

Package leaflet: Information for the user

Dianette® 2 mg/35 micrograms coated tablets

cyproterone acetate/ethinylestradiol

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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1. What Dianette is and what it is used for

- Dianette contains ethinylestradiol, an estrogen, and cyproterone acetate, an antiandrogen.
- Dianette 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 Dianette if your skin condition has not improved after use of other anti-acne treatments, including topical treatments and antibiotics.

2. What you need to know before you take Dianette

General notes

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

In this leaflet, several situations are described where you should stop using Dianette, or where the reliability of Dianette may be decreased. In such situations you should either not have sex or you should take extra non-hormonal contraceptive precautions, e.g. use a condom or another barrier method. Do not use rhythm or temperature methods. These methods can be unreliable because Dianette alters the monthly changes of body temperature and of the cervical mucus.

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

Do not take Dianette:

- if you have a severe or multiple risk factor(s) for blood clots (see 'Blood clots (thrombosis)') and consult your doctor who will decide whether you may use Dianette)
- if you have a disturbance of blood clotting (for example, antithrombin III deficiency, protein C deficiency, protein S deficiency, Activated Protein C (APC) resistance (e.g. Factor V Leiden), hyperhomocysteinaemia, and antiphospholipid antibodies)
- if you have (or have ever had) a certain form of migraine (with so-called focal neurological symptoms)
- if you have diabetes with damaged blood vessels
- if you have (or have ever had) a liver disease and your liver function is still not normal
- if your kidneys are not working well (renal failure)
- if you have (or have ever had) a tumour in the liver
- if you have 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 (or have ever had) or if you are suspected of having breast cancer or cancer of the genital organs
- if you have any unexplained bleeding from the vagina
- if you are or think you might be pregnant
- if you are breastfeeding
- if you are allergic to ethinylestradiol or cyproterone acetate, or any of the other ingredients of this medicine. This may cause itching, rash or swelling.
- if you have blood disease called porphyria

Do not take Dianette if you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir or glecaprevir/pibrentasvir (see also in section "Other medicines and Dianette")Dianette is not for use in men.

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

- 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** (for example, antithrombin III deficiency, protein C deficiency, protein S deficiency, Activated Protein C (APC) resistance (e.g. Factor V Leiden), hyperhomocysteinaemia, and antiphospholipid antibodies)
- if you have (or have ever had) a **migraine, with visual disturbances** or other so-called focal neurological symptoms.

Warnings and precautions

Talk to your doctor or pharmacist before taking Dianette

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)'.

Dianette 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 Dianette 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 Dianette compared with women who do not take Dianette 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 Dianette 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.

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. This may be life-threatening or may have a fatal outcome.

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 Dianette 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)

If any of the above risk factors (for clots in veins or arteries) apply to you, it is important to tell your doctor, as Dianette may not be an appropriate treatment for you. The more risk factors that apply to you, the greater the risk of developing a clot in an artery or vein. This risk increases with the severity of each individual risk factor. It may even multiply, depending on the combination of the risk factors that apply to you. (See 'Do not take Dianette').

Your doctor may tell you to stop using Dianette several weeks before surgery or while you are less mobile. Your doctor will also tell you when you can start using Dianette again after you are back on your feet.

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 Dianette.

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

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

- if you have Crohn's disease or inflammatory bowel disease (ulcerative colitis)
- if you have a blood disease called HUS (haemolytic uraemic syndrome) which causes kidney damage
- if you have a blood disease called sickle cell anaemia
- if you have epilepsy (see "Other medicines and Dianette")
- if you have a disease of the immune system called SLE (systemic lupus erythematosus)
- if you have a disease that first appeared during pregnancy or earlier use of sex hormones (for example, hearing loss, a blood disease called porphyria, skin rash with blisters during pregnancy (gestational herpes), a disease of the nerves in which sudden movements of the body occur (Sydenham's chorea))
- if you have or have ever had chloasma (a discolouration of the skin especially of the face or neck known as "pregnancy patches"). If so, avoid direct sunlight or ultraviolet light.
- if you have hereditary angioedema, products containing oestrogens may cause or worsen the symptoms. You should see your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing, or hives together with difficulty breathing.

Dianette and cancer

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

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

Malignant tumours may be life-threatening and, in some cases, may be fatal.

