

## Brenda-35 ED

contains the active ingredient cyproterone acetate and ethinyloestradiol

### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some common questions about Brenda-35 ED.

It does not contain all the available information. It does not take the place of talking to your doctor, pharmacist or health clinic.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Brenda-35 ED against the benefits expected for you.

**If you have any concerns about taking this medicine, talk to your doctor or pharmacist.**

**Keep this leaflet with your medicine.**

You may need to read it again.

#### What Brenda-35 ED is used for

Brenda-35 ED is a hormonal preparation used to treat the following androgen-dependent conditions in women:

- severe acne when other treatments have failed
- mild to moderate increased growth of facial or body hair (hirsutism).

Androgens are male sex hormones, produced by women in small amounts. If a woman's body produces too much of these hormones or is overly sensitive, then androgen-dependent conditions occur. Brenda-35 ED works by blocking the action of these hormones.

Brenda-35 ED is also an effective oral contraceptive, commonly known as the "Pill" or "birth control pill".

As a contraceptive, Brenda-35 ED prevents pregnancy by:

- inhibiting the egg release by stopping it maturing
- thickening the cervical mucus to act as a barrier to sperm
- making the lining of the uterus less suitable for implantation of the fertilised egg.

Oral contraceptives such as Brenda-35 ED may have the following theoretical benefits:

- a decrease in the amount of blood you lose each cycle during your period
- a decrease in anaemia
- a decrease in period pain
- a reduced risk of pelvic inflammatory disease
- a reduced risk of developing ovarian cysts
- an improvement in acne
- a reduced risk of tubal (ectopic) pregnancy
- a reduced risk of benign breast disease (breast lumpiness)
- a reduced risk of getting cancer of the uterus (womb) lining and ovaries.

Brenda-35 ED is not for use in men.

When the pill is taken by women under close observation in clinical trials, it is more than 99% effective in preventing pregnancy. However, in real life the pill is around 92% effective. This is because pills might be missed, or taken with medicines that may interfere with their effectiveness.

Like all oral contraceptives, Brenda-35 ED does not protect against HIV infections (AIDS) or other sexually transmitted diseases (STDs). A barrier form of contraception such as a condom is needed.

Brenda-35 ED is available only with a doctor's prescription.

**Ask your doctor if you have any questions about why Brenda-35 ED has been prescribed for you.**

Your doctor may have prescribed Brenda-35 ED for another reason.

#### Before you take Brenda-35 ED

*When you must not take it*

**Do not take Brenda-35 ED if you are allergic to:**

- any other medicines containing cyproterone or ethinyloestradiol
- any other oral contraceptive
- any other medicine known as a progestogen or oestrogen, including injections and implants
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

**Do not take Brenda-35 ED if you have or have had a blood clot in:**

- the blood vessels of the legs (deep vein thrombosis)
- the lungs (pulmonary embolism)
- the heart (heart attack)
- the brain (stroke)
- other parts of the body

**Do not take Brenda-35 ED if you are concerned about an increased risk of blood clots.**

Blood clots are rare. Very occasionally blood clots may cause serious permanent disabilities, or may even be fatal.

All combined oral contraceptive pills, including Brenda-35 ED, increase the risk of having a blood clot. However, the risk of having a blood clot when taking the Pill is less than the risk of having a blood clot during pregnancy.

**Do not take Brenda-35 ED if you are concerned about an increased risk of blood clots because of age or smoking.**

The risk of having a heart attack or stroke increases as you get older. It also increases if you smoke.

You should stop smoking when taking the Pill, especially if you are older than 35 years of age.

**Do not take Brenda-35 ED if you have or have had:**

- angina (chest pain)
- mini-stroke (also known as TIA or transient ischaemic attack)
- a migraine accompanied by visual symptoms, speech disability or weakness or numbness in any part of the body
- diabetes mellitus with blood vessel complications
- pancreatitis, an inflammation of the pancreas associated with high triglyceride (blood fats) levels in the blood
- severe liver disease and your liver function has not returned to normal
- benign or malignant liver tumours

- cancer that may grow under the influence of sex hormones (e.g. cancer of the breast or genital organs)
- unexplained vaginal bleeding.

