PATIENT INFORMATION LEAFLET

GINETTE

SCHEDULING STATUS:

S4

GINETTE 2,0 mg/ 0,035 mg film-coated tablets.

Cyproterone acetate and Ethinylestradiol.

Contains sugar: Lactose monohydrate (36,765 mg/active tablet; 84,357 mg/inactive tablet).

Read all of this leaflet carefully before you start taking GINETTE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- GINETTE has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

6. Contents of the pack and other information.

1. What GINETTE is and what it is used for

GINETTE is an oral contraceptive and belongs to a group of medicines called progesterones with oestrogens (which are hormones).

GINETTE is used for:

- Oral contraception in women who require anti-androgen therapy (Blocks the effects of the hormone testosterone in the body).
- Control of abnormal hair growth of unknown cause, on the body and face of women.
- Treatment of severe acne that is accompanied by excessive discharge, inflammation or formation of nodes (pimples).

2. What you need to know before you take GINETTE

Do not take GINETTE:

- If you are hypersensitive (allergic) to cyproterone acetate, ethinylestradiol or any of the other ingredients of GINETTE (listed in section 6).
- If you are pregnant or suspected of being pregnant.
- If you are lactating.
- If you have undergone a procedure to remove a hydatiform mole (abnormal fertilized egg) until the gonadotropin (hormone) levels in the blood and urine have returned to normal).
- If you have known or suspected cancer.
- If you are using another hormonal contraceptive.
- If you have liver disease.

- If you have a history of arterial or venous blood clotting disorders.
- If you have severe chronic depression.
- If you have depression, which is not well controlled with treatment.
- If you have had depression with previous use of hormonal contraceptives.
- If you have sickle cell anaemia.
- If you have an oestrogen dependent cancer, functional ovarian cysts, Dubin-Johnson or Rotor syndromes.
- If you have disorders of lipid (fat) metabolism, poor liver function, cerebrovascular insufficiency, coronary artery disease, thrombophlebitis (inflammation of veins associated with blood clots).
- If you have deteriorating otosclerosis (calcification of the labyrinth of the inner ear).
- If you have a history pruritus (itching) during previous pregnancy.
- If you have undiagnosed vaginal bleeding.
- If you have herpes, repeated cholestatic jaundice or porphyria.
- If you suffer with classical migraines.

Warnings and precautions

Special care should be taken with GINETTE:

- If you smoke as there is an increased risk of a heart attack.
- If you suffer from any of the following conditions you should notify your doctor:
    - Diabetes mellitus with mild vascular disease or mild kidney, eye or nerve disease.
    - High blood pressure that is adequately controlled.
    - Porphyria.
    - Clinical depression.

- Obesity.
- Migraine.
- Cardiovascular (heart) disease.
- Chloasma (formation of large brown patches on the skin).

- Tell your doctor before using GINETTE:
  - That you are on treatment for depression.
  - That you have had depression with previous use of hormonal contraceptives.
  - That you have a substance abuse problem.
  - You have underlying psychiatric disorder such as post-traumatic disorder or bipolar disorder.
  - That you have a family history of mental disorders.
  - That you have a history of physical or sexual abuse

Depressed mood and depression are well-known undesirable effects of hormonal contraceptive use (see possible side effects). Depression can be serious and is a well-known risk factor for suicidal behaviour and suicide. Women should be advised to contact their medical practitioner in case of mood changes and depressive symptoms, including shortly after initiating the treatment.

- When taking medicines like GINETTE the risk of heart and circulatory diseases are higher. Stroke and blood clots are more likely in woman aged over 35, especially if they have been using contraceptives for more than 5 years or are cigarette smokers. It is also more common in women who are overweight or have high blood pressure.
- The incidence of heart disease is also higher in women who suffer from diabetes and high cholesterol. Blood clots may be more common in women with Type A, B or AB blood groups.

