese)
- an intolerance to contact lenses
- systemic lupus erythematosus (inflammation of connective tissue)
- asthma
- uterine fibroids (benign tumour of the womb)
- gallstones
- migraine
- brown patches on the face and body (chloasma)
- any disease that is likely to worsen during pregnancy

The worsening or first appearance of any of these conditions may mean that treatment with Co-cyprindiol Tablets **should be stopped**. You should contact your doctor for further advice.

### Psychiatric disorders:

Some women using hormonal contraceptives including Co-cyprindiol have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

### SUNBEDS/SUN-RAY LAMPS (ULTRA VIOLET)

Ultraviolet lamps are used by some women for acne as well as to tan the skin. These lamps and prolonged sunbathing **should be avoided** if you are taking Co-cyprindiol Tablets as their use increases the chance of chloasma, a patchy discoloration of the skin.

### ORAL CONTRACEPTIVES AND 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.

### Blood Clots (thrombosis)

Taking Co-cyprindiol may slightly increase your risk of having a blood clot (called thrombosis). Your chances of having a blood clot are only increased slightly by taking Co-cyprindiol compared with woman who does 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 a 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 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 when on the pill, especially if you are over 35 years old.**

- if any close family member has had a **blood clot in the leg, lung or other organ at a young age**
- if you are **very 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.

And also if you have:

- a **disorder of blood fat** (lipid) metabolism, or other very rare blood disorders
- **high blood pressure**
- a **heart valve disorder** or a certain **heart rhythm disorder**
- **given birth recently** – the risk of thrombosis is increased for up to 6 weeks after giving birth
- **diabetes mellitus**
- **systemic lupus erythematosus** (SLE; a disease affecting the skin all over the body)
- **haemolytic uraemic syndrome** (HUS; a disorder where blood clots make the kidneys fail)
- **Crohn's Disease or ulcerative colitis** (chronic inflammatory bowel disease)
- **sickle cell disease**
- had a **subarachnoid haemorrhage** (bleeding from the blood vessels of the brain)

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)

**Signs and symptoms of blood clots are given in Section 4, Possible side effects.**

**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)'.**

The skin problems that Co-cyprindiol is used to treat may sometimes be caused by conditions such as polycystic ovarian syndrome, which may also increase the risk of cardiovascular disease.

### ORAL CONTRACEPTIVES AND CANCER

#### Ovarian and endometrial cancer:

While high doses of combined oral contraceptives (COC's) reduce the risk of cancer of the ovary and the lining of the womb (endometrium), it is not clear whether estrogen-progesterone containing Pills like Co-cyprindiol also provide the same protective effects. However, it also seems taking Co-cyprindiol slightly increases your risk of cervical cancer although this may be due to other factors such as sexual behaviour including having sex without a condom rather than Co-cyprindiol. All women should have regular **smear tests**.

#### Breast cancer:

Every woman is at risk of breast cancer whether or not she takes the Pill (Co-cyprindiol in this case). 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.

Of 10,000 women who have never taken the Pill or Co-cyprindiol, about 16 will have breast cancer by the time they are 35. Of 10,000 women who have taken the Pill or Co-cyprindiol for 5 years, whilst in their early 20's, about 17-18 will have breast cancer by the time they are 35. Of 10,000 women who have never taken the Pill or Co-cyprindiol, about 100 will have breast cancer by the time they are 45. Of 10,000 women who have taken the Pill or Co-cyprindiol for 5 years, whilst in their early 30's, about 110 will have breast cancer by the time they are 35.

Your risk of breast cancer is higher

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

**You should check your breasts regularly whilst taking this medicine and tell your doctor if you notice any changes, to your breasts such as the appearance of lumps or dimpling of the skin.**

#### Liver cancer:

In rare cases benign liver tumours and even more rarely malignant liver tumours have been reported in users of Co-cyprindiol.

#### Other medicines and Co-cyprindiol Tablets

Do not use Co-cyprindiol 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. Co-cyprindiol can be restarted approximately 2 weeks after completion of this treatment. See section "Do not use Co-cyprindiol".

Some medicines may affect the way Co-cyprindiol works as a contraceptive. Please tell your doctor, any hospital or dentist you visit that you are taking Co-cyprindiol Tablets. Also, you should tell your doctor/dentist or pharmacist if you are taking or have recently taken **any other medicines**, including medicines obtained without a prescription.

Medicines which can sometimes stop Co-cyprindiol Tablets from working properly as a contraceptive are:

- antibiotics to treat a bacterial infection (such as ampicillin and rifampicin);
- tetracycline antibiotics taken by mouth;
- griseofulvin (used to treat fungal infections);
- phenylbutazone (used as an anti-inflammatory drug to treat some types of joint diseases);
- medicines used to treat epilepsy such as phenytoin, primidone, phenobarbitone, barbiturates and carbamazepine (which can be used to treat epilepsy or other illnesses);
- arthritis, arthrosis (etoricoxib).