The important risk factor for cancer of the cervix is lasting Human Papilloma Virus (HPV) infection. Some studies suggest that long-term use of the pill increases a woman's risk of developing cervical cancer. However, it is not clear to what extent sexual behaviour or other factors, such as HPV, increase this risk.

Meningioma

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 Dianette as a precautionary measure (see section 'Do not take Dianette').

Psychiatric disorders

Some women using hormonal contraceptives including Dianette 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.

Bleeding between periods

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

What to do if no bleeding occurs during the gap week

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

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

Other medicines and Dianette

Tell your doctor if you are taking, have recently taken or might take any other medicines including herbal products. Also tell any other doctor or dentist who prescribes another medicine (or the pharmacist) that you take Dianette. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long, or, whether the use of another medicine you need must be changed.

Some medicines can make Dianette less effective in preventing pregnancy, or can cause unexpected bleeding. These include:

- medicines used for the treatment of
 - epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine)
 - tuberculosis (e.g. rifampicin)
 - HIV and Hepatitis C Virus infections (so-called protease inhibitors and non- nucleoside reverse transcriptase inhibitors, such as ritonavir, nevirapine, efavirenz)
 - fungal infections (e.g. griseofulvin, ketoconazole)
 - arthritis, arthrosis (etoricoxib)
 - high blood pressure in the blood vessels in the lungs (bosentan)
- the herbal remedy St. John's wort

Other medicines may either increase or decrease Dianette levels in your blood. These include:

- medicines used in the treatment of
 - HIV and Hepatitis C (e.g. HIV/HCV protease inhibitors and non-nucleoside reverse transcriptase inhibitors (NNRTIs)

Dianette may influence the effect of other medicines, e.g.

- medicines containing ciclosporin
- the anti-epileptic lamotrigine (this could lead to an increased frequency of seizures)
- theophylline (used to treat breathing problems)
- tizanidine (used to treat muscle pain and/or muscle cramps).

Do not take Dianette if you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir or glecaprevir/pibrentasvir 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. Dianette can be restarted approximately 2 weeks after completion of this treatment. See section "Do not take Dianette".

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

Dianette with food and drink

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

Laboratory tests

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

Pregnancy and breast-feeding

Pregnancy

If you are pregnant, do not take Dianette. If you become pregnant while taking Dianette stop immediately and contact your doctor. If you want to become pregnant, you can stop taking Dianette at any time (see also "If you stop taking Dianette").

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

Breast-feeding

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

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

Driving and using machines

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

Dianette contains lactose and sucrose

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

3. How to take Dianette

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

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

The strip contains 21 tablets. Next to each tablet is printed the day of the week that it should be taken. If, for example you start on a Wednesday, take a tablet with "WED" next to it. Follow the direction of the arrow on the strip until all 21 tablets have been taken.

Then take no tablets for 7 days. In the course of these 7 tablet-free days (otherwise called a stop or gap week) bleeding should begin. This so-called "withdrawal bleeding" usually starts on the 2nd or 3rd day of the gap week.

On the 8th day after the last Dianette tablet (that is, after the 7-day gap week), you should start with the following strip, whether your bleeding has stopped or not. This means that you should start every strip on the same day of the week and that the withdrawal bleed should occur on the same days each month.

If you use Dianette in this manner, you are also protected against pregnancy during the 7 days when you are not taking a tablet.

When can you start with the first strip?

- If you have not used a contraceptive with hormones in the previous month*
Begin with Dianette on the first day of the cycle (that is, the first day of your period). If you start Dianette on the first day of your period you are immediately protected against pregnancy. You may also begin on day 2-5 of the cycle, but then you must use extra protective measures (for example, a condom) for the first 7 days.
- Changing from a combination hormonal contraceptive, or combination contraceptive vaginal ring or patch*
You can start Dianette preferably on the day after the last active tablet (the last tablet containing the active substances) of your previous pill, but at the latest on the day after the tablet-free days of your previous pill (or after the last inactive tablet of your previous pill). When changing from a combination contraceptive vaginal ring or patch, follow the advice of your doctor.
- Changing from a progestogen-only-method (progestogen-only pill, injection, implant or a progestogen-releasing IUD)*
You may switch any day from the progestogen-only pill (from an implant or an IUD on the day of its removal, from an injectable when the next injection would be due) but in all of these cases use extra protective measures (for example, a condom) for the first 7 days of tablet-taking.
- After a miscarriage*
Follow the advice of your doctor.
- After having a baby*
You can start Dianette between 21 and 28 days after having a baby. If you start later than day 28, use a so-called barrier method (for example, a condom) during the first seven days of Dianette use.
If, after having a baby you have had sex before starting Dianette (again), be sure that you are not pregnant or wait until your next period.
- If you are breastfeeding and want to start Dianette (again) after having a baby*
Read the section on "Breast feeding".