- The risk of blood clot sis increased when using GINETTE.
- The risk for heart attacks and mini strokes are increased when using GINETTE.
- If you experience symptoms such as severe chest pain, sudden breathlessness or coughing, any headache that is severe, unusual or present for a long time, double vision or sudden partial or total loss of vision, inability to use of understand language, slurred speech, fainting without seizure, weakness or sudden numbness affecting one side of your body and disturbance of movement, you should contact your doctor immediately.
- The risk for blood clots increases with age, smoking, family history of blood clots, being overweight, high blood pressure, migraines, irregular heartbeat and extended period of immobility, which includes major surgery.
- Tell your doctor if you have these conditions as they have been associated with negative circulatory events:
  - Diabetes mellitus.
  - Systemic lupus erythematosus.
  - Haemolytic uraemic syndrome.
  - Chronic inflammatory bowel disease (e.g., Crohn’s disease or ulcerative colitis).
  - Sickle cell anaemia.
- The risk for breast, cervical and liver cancer is increased when using GINETTE.
- Certain conditions like hyperlipidaemias (increased quantity of fat in the blood) and high blood pressure may worsen while taking GINETTE.

- Tell your doctor if any of the following occurs while taking GINETTE:
  - Jaundice (yellowing of the skin or white part of the eye as a result of liver disease).

- Gallstones.
- Systemic lupus erythematosus.
- Herpes gestationis.
- Otosclerosis-related hearing loss.
- Sickle cell anaemia.
- Kidney disease.
- Swelling of the deeper layers of the skin.
- Epilepsy.

- If chloasma occurs (brown patches on the skin), avoid ultraviolet radiation and exposure to the sun while taking GINETTE.
- If you experience menstrual changes. Either a reduction of menstrual flow (this is normal), missed menstruation (You may be pregnant) or intermenstrual bleeding (If it continues after 3 cycles consult your doctor.
- Do not stop taking GINETTE without having discussed an alternative contraception with your doctor.
- GINETTE contains lactose. Patients with rare hereditary conditions of lactose intolerance should not take GINETTE.

Other medicines and GINETTE

Always tell your health care provider if you are taking any other medicine (This includes all complementary or traditional medicines).

Please tell your doctor if you are taking any of the following medicines as they affect the levels of GINETTE in your blood. Levels may decrease and breakthrough bleeding and pregnancy may occur.

- Antiretroviral medicines used to treat HIV/AIDS such as ritonavir, nelfinavir and nevirapine.
- Anticonvulsants (medicines used to treat epilepsy) such as barbiturates (including phenobarbitone), primidone, phenytoin, carbamazepine, oxycarbazepine and topiramate.
- Antibiotics/antifungals such as griseofulvin, rifampicin, aminopenicillins (e.g., ampicillin, amoxicillin) and tetracyclines.
- Herbal medicines such as St John's wort (*Hypericum perforatum*).
- The use of a large supplement of vitamin C may affect the effects of GINETTE and if vitamin C is stopped breakthrough bleeding may occur.
- GINETTE may reduce the effectiveness of anticoagulants (blood thinners), anti-depressants, anti-diabetics, anti-hypertensives, beta-blockers and diuretics (water tablets) and increase concentrations of medicines such as ciclosporin and theophylline.
- Some laboratory tests may be changed, especially hormone tests, blood thickening, thyroid function, glucose tolerance, liver function and serum triglyceride tests.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

GINETTE is contraindicated during pregnancy. If you become pregnant while on treatment with GINETTE, treatment must be stopped and you should contact your doctor.

GINETTE should not be taken if you are breastfeeding your child as it leads to a reduction in the volume of milk produced and small amounts of the medicine are excreted in the milk which may affect your child, particularly in the first 6 weeks after giving birth. GINETTE should not be taken until your child has been weaned off breast milk.

Driving and using machines

It is not always possible to predict to what extent GINETTE may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which GINETTE affects them.

GINETTE contains lactose

GINETTE contains lactose. Patients with rare hereditary conditions of lactose intolerance should not take GINETTE.

3. How to take GINETTE

Do not share medicines prescribed for you with any other person.