**If any of these conditions appear for the first time while using the Pill, stop taking it at once and tell your doctor. In the meantime use non-hormonal (barrier) methods of contraception (such as condoms or a diaphragm).**

**Do not take Brenda-35 ED if you are using another hormonal contraceptive.**

**Do not take Brenda-35 ED if you are pregnant or think you might be pregnant.**

**Do not take this medicine if you are breastfeeding.**

**Do not give this medicine to a child.**

**Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you should start taking this medicine, talk to your doctor.**

*Before you start to take it*

**Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.**

**Tell your doctor if:**

- you smoke
- you or anyone in your immediate family has had blood clots in the legs (thrombosis), a heart attack, a stroke, breast cancer or high cholesterol.

**Tell your doctor if you have, or have had, any medical conditions, especially the following:**

- diabetes
- high blood pressure
- heart valve disorders or certain heart rhythm disorders
- inflammation of your veins (superficial phlebitis)
- varicose veins
- migraine
- epilepsy

**Ask your doctor to check if you:**

- are overweight
- have high cholesterol or triglycerides
- have liver disease
- have gall bladder disease
- have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- have systemic lupus erythematosus (SLE - an autoimmune disease affecting different parts of the body)
- have haemolytic uraemic syndrome (HUS - a disorder of blood coagulation causing failure of the kidneys)
- have sickle cell disease
- have a condition that occurred for the first time, or worsened during pregnancy or previous use of sex hormones (e.g. hearing loss, a metabolic disease called porphyria, a skin disease called herpes gestationis, a neurological disease called Sydenham's chorea)
- have chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face) - if so, avoid exposure to the sun or ultraviolet radiation

- have hereditary angio-oedema - you should see your doctor immediately if you experience symptoms of angio-oedema, such as swollen face, tongue and/or pharynx and/or difficulty swallowing, or hives together with difficulty in breathing.

**If any of the above conditions appear for the first time, or recur or worsen while taking Brenda-35 ED, you should contact your doctor.**

**Brenda-35 ED contains lactose.**

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before you start taking Brenda-35 ED.

**If you have not told your doctor about any of the above, tell him/her before you start taking Brenda-35 ED.**

*Taking other medicines*

**Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.**

Some medicines may interact with Brenda-35 ED. These include:

- medicines used to treat tuberculosis such as rifampicin, rifabutin
- medicines used to treat epilepsy such as phenytoin, primidone, barbiturates (e.g. phenobarbitone), carbamazepine, oxcarbazepine, topiramate, felbamate, lamotrigine
- medicines used to treat HIV, such as ritonavir or nevirapine
- some medicines used to treat Hepatitis C Virus (HCV) such as boceprevir, telaprevir
- antibiotics (erythromycin) medicines used to treat fungal infections, such as ketoconazole and griseofulvin
- cyclosporin, an immunosuppressant medicine
- herbal medicines containing St John's Wort

**If you are using any of the above medicines on a short-term basis, use an additional barrier method of contraception (such as a condom or diaphragm) while you are taking any of these medicines and continue using it for some time after finishing the other medicine.**

Your doctor or pharmacist will be able to advise you about how long you will need to use additional contraceptive methods.

These medicines may be affected by Brenda-35 ED or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Brenda-35 ED.

## How to take Brenda-35 ED

**Follow all directions given to you by your doctor and pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the pack, ask your doctor or pharmacist.**

*How much to take*

**Take one tablet once a day, at about the same time each day.**

*How to take it*

**Swallow the tablet whole with water.**

*When to take it*

Brenda-35 ED can be taken with or without food.

**Take your medicine at about the same time each day.**

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

**You must take Brenda-35 ED every day regardless of how often you have sex.**

*How to use it*

The Brenda-35 ED pack contains 28 tablets. On the pack each tablet is marked with the day of the week on which it is to be taken.

The ED in the name refers to the "every day" presentation where 7 white lactose tablets (placebos or sugar tablets) are also included in the pack so that a tablet is taken each day of the month instead of having a break.

**Take your first tablet from the red section marked with the appropriate day of the week, e.g., if starting on Sunday - select SUN in the red section.**

Follow the direction of the arrows on the pack until all 28 tablets have been taken.

