

# Consumer Medicine Information

## **GINET**

*Cyproterone acetate 2mg and Ethinylestradiol 35mcg tablets*

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

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This leaflet answers some common questions about GINET. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of your taking GINET against the benefits this medicine is expected to have for you.

If you have any concerns about taking this medicine, ask your doctor, professional health care provider or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

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### **What is GINET used for**

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GINET is used to treat women with acne, hair loss or increased growth of facial and body hair if these conditions are the result of over-production of male-type hormones called androgens. GINET contains two substances that act against the androgens, cyproterone acetate and ethinylestradiol.

As well as being an antiandrogen, cyproterone acetate acts like the female sex-hormone progestogen, and when combined with an estrogen (as in GINET, with ethinylestradiol), is an oral contraceptive for women being treated for androgen- dependent symptoms; however, GINET is not recommended in women solely for contraception.

GINET can also be used to treat polycystic ovary syndrome, a hormone imbalance that can cause irregular or absent periods, acne, excessive hair growth, infertility, recurrent miscarriage and obesity.

Your doctor may have prescribed GINET for another purpose.

Ask your doctor if you have any questions why GINET has been prescribed for you.

GINET is not addictive.

This medicine is available only with a prescription.

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## Before you use GINET

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### ***When you must not take it***

Do not take GINET if:

1. you are pregnant or think you might be pregnant, GINET must not be used by women who are pregnant or who think they might be pregnant.
2. you are breast-feeding, GINET must not be used by women who are breast-feeding.
3. you have, or have ever had, a condition involving formation of a blood clot. This could be in the blood vessels of the legs (deep vein thrombosis), the lungs (pulmonary embolism), the heart (heart attack), the brain (stroke), or other parts of the body.
4. you have, or have ever had, a mini-stroke which is a small reversible stroke called a transient ischaemic attack.
5. you have, or have ever had, first signs of a heart attack (such as angina or chest pain)
6. you have epilepsy, or a history of epileptic fits
7. you have, or have ever had, migraine headaches with symptoms such as visual disturbances, speech disability or weakness or numbness in any part of your body
8. you have diabetes mellitus with blood vessel damage
9. you have, or have had, pancreatitis (an inflammation of the pancreas) associated with high levels of triglycerides
10. you have, or have had, jaundice (yellowing of the skin), severe liver disease, benign or malignant liver tumours, or other problems associated with the liver
11. you have cancer of the breast or the genital organs, or a cancer that is suspected to be estrogen related
12. you have any unexplained vaginal bleeding
13. you are hypersensitive (allergic) to any of the ingredients of GINET
14. the package is torn or shows signs of tampering
15. the expiry date printed on the pack has passed. If you take this medicine after the expiry date has passed, it may not work as well.

If you are not sure if you should be taking GINET, talk to your doctor.

### ***Before you start to take GINET***

Tell your doctor if:

- you smoke
- anyone in your family has had a condition associated with a blood clot such a deep vein thrombosis, pulmonary embolism, heart attack or stroke
- you are overweight (BMI over 30)
- you have a blood protein disorder
- you have high blood pressure
- you have, or have had, a heart valve disorder or an abnormal heart rhythm (atrial fibrillation)
- you suffer from migraines
- you have diabetes
- you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel diseases)
- you have sickle cell anaemia
- you have systemic lupus erythematosus (a disease affecting the skin all over the body)

- you have haemolytic uraemic syndrome (a blood coagulation disorder causing failure of the kidneys)
- you suffer from epilepsy
- you have liver disease
- you, or someone in your immediate family, have or have had high blood levels of cholesterol or triglycerides
- you have had a medical condition that occurred for the first time or worsened during pregnancy or previous use of “the Pill”
- you have or have had chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face). If so, you should avoid too much exposure to the sun or ultraviolet radiation while you are taking GINET
- you suffer from hirsutism (excessive or increased hair growth) and it has only recently appeared, or worsened
- you are allergic to any other medicines, foods, dyes or preservatives

If you have not told your doctor about any of the above, do so before you start taking GINET.

### **What else you should know**

GINET does not protect you against HIV infection (AIDS) or any other sexually transmitted disease.

GINET is not for use in men.

In situations described below where you should stop taking GINET, or where the reliability of GINET may be decreased, you should not have sex or you should take extra non-hormonal contraceptive precautions, e.g. use a condom or another barrier method of contraception. Do not use rhythm or temperature methods of contraception, these methods can be unreliable because GINET alters the usual changes in temperature and cervical mucus that occur during the menstrual cycle.