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

First cycle: Take the first tablet on the first day your cycle (first day of menstrual bleeding) from the silver section (of the calendar pack). Start with the applicable day as shown on the strip. Take one tablet daily, thereafter, following the sequence of the arrows, at the same time, until all the tablets have been taken.

Subsequent cycles: A new pack should be started the very next day after completing the previous pack, once again starting from the appropriate day within the silver section of the strip. This method should be followed as long as the contraception is desired.

For treatment of androgen-dependent acne: The dose is the same as for contraception.

Your doctor will tell you how long your treatment with GINETTE will last. Do not stop treatment early. If you have the impression that the effect of GINETTE is too strong or too weak, tell your doctor or pharmacist.

Take GINETTE once a day, every day, at about the same time each day.

If you take more GINETTE than you should

In the event of overdosage (if you take too many tablets) you may experience symptoms such as nausea, vomiting and withdrawal bleeding.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take GINETTE

Take the dose you missed as soon as possible, within the next 12 hours, but not when it is nearly time for the next dose. Do not double dose. Take the next tablet at the usual time to prevent withdrawal bleeding.

If you stop taking GINETTE

Do not stop taking GINETTE for contraception without using an alternative contraception as pregnancy may occur.

4. Possible side effects

GINETTE can have side effects.

Not all side effects reported for GINETTE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking GINETTE, please consult your health care provider for advice.

If any of the following happens, stop taking GINETTE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Hypersensitivity (allergic reaction to any of the ingredients in GINETTE).
- Fluid retention.
- Swelling of the limbs.
- Rash, itching, or painful sensitive lumps appearing on the body.
- Suicidal thoughts/behaviour and suicide.

These are all very serious side effects. If you have them, you may have had a serious reaction to GINETTE. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Increased incidence of benign liver tumours.
- Obstruction of blood vessel by blood clot.
- Gallbladder obstruction or hepatitis (Inflammation of the liver).
- Breast pain and breast tenderness.
- Increase in size of breast, vaginal discharge and breast discharge.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Depressed mood or altered mood.
- Headache.
- Nausea.
- Abdominal pain.
- Weight increase.

Less frequent side effects:

- Vaginal candidiasis (fungal infection of the vagina).
- Anaemia.
- Increased or decreased libido (sex drive).
- Migraine.
- Dizziness.
- Intolerance to contact lenses has been reported and vision may deteriorate in myopic patients (short-sighted patients).

- Vomiting.
- Diarrhoea.
- Bloating.
- Gastrointestinal irritation.
- Chloasma (brown patches on the skin), skin pigmentation and skin reactions.
- Alteration in hair pattern.
- Changes in menstrual flow (spotting, breakthrough bleeding, absence of menstrual bleeding) and intermenstrual bleeding.
- Weight decrease.

If you notice any side effects not mentioned in this leaflet, inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 and to Cipla Medpro (Pty) Ltd., at drugsafetysa@cipla.com or telephone 080 222 6662 (toll free).

By reporting side effects, you can help provide more information on the safety of GINETTE.

5. How to store GINETTE

Store all medicines out of reach of children.

Store in a cool dry place, below 25 °C.

Do not use after the expiry date stated on the label.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g., toilets).

6. Contents of the pack and other information

The active substances are cyproterone acetate 2,0 mg and ethinylestradiol 0,035 mg.

The other ingredients are: Colloidal anhydrous silica, hypromellose, lactose monohydrate, magnesium stearate, maize starch, microcrystalline cellulose, polyvinyl pyrrolidone (only active tablets), propylene glycol, purified talc, quinoline yellow (only active tablets) and titanium dioxide.

What GINETTE looks like and contents of the pack

Carton containing a blister strip containing 21 yellow film-coated biconvex tablets and 7 white film-coated biconvex tablets (calendar pack).

Aluminium foil with VMCH coating: Hard tempered, heat sealable against PVC, VMCH

coated.

PVC Film: Clear, colourless, transparent non-toxic PVC film.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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R.S.A

Customer Care: 080 222 6662

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