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Due to regulatory changes, the content of the following Patient Information Leaflet may vary from the one found in your medicine pack. Please compare the 'Leaflet prepared/revised date' towards the end of the leaflet to establish if there have been any changes.

If you have any doubts or queries about your medication, please contact your doctor or pharmacist.



Dianette Patient Information Leaflet

Package leaflet: Information for the user

Dianette[®]

cyproterone acetate/ethinylestradiol.

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

- Keep this leaflet. You may need to read it again.
- If you have any questions or need more advice, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them.
- **If any of the side effects gets severe**, or if you notice any not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT DIANETTE IS AND WHAT IT IS USED FOR

Dianette contains an oestrogen and an anti-androgen.

Dianette is used to treat skin conditions - severe acne that has not improved after the long term use of oral antibiotics and excessive hair growth.

Dianette also works as an oral contraceptive. However, do not use Dianette as a contraceptive unless you are also using it to treat your skin condition. You and your doctor will have to consider all the things that would normally apply to the safe use of an ordinary oral contraceptive ('the Pill').

If you are taking Dianette for skin treatment, **you must not take any other hormonal contraceptive at the same time.**

When your skin condition has cleared up and you stop taking Dianette, you will need to go back to your original/preferred method of contraception.

Treating skin conditions

Androgens are hormones that stimulate hair growth and the grease glands in your skin. If you produce too much androgen, or if you are sensitive to the effect, the grease glands may produce too much sebum. This can block the grease glands, which can become infected and inflamed causing acne spots. Dianette stops the androgens affecting your skin and reduces the amount of androgens produced.

Contraception

Dianette is a 21-day Pill – you take one each day for 21 days, followed by 7 days when you take no pills.

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

Dianette needs to be taken as directed to prevent pregnancy.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE DIANETTE

2.1 Before you take Dianette

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

→ **Tell your doctor** if you have any of the illnesses or risk factors mentioned in this leaflet.

Before you start taking Dianette

- 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.

While you're on Dianette

- You will need **regular check-ups** with your doctor, usually when you need another prescription of Dianette.
- 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 Dianette, 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 Dianette about 4–6 weeks before the operation. This is to reduce the risk of a blood clot (see section 2.1). Your doctor will tell you when you can start taking Dianette again.

- **If you need to stop taking Dianette**, remember to use another contraceptive (e.g. condoms) if you are relying on Dianette for contraception.

Dianette and blood clots

Taking Dianette 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, collapse or even death. This is called a *pulmonary embolism* and is very rare.

Your chances of having a blood clot are only increased slightly by taking Dianette.

- Of 100,000 women who are **not taking Dianette, 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 Dianette 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.

You are more at risk of having a blood clot:

- If you have **polycystic ovary syndrome**
- as you get **older**
- if you **smoke**
- if you or any of your close family have had **blood clots**
- if you are seriously **overweight**
- if you have a **disorder of blood fat (lipid) metabolism**, or some other **very rare blood disorders**
- if you get **migraines**
- if you have a **heart valve disorder** or a particular type of **irregular heartbeat** (atrial fibrillation)
- if you have **recently had a baby**
- if you have **high blood pressure**
- 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're **off your feet for a long time** because of major surgery, injury or illness.

→ **Tell your doctor if any of these apply to you.** Taking Dianette may add to this risk so may not be suitable for you.

Signs of a blood clot include:

- 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**.

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

Dianette 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 Dianette also provide the same protective effects. However, it also seems that taking Dianette slightly increases your risk of **cancer of the cervix** – although this may be due to having sex without a condom, rather than Dianette. All women should have regular **smear tests**.

If you have **breast cancer**, or have had it in the past, you should not take Dianette or other oral contraceptives, as they slightly increase your risk of breast cancer. This risk goes up the longer you're on Dianette, 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 Dianette users is small. For example:

- Of 10,000 women who have **never taken Dianette or the Pill**, about **16** will have breast cancer by the time they are 35 years old.
- Of 10,000 women who **take Dianette or the Pill for 5 years in their early twenties**, about **17–18** will have breast cancer by the time they are 35 years old.
- Of 10,000 women who have **never taken Dianette or the Pill**, about **100** will have breast cancer by the time they are 45 years old.
- Of 10,000 women who **take Dianette or the Pill for 5 years in their early thirties**, about **110** will 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 Dianette has also been linked to liver diseases, such as jaundice and non-cancer liver tumours, but this is rare. Very rarely, Dianette 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 Dianette.

2.2 Make sure Dianette is OK for you

Dianette should not be taken by some women

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

Do not take Dianette if any of the following apply to you. Taking Dianette would put your health at risk.

- 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 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 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 2.1, *Dianette and blood clots*)
- If you have any **symptoms of a blood clot**, such as **chest pain** (*angina pectoris*) or **‘mini-stroke’** (*transient ischaemic attack*)
- If you have **very high** or **uncontrolled blood pressure**
- If you 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 ever had **liver tumours**
- If you have severe **diabetes affecting your blood vessels**
- If you are **allergic** (*hypersensitive*) to any of the ingredients in Dianette.

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

Dianette can make some illnesses worse

Some of the conditions listed below can be made worse by taking Dianette. Or they may mean it is less suitable for you. You may still be able to take Dianette 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**
- 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 ‘Dianette and sun-beds or sun-lamps’)
- If you have **any illness that worsened during pregnancy or previous use of the Pill or Dianette** (see section 4)

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

Taking other medicines

If you ever need to take another medicine at the same time as taking Dianette, always tell your doctor, pharmacist or dentist that you’re taking Dianette. Also check the leaflets that come with all your medicines to see if they can be taken with hormonal contraceptives.