### **GINET and blood clots**

Formation of a blood clot (thrombosis) sometimes occurs in the deep veins of the legs (DVT - deep vein thrombosis). If a blood clot breaks away from the vein wall where it formed, it may reach and block the arteries supplying blood to the lungs (causing pulmonary embolism), the heart (causing heart attack) or the brain (causing stroke). Deep vein thrombosis is rare. It can develop naturally, or it can develop if you are taking GINET or if you are pregnant. The risk is highest for pregnant women, and in-between for women taking GINET, compared to occurring naturally. Extremely rarely, blood clots can occur in the liver, gut, kidney or eye.

The risk of blood clots increases with smoking, a family history of problems with blood clots, being overweight, high blood pressure, heart disease, during surgery and as you get older (see “When taking GINET” for more information).

When using GINET you should stop smoking, especially if you are older than about 35 years of age.

### **GINET and cancer**

Breast cancer has been diagnosed slightly more often in women who use “the Pill” than in women of the same age not using it. It is not known whether this difference is caused by “the

Pill". It may be that the women were examined more often, and so that the breast cancer was noticed earlier.

Occasionally benign, or very rarely malignant, liver tumors have been reported in users of "the Pill". These tumors may lead to internal bleeding. Contact your doctor immediately if you have severe pain in your abdomen.

### ***Taking other medicines***

Tell your doctor if you are taking any other medicines including any that you have bought from a pharmacy, supermarket or health food shop.

Some medicines may interfere with GINET. These medicines include:

- medicines used to treat epilepsy such as primidone, phenytoin, carbamazepine, oxcarbamazepine, topiramate, felbamate and barbiturates
- antibiotics such as penicillins, tetracyclines, griseofulvin, rifampicin and rifabutin
- HIV/AIDS medicines such as ritonavir
- St. John's Wort, a herbal preparation sometimes used for depression

These medicines may be affected by GINET, or may affect how well GINET works. Your doctor will advise you.

Ask your doctor or pharmacist if you are not sure about this list of medicines. Any topical acne treatment can be used at the same time you are taking GINET.

### **GINET and laboratory tests**

GINET may affect the results of some laboratory tests.

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## **How to take GINET**

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Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

### ***How much to take***

GINET must be taken every day to achieve efficacy and reliable contraceptive protection. Irregular intake of GINET may reduce the therapeutic and contraceptive effect.

The contraceptive effect of GINET is continuous when it is taken every day. Unlike some other contraceptive pills, there is no tablet-free break. Additional contraceptive precautions are required during your first pack (follow the starting instructions) or when circumstances such as forgetting tablets, vomiting or some medications reduce the reliability of GINET.

### ***When and how to take the tablets***

Take one GINET tablet every day.

Take each tablet at the same time each day (with some water if necessary). This will help you remember when to take them.

The GINET pack contains blister strips with each blister tray containing 21 yellow (active) tablets and 7 white (inactive) tablets. On the blister tray each tablet is marked with the day of the week on which it is to be taken. Follow the direction of the arrows until all the tablets have been taken. A period should begin during the 7 days of taking the white tablets. Start taking your next pack the day after you complete the last pack.

This means that you will always start new packs on the same day of the week, and also that you will have your period on about the same day each month.

### **Starting your first pack of GINET**

A. When hormonal contraception has NOT been used in the past month.

Start taking GINET on the first day of menstrual bleeding. Take a tablet marked with that day of the week from the red section of the pack. Then follow the days in order of the directional arrows. If you start taking GINET towards the end of the week, your first cycle may be shorter than usual.

An additional non-hormonal method of contraception such as condoms or a diaphragm must be used for the first 14 days of your first pack. The rhythm, temperature and cervical mucus methods are not suitable for this purpose.

B. Changing from another combined oral contraceptive (COC) - "pill"

Start taking GINET the day after you take the last active tablet from your present "pill" pack. Take a tablet marked with that day of the week from the red section of the pack. If your present "pill" pack contains inactive (placebo) tablets, you should throw away the inactive tablets and start GINET on the day after taking the last active tablet from your present pack (if you are not sure which this is, ask your doctor or pharmacist). If you follow these instructions, an additional contraceptive method is not necessary. A withdrawal bleed may not occur until the end of the first pack of GINET.

C. Changing from a progestogen-only pill ("minipill")

Stop taking the "minipill" any day and begin GINET the next day, at around the same time of day. Take a tablet marked with that day of the week from the red section of the pack. An additional barrier contraceptive method (condoms or diaphragm) is required for the first 14 days of GINET when having intercourse.