**Always start a new blister pack on the same day of the week as your previous pack.**

*Taking Brenda-35 ED for the first time*

If you are starting Brenda-35 ED after a natural cycle, and you have not used a hormonal contraceptive in the past month, start on the first day of your period, i.e. on the first day of your menstrual bleeding.

**You must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm) for the first 14 days of tablet-taking when having intercourse.**

**Your doctor will advise you when to start if you:**

- are taking Brenda-35 ED after having a baby
- have had a miscarriage or an abortion

*Changing from another contraceptive*

**1. Switching from another combined oral contraceptive**

Start Brenda-35 ED on the day after the last active tablet from the previous pill pack. Bleeding may not occur until the end of the first pack of Brenda-35 ED.

**Ask your doctor or pharmacist if you are not sure which the active tablets were in your previous Pill pack.**

Your previous Pill pack may have different coloured tablets to those of Brenda-35 ED.

**2. Changing from progestogen-only pill 'minipill'**

Stop taking the minipill on any day and start taking Brenda-35 ED at the same time the next day.

**You must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm) for the first 14 days of tablet taking when having intercourse.**

**3. Changing from a progestogen only injection, implant, intrauterine system (IUS) or vaginal ring**

Start taking Brenda-35 ED when your next injection is due, or on the day that your implant, IUS or vaginal ring is removed.

**You must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm) for the first 14 days of tablet taking when having intercourse.**

*How long to take it for*

**Keep taking Brenda-35 ED for as long as your doctor tells you to.**

You may need to take Brenda-35 ED for about 6 months before you notice an improvement in your condition. The length of treatment depends on the severity of the condition and how well it

responds to treatment. To effectively treat your acne and excess hair you may need to take it for much longer.

You may be advised by your doctor to stop Brenda-35 ED 3 to 4 months after your symptoms have completely resolved.

*Stopping Brenda-35 ED*

You can stop taking Brenda-35 ED at any time.

It is possible that acne and excess hair may return when treatment is stopped.

Do not start taking Brenda-35 ED again without seeing your doctor first.

If you are considering becoming pregnant, it is recommended that you begin taking a vitamin supplement containing folic acid. It is best that you start taking folic acid tablets before you stop taking Brenda-35 ED and not stop until your doctor advises this. Seek advice from your doctor or pharmacist about suitable supplements. It is both safe and recommended that you take folic acid during pregnancy.

*If you forget to take it*

If you miss a tablet and take the missing tablet within 12 hours of missing it, contraceptive protection is not reduced.

If you are more than 12 hours late follow these detailed instructions:

**For Brenda-35 ED to be most effective, beige active tablets need to be taken uninterrupted for 7 days.**

**If you have been taking the beige active tablets for 7 uninterrupted days and miss a beige active tablet, take the missed tablet as soon as you remember, then go back to taking your medicine as you would normally, even if it means taking 2 tablets in one day.**

You will not need to use additional barrier contraceptive precautions.

The chance of pregnancy after missing a beige active tablet depends on when you missed the tablet.

**There is a higher risk of becoming pregnant if you miss a tablet at the beginning or end of a pack.**

**If after taking your missed tablet you have less than 7 days of beige active tablets left in a row, you should finish the active tablets in your pack but skip the white inactive tablets and start a new pack.**

This is the best way to maintain contraceptive protection. However, you may not have a period until the end of the beige active tablets of the second pack.

You may have spotting or breakthrough bleeding on tablet-taking days.

**If you have been taking the beige active tablets for less than 7 days and miss a beige active tablet, take the missed tablet as soon as you remember, then go back to taking your medicine as you would normally, even if this means taking two tablets in one day. In addition, you must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm) for the next 7 days.**

If you have had sexual intercourse during that time, there is a possibility of pregnancy and you may need emergency contraception.

**If you forget to take more than one beige active tablet, seek advice from your doctor or pharmacist about what to do.**

If you have had sexual intercourse in the week before missing your tablets, there is a possibility of becoming pregnant.

**If you forget to take a white inactive tablet, take it as soon as you remember and take the next tablet at the usual time.**

The contraceptive efficacy of Brenda-35 ED is not reduced because the white tablet do not contain any active ingredients.

**Ask your doctor or pharmacist to answer any questions you may have.**

*If you take too much (overdose)*

**Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Brenda-35 ED. Do this even if there are no signs of discomfort or poisoning.**

You may experience nausea, vomiting and vaginal bleeding.