If you are relying on Co-cyprindiol Tablets for contraception and you are taking any of the above listed medicines **you will also need to use an extra contraceptive method** (condoms or cap plus spermicide) while you are taking the other medicine and for 7 days after you stop taking it. If your present pack ends before these 7 days, start the next pack the next day without a break. If you run two packs together you may not have a period until the end of two packs. If you do not have a period after the second pack, you must talk to your doctor before you start the next pack.

If your doctor prescribes **oral antibiotics** as well as Co-cyprindiol Tablets for the treatment of your acne, you must tell your doctor that you want to rely on this medicine for contraception. Medicines applied to the skin, including antibiotics, will not affect the contraceptive reliability of Co-cyprindiol Tablets.

If you are taking **rifampicin**, and you are relying on Co-cyprindiol Tablets for contraception, **you will need to use another method of contraception as well.** You should do this while you are taking the rifampicin and for 4 weeks after you stop. If you are **diabetic** your doctor may tell you to use more insulin or other anti-diabetic medicines.

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 it and mention it to your

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doctor at your next visit. The use of this medicine may affect the results of certain laboratory tests. Always tell your doctor or the laboratory staff that you are taking Co-cyprindiol Tablets.

Co-cyprindiol may influence the effect of other medications (such as cyclosporine and lamotrigine) and may need to be adjusted by your doctor.

#### **Pregnancy, breast-feeding and fertility**

Androgens (male sex hormones) are necessary for the development of the sexual organs in males. Cyproterone acetate, one of the active ingredients in these tablets, has a strong action against androgens and studies in pregnant animals have shown that it prevents the normal development of these male sexual organs. The risk of such an effect (called "feminisation") in humans is uncertain. Therefore it is absolutely essential that you **do not take Co-cyprindiol Tablets whilst pregnant.**

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. Use another contraceptive, such as a condom, until you talk to your doctor.

#### **Co-cyprindiol contains lactose.**

If you have been told by your doctor that you have an **intolerance to some sugars** contact your doctor before taking this medicine.

### **3. HOW TO TAKE CO-CYPRINDIOL TABLETS**

Always take **Co-cyprindiol Tablets** exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Your doctor will tell you how long you need to keep taking Co-cyprindiol Tablets. It is important that you follow these instructions carefully especially if you are relying on this medicine for contraception. This pack is designed to help you remember to take your pills.

#### **When to start**

- if you haven't taken Co-cyprindiol Tablets before or are starting it again after a break, take your first tablet on the first day of bleeding of your next period.
- start with a pill marked with the correct day of the week. For instance, if your period starts on a Wednesday, start with a pill marked "Wed".

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

- after taking your first pill, take one pill each day, following the directions of the arrows, until you have finished all 21 pills in the pack.
- you should try to take the pill at the same time every day, for example, after breakfast.
- swallow each pill whole, with water.
- by starting in this way you will have contraceptive protection at once.

#### **Your seven pill-free days**

After you have taken all 21 tablets, you have 7 days when you take no tablets. A few days after you have taken the last pill from each pack, you will have a period. Your periods will be regular, probably lighter than before and almost always painless. The feelings that often make the last days before a period unpleasant (called premenstrual syndrome) usually disappear. You are very unlikely to become pregnant during the 7 day break from taking the pill, as long as you have taken your pills correctly, and start the next pack on time.

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

Start taking your next pack of Co-cyprindiol Tablets after 7 pill-free days. Each new pack will begin on the same day of the week as the one before, so it is easy to remember when to start again. You should start taking your next pack after 7 days, even if you are still bleeding.

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

If you are taking a 21 day contraceptive pill, finish that pack and then start taking Co-cyprindiol the next day. Do not leave a gap between packs. Start with a pill marked with the correct day of the week. Then follow the instructions as described before (see "*Taking your first pack of Co-cyprindiol Tablets*"). By starting in this way you will have contraceptive protection at once. You may not have a period until the end of the first Co-cyprindiol Tablets pack, but this is not harmful. You may have some bleeding on pill-taking days, but do not worry.

#### **Every Day (ED) combined pill (28 day pill):**

Co-cyprindiol should be started after taking the last active tablet from the Every Day pill pack. If you are not sure which tablets are the active ones, ask your doctor or pharmacist. The first Co-cyprindiol tablet is taken the next day, which means that you do not leave a gap between packs. Start with a pill marked with the correct day of the week. Return to your pharmacist any remaining inactive tablets from your old Every Day pack. Then follow the instructions as before (see "*Taking your first pack of Co-cyprindiol Tablets*"). By starting in this way you will have contraceptive protection at once. You may not have a period until the end of the first pack, but this is not harmful. You may have some bleeding on pill-taking days, but do not worry.