D. Changing from an injectable or implant

Start using GINET when your next injection is due or on the day that your implant is removed. Take a tablet marked with that day of the week from the red section of the pack. An additional barrier contraceptive method is required for the first 14 days of GINET when having intercourse.

E. After a miscarriage or an abortion

Your doctor will advise you.

### ***How long to take it***

How long to use GINET depends on the severity of your symptoms and the response to treatment. Usually, treatment is over several months. Acne and seborrhoea usually respond faster than hirsutism or alopecia.

GINET should be taken for at least another 3 to 4 cycles after symptoms have gone. If symptoms reoccur, treatment with GINET may be resumed. A longer period of treatment is likely for polycystic ovary syndrome.

### ***If you forget to take GINET***

If you forget to take your tablets follow the instructions below. The more tablets you have missed, the higher the risk that the contraceptive effect is lost. There is a particularly high risk of becoming pregnant if you miss tablets at the beginning or at the end of the pack.

- If you have forgotten to take one or more of the large white inactive tablets, simply take your next tablet on the next day as usual.
- If you are less than 12 hours late in taking one of the active yellow GINET tablets, you are still protected against pregnancy. Take the tablet as soon as you remember and take the next one at your usual time.
- If you are more than 12 hours late taking one of your active yellow GINET tablets you will not be protected from pregnancy. Take the last tablet as soon as you remember and take the next one at your normal time. This may mean taking 2 tablets in one day. You must take extra contraceptive precautions and you must follow the 7 day rule. Read the sections on “*Extra contraceptive precautions*” and “*The 7 day rule*” carefully.
- If you forgot tablets in the first week of taking the active yellow tablets and had intercourse in the seven days before, consult your doctor as the possibility of pregnancy should be considered.
- If you have forgotten to take active yellow GINET tablets for a few days, consult your doctor to be sure you are not pregnant, then discard the missed tablets and follow the 7 day rule.

### **Extra Contraceptive Precautions**

When extra contraceptive precautions are required, either:

- don't have sex; or
- use a cap plus spermicide or a condom

Do not use the rhythm or temperature methods.

### **The 7 Day Rule**

- keep on taking your tablets as usual
- you are not protected from pregnancy until you have taken an active yellow tablet daily for the next 7 days
- use “extra contraceptive precautions” while taking these 7 active yellow tablets
- if there are less than 7 yellow tablets left in the blister tray, finish them, taking one tablet a day, and then go straight on to the active yellow tablets in the next tray (miss out the white tablets). You may not have a period until the end of this blister tray. This is not harmful.

### **If you vomit or have diarrhoea**

If you vomit within 3 to 4 hours of taking GINET, it is like missing a tablet. Follow the advice for missed tablets.

This advice should also be followed in the case of severe diarrhoea.

### **Taking medicines that affect GINET**

Some medicines may stop GINET from working properly (see Taking other medicines). While you are taking the medicine, and for 7 days after stopping the medicine, follow the advice for missed tablets. If you are taking rifampicin, or you are taking these medicines continuously, ask your doctor for advice.

### **To delay a period**

To delay your period miss out the white tablets and go straight to the active yellow tablets in your next blister tray. Continue with this tray until it is empty. Your period will start while you are taking the white inactive tablets in the next blister tray. You may have some breakthrough bleeding or spotting while you are taking the active yellow tablets.

### **To change the starting day of your period**

Just shorten, (never lengthen) the duration of taking the white inactive tablets. If you make the duration of taking the white tablets very short (3 days or less), you may not have any bleeding during the break. You may have some breakthrough bleeding or spotting during the next blister tray.

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## **While you are taking GINET**

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### ***Things you must do***

Stop taking GINET and see your doctor IMMEDIATELY if you think you have a blood clot. Symptoms of a blood clot are:

- an unusual cough
- severe or sharp pain in the chest which may extend down the left arm
- breathlessness
- an increase in the number, duration or severity of migraines
- any unusual, severe or prolonged headache
- partial or complete loss of vision, double vision
- slurring or changes in speech
- changes in hearing, sense of smell, or taste
- dizziness, fainting
- weakness or numbness in any part of your body
- movement disturbances
- severe stomach pain
- severe pain or swelling in one or both legs, or enlarged veins in your legs

Contact your doctor as soon as possible if you:

- notice any changes in your health
- feel a lump in your breast
- have unusual, heavy vaginal bleeding
- forgot tablets in the first week of taking active yellow tablets and had intercourse in the seven days before
- you suspect you are pregnant

**If you are to be immobilized or are having surgery**

The risk of deep vein thrombosis is temporarily increased when having an operation or being immobilized (for example, if your leg is in a plaster cast or splint). The risk may be higher in women taking GINET. Advise your doctor at least 4 weeks before any expected hospitalisation or surgery, that you are taking GINET. Your doctor may tell you to stop taking GINET for several weeks, and when you can start taking GINET again.