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### While you are taking Brenda-35 ED

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#### *Things you must do*

**Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.**

**If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.**

**Have regular check-ups with your doctor.**

When you are taking the Pill, your doctor will tell you to return for regular check-ups, including getting a pap smear test. Your doctor will advise how often you need a pap smear test. A pap smear test can detect abnormal cells lining the cervix. Sometimes abnormal cells can progress to cancer.

**If you are about to start on any new medicine, remind your doctor and pharmacist that you are taking Brenda-35 ED.**

**Stop taking Brenda-35 ED and see your doctor immediately if you notice possible signs of thrombosis (blood clot). These include:**

- an unusual cough
- severe pain or heaviness in the chest
- breathlessness
- any unusual, severe, or prolonged headache
- 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, swelling or discolouration in either of your legs

**If you are going to have surgery, tell the surgeon or anaesthetist beforehand that you are taking Brenda-35 ED.**

The risk of having deep venous thrombosis is temporarily increased as a result of an operation or immobilisation. In women who take the Pill, the risk may be higher.

Your doctor may advise you stop taking Brenda-35 ED several weeks before surgery, or at the time of immobilisation, and when you can start taking it again. If you notice possible signs of a thrombosis, stop taking Brenda-35 ED and consult your doctor immediately.

**Consult your doctor if you develop high blood pressure while taking Brenda-35 ED - you may be told to stop taking it.**

**If you become pregnant while taking this medicine, tell your doctor immediately.**

**If you vomit within 3-4 hours or have severe diarrhoea after taking a beige active tablet, the active ingredients may not have been completely absorbed. This is like missing a tablet. Follow the advice for missed tablets**

**If you have unexpected bleeding and it continues, becomes heavy, or occurs again, tell your doctor.**

When taking these tablets for the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding) between your periods. You may need to use sanitary protection, but continue to take your tablets as normal. Irregular vaginal bleeding usually stops once your body has adjusted to the Pill, usually after about 3 months.

**If you have missed a period, but you have taken all your tablets, it is very unlikely that you are pregnant, as long as:**

- you have taken the beige active tablets at the right time,
- you have not vomited or had severe diarrhoea during this cycle,
- you have not been taking other medicines that interfere with Brenda-35 ED.

If this is so, continue to take Brenda-35 ED as usual. If you have any concerns consult your doctor or pharmacist.

**If you miss your period twice in a row, you may be pregnant even if you have taken the Pill correctly. Stop taking Brenda-35 ED and seek advice from your doctor. You must use a non-hormonal method of contraception (such as condoms or a diaphragm) until your doctor rules out pregnancy.**

Brenda-35 ED will not protect you from HIV-AIDS or any other Sexually Transmitted Infections (STIs), such as chlamydia, genital herpes, genital warts, gonorrhoea, hepatitis B, human papilloma virus and syphilis.

**To protect yourself from STIs, you will need to use additional barrier contraceptives (e.g. condoms).**

#### *Things you must not do*

**Do not use Brenda-35 ED to treat any other conditions unless your doctor tells you to.**

**Do not give Brenda-35 ED to anyone else, even if they have the same condition as you.**

**Do not stop taking your medicine or change the dosage without checking with your doctor.** You may become pregnant if you are not using any other contraceptive and you stop taking Brenda-35 ED, or do not take a table every day.

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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 Brenda-35 ED.**

Like all other medicines, Brenda-35 ED may have unwanted side effects in some people. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

**Ask your doctor or pharmacist to answer any questions you may have.**

The following list includes the more common side effects of Brenda-35 ED. These are usually mild and lessen with time.

**Tell your doctor if you notice any of the following and they worry you:**

- nausea
- abdominal pain

- changes in weight
- headache, including migraines
- mood changes, including depression
- breast tenderness or pain

The following list includes very serious but rare side effects. You may need urgent medical attention or hospitalisation.

**If you experience any of the following, tell your doctor immediately, or go to the Emergency Department at your nearest hospital:**

- pain in the chest, arm, or below the breastbone
- discomfort radiating to the back
- breathlessness and/or difficulty breathing
- swelling, pain or tenderness of one leg
- sudden weakness, numbness or bad 'pins and needles' of the face, arm or leg, especially on one side of the body
- sudden trouble walking, dizziness, loss of balance or coordination
- severe, sudden stomach pains
- a fainting attack or you collapse
- unusual headaches or migraines that are worse than usual
- sudden problems with speech, understanding or eyesight

The side effects listed above are possible signs of a blood clot (thrombosis).