#### **Mini pill (progestogen-only pill):**

The first Co-cyprindiol Tablet should be taken on the first day of the period, even if you have already taken a mini pill on that day. Return to your pharmacist any mini pills left in your old pack. Start with a pill marked with the correct day of the week. Follow the instructions as before (see "*Taking your first pack of Co-cyprindiol Tablets*"). By starting in this way you will have contraceptive protection at once.

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

If you have just had a baby, your doctor may advise you to start taking Co-cyprindiol 21 days after delivery. You do not have to wait for a period. You will need to use another method of contraception until you start Co-cyprindiol and for the first 7 days of pill taking. Follow the instructions as before (see "*Taking your first pack of Co-cyprindiol Tablets*"). You must not breast-feed if you take Co-cyprindiol.

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

If you have just had a miscarriage or an abortion your doctor may advise you to start using Co-cyprindiol immediately. Follow the instructions as before (see "*Taking your first pack of Co-cyprindiol Tablets*").

#### **While you are taking Co-cyprindiol Tablets**

Unlike treatments that are rubbed on the skin, this medicine does not treat existing spots but instead reduces the formation of new spots. It does this by stopping androgens from stimulating the grease-glands in the skin to produce too much grease. After a few weeks of taking the medicine you should notice that your skin has become much less greasy. After about three months you should see a definite improvement in acne. If you are taking this medicine to treat excessive hair growth on your body or face, you may have to wait a few months, possibly longer, to see a definite improvement.

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

Your doctor may stop treating you with this medicine when your skin is completely clear, or the amount of body and facial hair growth has decreased. You will be able to have further courses of treatment, for as long as is necessary, if the problem keeps returning.

#### **What to do if you miss a period?**

If you have no bleeding in the 7 day break, whether you have missed tablets or not, tell your doctor as soon as possible and do not start another pack until your doctor tells you to, as you could be pregnant. In the meantime, do not have sex unless you use condoms or a cap plus spermicide.

#### **What if you have bleeding between periods?**

A small number of women may have a little breakthrough bleeding or spotting while taking this medicine, especially during the first few months. Normally, this bleeding is nothing to worry about, and will stop in a day or two. Keep taking the pills as usual, and the problem should disappear after the first few packs. If the bleeding keeps on returning, is annoying or long-lasting, talk to your doctor. Also, if you have breakthrough bleeding for the first time after being on this medicine for a long time, you should see your doctor. Unexpected bleeding may also be a sign of irregular pill-taking, so try to take your pill at the same time every day.

#### **What if you forget to take Co-cyprindiol Tablets**

1. If one pill is **12 hours late or less:**  
Don't worry. Contraceptive protection should not be affected if you take the late pill at once, and keep taking your next pills at the usual time.
2. If you are **more than 12 hours late** in taking a pill, or have **missed more than one pill:**  
Contraceptive protection may 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 your normal times **and**
  - use an extra contraceptive method (condoms or cap plus spermicide) for the next 7 days **and**
  - if your present pack ends before the 7 days do, start the next pack the next day, without a break. This means taking a pill every day during your normal 7 pill-free days. You will not have a period until you have finished the next pack, but this is not harmful. You may see some bleeding on pill-taking days, but do not worry. If no bleeding occurs in the 7 day break at the end of this next pack, see the section entitled "What to do if you miss a period".

#### ***What should you do if you lose a pill?***

If you lose a pill, the easiest thing to do is to **take the last pill of the pack in place of the lost pill.** Then take all the pills on their proper days. Your cycle will be one day shorter than normal, but contraceptive protection is not affected. After your 7 pill-free days you will have a new starting day. One day earlier than before. Should you lose a pack of pills halfway through, ask your doctor or pharmacist what to do.

#### ***If you have a stomach upset***

Vomiting and diarrhoea may stop Co-cyprindiol from working properly. If this happens and you are relying on the medicine for contraception, carry on taking it as usual, but **you should also use another method of contraception** (condoms or cap plus spermicide), for 7 days after you have recovered from the stomach upset. If you finish your pack before these 7 days, start the next pack the next day without a break. If you run two packs together you may not have a period until the end of two packs. If you do not have a period after the second pack, you must talk to your doctor before starting the next pack. If your stomach upset continues for some time, consult your doctor who may consider another form of contraception.

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

The bleeding you have after each pack (including the last pack) is not a true period. Your doctor relies on the date of your last true period before you get pregnant to tell you when your baby will be born. So, if you stop taking Co-cyprindiol Tablets to have a baby, use another method of contraception until you have had a true period. However, it will not be harmful if you become pregnant straight away. You should be aware that when you stop taking Co-cyprindiol Tablets, your periods may not return immediately.