**If you have unexpected bleeding**

For the first few months of treatment with GINET you may have irregular vaginal bleeding between your periods. Continue taking your tablets as normal. This normally only lasts until your body has adjusted to GINET (usually about 3 tablet-taking cycles).

**If you have missed a period**

If you have taken all of your tablets at the right time, and you have not vomited, had diarrhoea, or used other medicines, then you are very unlikely to be pregnant. Continue to take GINET as usual.

If you miss your period twice in a row, you may be pregnant. Tell your doctor immediately.

Do not start the next blister tray of GINET until your doctor tells you to.

**Regular check-ups**

Your doctor will tell you to return for regular check-ups while you are taking GINET.

Be sure to keep all your appointments with your doctor so that your progress can be checked.

***Things you must not do***

Do not stop taking GINET without first checking with your doctor. Do not let yourself run out of medicine.

Do not give GINET to anyone else, even if they have the same condition as you.

Do not take any other medicines, whether they require a prescription or not and including herbal medicines, without first telling your doctor.

Also tell any other doctor or dentist prescribing another medicine for you that you are taking GINET. They can tell you if you need to take additional contraceptive precautions and if so, for how long.

***Things to be careful of***

Be careful driving or operating machinery until you know how GINET affects you.

However, GINET is not expected to affect your ability to drive or operate machinery.

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## In case of overdose

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### *If you take too much (overdose)*

Immediately telephone your doctor or the National Poisons Information Centre (telephone 0800 POISON or 0800 764 766) for advice or go to your nearest Accident and Emergency Centre if you think that you or anyone else may have taken too much GINET. Do this even if there are no signs of discomfort or poisoning.

Serious harmful effects from taking too many GINET tablets at one time have not been reported. The following are some symptoms which may or may not occur:

- nausea
- vomiting
- vaginal bleeding

If you are not sure what to do, or if a child has taken GINET, contact your doctor or pharmacist for advice.

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## Side Effects

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Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking GINET.

GINET helps most people but it may have unwanted side effects.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Rarely, serious side effects can occur with GINET. If any of the symptoms listed in the section "While you are taking GINET" occur follow the instructions given in that section.

Ask your doctor or pharmacist to answer any questions you may have. Tell your doctor if you notice any of the following and they worry you:

- reduced tolerance for contact lenses
- nausea, vomiting or stomach pain
- diarrhoea
- weight changes
- puffiness or fluid retention
- headache, migraine
- altered mood or feeling depressed
- changes in libido
- breast pain, tenderness, enlargement or discharge
- abnormal vaginal discharge
- rash or itchiness

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything on this list. Do not be alarmed by this list of possible side effects. You may not experience any of them.

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## **After taking GINET**

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### ***Storage***

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the blister pack they may not keep well. Also, the blister pack helps remind you which days you have taken tablets on.

Keep your tablets in a cool, dry place where the temperature is at or below 25°C. Do not store GINET, or any other medicine, in a bathroom or near a sink.

Do not leave in the car or on windowsills.

Heat and dampness can destroy some medicines.

Keep GINET where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### ***Disposal***

If your doctor tells you to stop taking GINET, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

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## **Product Description**

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### ***What GINET looks like***

GINET is provided in blister strips containing 21 yellow active tablets and 7 white inactive tablets (total of 28 tablets). It is available in packs of 3 x 28 Tablets or 6 x 28 Tablets.

### ***Ingredients***

Active ingredients (in each yellow tablet)  
Cyproterone acetate 2 mg and ethinylestradiol 0.035 mg

Inactive ingredients

*Yellow active tablets:* lactose, povidone, starch, talc, magnesium stearate, hypromellose, titanium dioxide, quinoline yellow, propylene glycol.

*White inactive tablets:* lactose, starch, microcrystalline cellulose, talc, magnesium stearate, colloidal anhydrous silica, hypromellose, titanium dioxide, propylene glycol.

GINET does not contain gluten. GINET contains lactose.

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## **Sponsor Details**

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Ginet is supplied in New Zealand by

REX Medical Limited

P. O. Box 18-119

Glen Innes

AUCKLAND 1743

If you have any concerns about taking this medicine, ask your doctor, professional health care provider or pharmacist.

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## **Date of Preparation**

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This leaflet was prepared on 14 May 2014.