- breast lumps
- unexplained vaginal bleeding
- you cough up blood
- jaundice (yellowing of the skin or eyes)

**Tell your doctor or go to the Emergency Department at your nearest hospital if you experience any of these signs of thrombosis.**

**Tell your doctor if you notice anything that is making you feel unwell.**

This is not a complete list of all possible side effects. Other side effects not listed above may also occur in some people.

Some of these side effects (for example, high blood pressure) can only be found when your doctor does tests from time to time to check your progress.

#### *Thrombosis and the Pill*

Thrombosis is the formation of a blood clot that may block a blood vessel.

Thrombosis sometimes occurs in the deep veins of the legs (deep venous thrombosis (DVT)). If a blood clot breaks away from the veins where it has formed, it may reach and block the arteries of the lungs, causing pulmonary embolism (PE).

Blood clots can also occur in the blood vessels of the heart (causing a heart attack) or the brain (causing a stroke).

Blood clots are a rare occurrence and can develop whether or not you are taking the Pill. They can also happen during pregnancy. The risk of having blood clots is higher in Pill users than in non-users, but not as high as during pregnancy.

The risk of a blood clot is highest during the first year of taking the Pill for the first time, or after having a break from the Pill for 4 weeks of more.

Therefore, one should keep the possibility of an increased risk of blood clots in mind, particularly where there is a history of thrombosis.

**If you notice possible signs of a thrombosis, stop taking Brenda-35 ED and consult your doctor immediately.**

## Cancer and the Pill

Breast cancer has been diagnosed slightly more often in women who take the Pill than in women of the same age who do not take the Pill.

This slight increase in the numbers of breast cancer diagnoses gradually disappears during the course of the 10 years after women stop taking the Pill.

It is not known whether the difference is caused by the Pill. It may be that these women were examined more often, so that the breast cancer was noticed earlier.

**It is important that you check your breasts regularly and contact your doctor if you feel any lump.**

In rare cases benign liver tumours and, even more rarely, malignant liver tumours have been reported in users of the Pill. These tumours may lead to internal bleeding.

**Contact your doctor immediately if you have severe pain in your abdomen.**

Cervical cancer has been reported to occur more often in women who have been taking the Pill for a long time. This finding may not be caused by the Pill, but may be related to sexual behaviour and other factors.

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## After taking Brenda-35 ED

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### Storage

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

If you take the tablets out of the pack they will not keep well.

**Keep your tablets in a cool dry place where the temperature stays below 25°C.**

**Do not store Brenda-35 ED or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills.**

Heat and dampness can destroy some medicines.

**Keep it where 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 Brenda-35 ED, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.**

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## Product description

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### What it looks like

Brenda-35 ED is available as a calendar pack and contains 2 different tablets:

- 21 small beige round active tablets
- 7 white round non-active tablets.

On the pack each tablet is marked with a day of the week on which it is to be taken.

### Ingredients

Each beige active tablet contains two active ingredients: cyproterone acetate 2 mg and ethinyloestradiol 35 mcg.

They also contain the following inactive ingredients:

- lactose
- maize starch
- povidone
- magnesium stearate
- sucrose
- macrogol 6000
- calcium carbonate
- purified talc
- glycerol

- titanium dioxide (E171)
- iron oxide yellow CI77492 (E172)
- glycol montanate
- purified water

Each white inactive tablet contains:

- lactose
- maize starch
- povidone
- magnesium stearate
- sucrose
- macrogol 6000
- calcium carbonate
- glycol montanate
- titanium dioxide

Brenda-35 ED tablets do not contain gluten, tartrazine or any other azo dyes.

### Supplier

Brenda-35 ED is supplied by:

**Alphapharm Pty Limited**  
(ABN 93 002 359 739)  
Level 1, 30 The Bond  
30-34 Hickson Road  
Millers Point NSW 2000  
Phone: (02) 9298 3999  
www.alphapharm.com.au

Australian Registration Number:

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