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

If you take more than your normal dose contact your doctor or the nearest hospital immediately. Take the carton containing any remaining tablets with you. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, **Co-cyprindiol Tablets** can cause some side effects, although not everybody gets them. If you experience any of the following symptoms, **STOP** taking the tablets and tell your doctor **IMMEDIATELY. Stop taking tablets and see your doctor immediately if you notice possible signs of a blood clot (thrombosis), for example:**

- **severe pains in the chest** which may reach the left arm
- **severe pain or swelling** in either of your **arms or legs**
- **severe pain in your abdomen**
- **weakness or numbness** in any part of your body
- **breathlessness**
- an **unusual sudden cough**, especially if you cough up blood
- **dizziness or fainting**
- partial or complete loss of vision, or double vision
- slurring or speech disability
- sudden changes in your hearing, sense of smell or taste anything unusual
- any unusual, severe, or long lasting headache or worsening of migraine
- a significant **rise in your blood pressure**
- yellowing of the skin (jaundice)
- an **increase in the number of fits** (epileptic seizures)
- **severe depression.**

#### **Common: may affect up to 1 in 10 people:**

Nausea, abdominal pain, weight increase, headache, depressed mood, mood altered, breast pain, breast tenderness.

#### **Uncommon: May affect up to 1 in 100 people:**

Vomiting, diarrhoea, fluid retention, migraine, loss of sex drive (libido decreased), enlargement of breast tissue (breast hypertrophy), rash, hives (urticaria)

#### **Rare: may affect up to 1 in 1,000 people:**

Contact lens intolerance, hypersensitivity or immune reactions, weight decreased, increased sex drive (libido increased), vaginal discharge, breast discharge, painful red nodulous lumps, (erythema nodosum), blistering "bullseye" skin rash (erythema multiforme), blood vessel obstruction (thromboembolism). 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.

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

- develop severe depression
- **a lump in your breast**
- severe **upper abdominal pains or unusual swelling of your abdomen**
- **worsening of conditions** which have got worse during a **previous pregnancy or whilst taking the pill or another hormonal contraception** (e.g., injection, implant, intra-uterine system) in the past.

#### **Side effects reported post marketing:**

- Worsening of hereditary angioedema
- High levels of triglycerides in the blood
- Worsening of pre-existing involuntary movements
- Crohn's disease or ulcerative colitis
- Disturbances in liver function

#### **If you suspect that you are pregnant, you should stop taking the tablets and contact your doctor for further advice.**

If you think that you have a serious adverse reaction to Co-cyprindiol Tablets, stop taking your tablets and consult your doctor as soon as possible. **However, remember that when you stop Co-cyprindiol Tablets you will need to use another contraception method if you want to avoid pregnancy.**

Sometimes the following mild unwanted effects can occur in the first few months after starting Co-cyprindiol Tablets:

- bleeding and spotting between your periods can sometimes occur for the first few months but this usually stops once your body has adjusted to Co-cyprindiol. If it continues, becomes heavy or starts again, contact your doctor
- headaches
- feeling sick, being sick and stomach upsets
- sore breasts
- depressive moods, loss of interest in sex
- chloasma (yellow brown patches on the skin). This may happen even if you have been using Co-cyprindiol for a number of months. Chloasma may be reduced by avoiding too much sunlight
- poor tolerance to contact lenses
- changes in body weight
- increased blood pressure

#### **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) or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects you can help provide more information on the safety of this medicine.

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

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

Do not take this medicine after the expiry date which is stated on the carton and blister strips after "EXP". The expiry date refers to the last day of the month. Store the tablets in their original package at a temperature below 25°C. Do not use this medicine if you notice any signs of deterioration to the carton, blister or tablets. Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away any medicines no longer in use. These measures will help protect the environment.

### **6. CONTENTS OF THIS PACK AND OTHER INFORMATION**

#### **What Co-cyprindiol Tablets contain:**

The **active substances** are cyproterone acetate 2 milligrams and ethinylestradiol 35 micrograms.

The other ingredients are lactose monohydrate, maize starch, povidone, purified talc, magnesium stearate, hypromellose, propylene glycol, titanium dioxide (E171) & quinoline yellow (E104).

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

Co-cyprindiol Tablets are yellow, round film coated tablets.

Your medicine is available in blister strips containing 21 tablets.

Each carton contains 1 or 3 blister strip packs.

Not all pack sizes may be marketed.

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

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

Kent Pharma UK Limited, The Bower, 4 Roundwood Avenue, Stockley Park, Heathrow, United Kingdom, UB11 1AF.

##### **Manufacturers responsible for batch release**

Kent Pharmaceuticals Limited, Crowbridge Road, Ashford, Kent, TN24 0GR, U.K.

Kent Pharmaceuticals Limited, Repton Road, Measham, DE12 7DT, U.K.

This leaflet was last revised in May 2020.