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

If you take more Dianette than you should

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

If you take several tablets at once then you may have symptoms of nausea or vomiting. Young girls may have bleeding from the vagina. Even girls who have not yet started to menstruate but have accidentally taken this medicine may experience such bleeding.

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

If you forget to take Dianette

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

The risk of incomplete protection against pregnancy is greatest if you forget a tablet at the beginning or at the end of the strip. Therefore, you should keep to the following rules (see the diagram):

- More than one tablet forgotten in this strip**
Contact your doctor.
- One tablet forgotten in week 1**

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

• One tablet forgotten in week 2

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

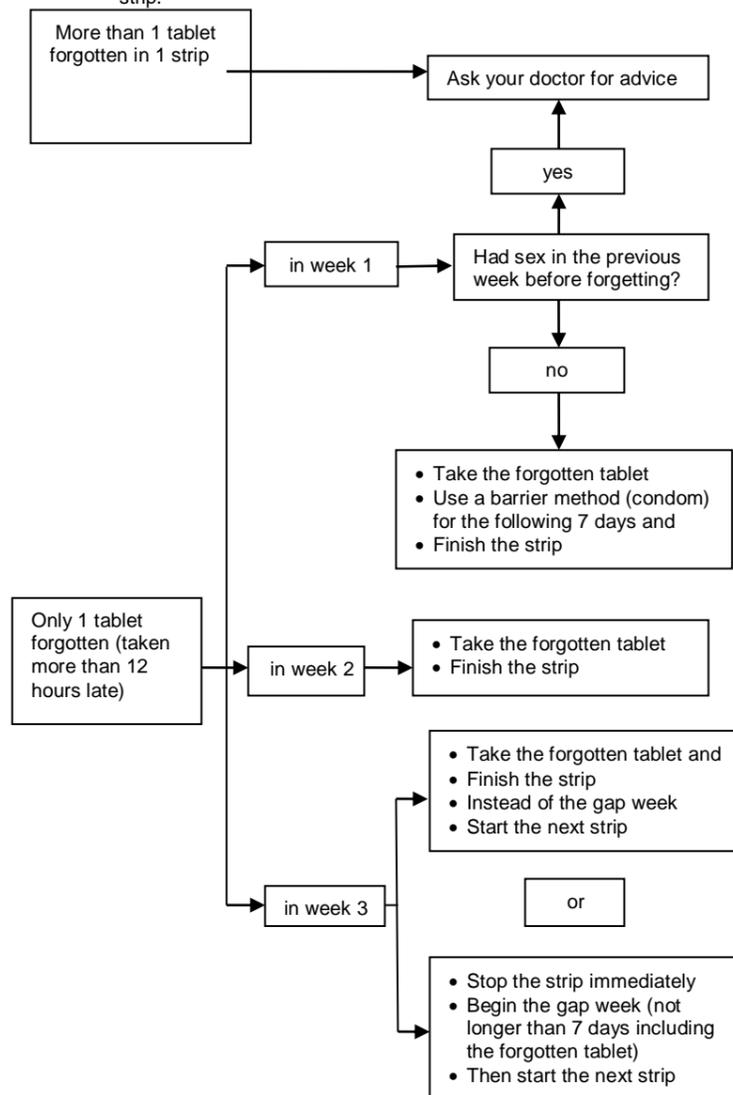
• One tablet forgotten in week 3

You can choose between two possibilities:

- Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time. Instead of taking the tablet-free period start the next strip. Most likely, you will have a period at the end of the second strip or you may also have light or menstruation-like bleeding during the second strip.
- You can also stop the strip and go directly to the tablet-free period of 7 days (**record the day on which you forgot your tablet**). If you want to start a new strip on the day you always start, make the tablet-free period *less than 7 days*.