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

Some medicines can stop Dianette from working properly – for example:

- **some medicines used to treat epilepsy**
- **some medicines used to treat HIV**
- **griseofulvin** (an anti-fungal medicine)
- **certain antibiotics** (oral tetracyclines)
- **certain sedatives** (called *barbiturates*)
- **St. John’s Wort** (a herbal remedy).

If you do need to take one of these medicines, Dianette 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.

Dianette can also affect how well other medicines work. Your doctor may need to adjust the dose of your other medicine.

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

Taking Dianette with food and drink

There are no special instructions about food and drink while on Dianette.

Pregnancy and breast-feeding

Do not use Dianette 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 Dianette.

Driving and using machines

Dianette has no known effect on the ability to drive or use machines.

Dianette contains lactose and sucrose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before using Dianette.

Dianette 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 Dianette. Their use increases the chance of chloasma, a patchy discolouration of the skin (as it does with ordinary oral contraceptives).

3. TAKING DIANETTE

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

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

How to take it

Take Dianette every day for 21 days

Dianette 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 Dianette 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 Dianette 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 Dianette correctly, you will always start each new strip on the same day of the week.

Starting Dianette

New users or starting Dianette after a break

It is best to take your first Dianette 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 Dianette from another contraceptive Pill

- **If you are currently taking a 21-day Pill:** start Dianette 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 Dianette.
- **If you are taking a 28-day Pill:** start taking Dianette 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 Dianette.
- **If you are taking a progestogen-only Pill (POP or ‘mini Pill’):** start Dianette on the first day of bleeding, even if you have already taken the progestogen-only Pill for that day. You will have contraceptive cover straight away.

Starting Dianette 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 Dianette 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 Dianette 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 Dianette and for the first 7 days of pill taking.

Do not take Dianette if you are breast-feeding

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 you 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 Dianette**, follow the instructions in section 3.4 *A lost pill*, which describes how to take another pill.

If you are still sick or have diarrhoea **more than 12 hours after taking Dianette**, see section 3.3, *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 Dianette 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 Dianette 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, Dianette can cause side effects, although not everybody gets them.

→ **Tell your doctor or pharmacist** if you are worried about any side effects which you think may be due to Dianette.

4.1 Serious side effects – see a doctor straight away

Severe depression:

Although, it is not considered a direct side effect of Dianette, you should stop Dianette as a precaution, if you develop severe depression, and see your doctor straight away.

Signs of a blood clot:

- 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**.

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

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

Signs of breast cancer include:

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

Signs of cancer of the cervix include:

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

Signs of severe liver problems include:

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

→ **If you think you may have any of these, see a doctor straight away.** You may need to stop taking Dianette.

4.2 Less serious side effects

Common side effects (between 100 and 1000 in every 10,000 users may be affected)

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

Uncommon side effects (between 10 and 100 in every 10,000 users may be affected)

- **being sick** and **stomach upsets**
- **fluid retention**
- **migraine**
- **loss of interest in sex**
- **breast enlargement**
- **skin rash, which may be itchy**

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

- **poor tolerance of contact lenses**
- **losing weight**
- **increase of interest in sex**
- **vaginal or breast discharge**

Other side effects reported

- **bleeding and spotting between your periods** can sometimes occur for the first few months but this usually stops once your body has adjusted to Dianette. 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 Dianette for a number of months. Chloasma may be reduced by avoiding too much sunlight and/or UV lamps
- occurrence or deterioration of the movement disorder **chorea**
- **Crohn's disease** or **ulcerative colitis**.
- **conditions that may worsen during pregnancy or previous use of the Pill:**
 - **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**
 - **swelling of body parts** (*hereditary angioedema*)
 - an inherited disease called **porphyria**
 - **cancer of the cervix**

→ **Tell your doctor or pharmacist** if you are worried about any side effects which you think may be due to Dianette. Also tell them if any existing conditions get worse while you are taking Dianette.

4.3 Bleeding between periods should not last long

A few women have a little unexpected bleeding or spotting while they are taking Dianette, especially during the first few months. Normally, this bleeding is nothing to worry about and will stop after a day or two. Keep taking Dianette 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 Dianette for a while

- carries on even after you've stopped taking Dianette.

5. HOW TO STORE DIANETTE

Keep all medicines out of the reach and sight of children.

Do not store above 25°C.

Do not use Dianette after the expiry date shown on the strip.

Do not throw away any medicines down a drain or into a bin. Ask your pharmacist what to do with any medicines you do not want. This will help to protect the environment.

6. WHAT IS IN DIANETTE AND WHO MAKES IT

What is in Dianette

Each box of Dianette contains three strips of 21 beige tablets.

Each tablet contains: 2 milligrams of the anti-androgen, cyproterone acetate, and 35 micrograms of the oestrogen, ethinylestradiol.

Dianette also contains the inactive ingredients:

lactose, maize starch, povidone, talc, magnesium stearate (E572), sucrose, polyethylene glycol 6000, calcium carbonate (E170), titanium dioxide (E171), glycerol (E422), montan glycol wax, yellow ferric oxide pigment (E172).

The company that holds the product licence for Dianette is:

Bayer plc, Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA

Dianette is made by:

Bayer Pharma AG, Berlin, Germany

or

Bayer Weimar GmbH & Co KG, Weimar, Germany

or

Delpharm Lille SAS, Lys-Lez-Lannoy, France

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