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

- If you have forgotten any of the tablets in a strip, and you do not have a bleeding during the first tablet-free period, you may be pregnant. Contact your doctor before you start the next strip.



What to do in the case of vomiting or severe diarrhoea

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

Duration of use

Your doctor will tell you how long you need to keep taking Dianette.

The length of use depends on the severity of your symptoms and how they respond to treatment. In general, treatment should be carried out over several months. It is recommended to take Dianette for at least another 3 to 4 cycles after the signs have lessened. If the symptoms come back, weeks or months after stopping Dianette, treatment with Dianette may be re-started. However, the increased risk of blood clots following a break of 4 or more weeks should be considered (see also the section 'Blood clots (thrombosis)').

If you stop taking Dianette

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

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

4. Possible side effects

Like all medicines, this medicine can cause side effects although not everybody gets them. If you get any side effect, particularly if severe and persistent, or have any change to your health that you think may be due to Dianette, please talk to your doctor.

An increased risk of blood clots in your veins (venous thromboembolism (VTE)) or blood clots in your arteries (arterial

thromboembolism (ATE)) is present for all women taking combined hormonal contraceptives. For more detailed information on the different risks from taking combined hormonal contraceptives please see section 2 "What you need to know before you take Dianette".

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

Common side effects (may affect up to 1 in 10 people):

- breast pain, breast tenderness
- depressed or altered mood
- headache
- nausea, stomach pain
- weight gain

Uncommon side effects (may affect up to 1 in 100 people):

- breast enlargement
- decreased interest in sex
- vomiting, diarrhoea
- skin rash, hives
- fluid retention
- migraine

Rare side effects (may affect up to 1 in 1,000 people):

- venous blood clot
- allergic reactions (hypersensitivity)
- contact lens intolerance
- breast discharge, vaginal discharge
- weight loss
- increased interest in sex
- the skin conditions erythema nodosum (characterized by painful reddish skin nodules) or erythema multiforme (characterized by rash with target-shaped reddening or sores).

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

- increase in blood pressure

If you have hereditary angioedema medicines containing certain female sex hormones (oestrogens) may induce or worsen the symptoms of angioedema (see section "What you need to know before you take Dianette").

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 HPRC Pharmacovigilance, website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Dianette

- Do not store above 25 °C.
 - Keep this medicine out of the sight and reach of children.**
- Do not use this medicine after the expiry date which is stated on the carton and on each blister after "EXP". 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 Dianette contains

- The active substances** are cyproterone acetate and ethinylestradiol
Each tablet contains 2 milligrams cyproterone acetate and 0.035 milligram ethinylestradiol.
- The other ingredients (excipients)** are
Product imported from UK: lactose, maize starch, povidone, talc, magnesium stearate (E572), sucrose, macrogol 6000, calcium carbonate (E170), glycerol (E422), titanium dioxide (E171), yellow ferric oxide pigment (E172), montan glycol wax.
Product imported from Romania: lactose monohydrate, maize starch, povidone 25000, magnesium stearate, sucrose, povidone 700000, macrogol 6000, calcium carbonate, talc, glycerol 85%, titanium dioxide (E171), yellow ferric oxide pigment (E172), montan glycol wax.

What Dianette looks like and contents of the pack

Dianette tablets come in calendar blister packs of 21 and 63 (3x21) round, beige, sugar-coated tablets. Not all pack sizes may be marketed.

As the days of the week are not listed on the blister in English, please use the following table should you require a translation:

English	Mon	Tue	Wed	Thu	Fri	Sat	Sun
Romanian	Lu	Ma	Mi	Jo	Vi	Sb	Du

Product is procured from within the EU, repackaged and distributed by the PPA Holder:

PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath Ashbourne, Co. Meath, Ireland.

Parallel Product Authorisation Holder Number:

PPA 465/50/1

Dianette is manufactured by: Bayer Pharma AG or Bayer AG, Müllerstraße 178, 13353 Berlin, Germany or Bayer Weimar GmbH & Co KG, Weimar, Germany or Delpharm Lille SAS, Lys-Lez-Lannoy, France.

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