

# **BROOKE®**

drospirenone 3 mg and ethinylestradiol 20 micrograms

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## **Consumer Medicine Information**

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

This leaflet answers some common questions about BROOKE.

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

All medicines have benefits and risks. Your doctor has weighed the risks of you taking BROOKE 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 BROOKE is used for**

BROOKE is a combined oral contraceptive, commonly known as a 'birth control pill' or 'the Pill'.

BROOKE is used to prevent pregnancy.

It is also used to treat moderate acne and symptoms of premenstrual dysphoric disorder (PMDD) in women seeking oral contraception.

You may also experience the following benefits:

- more regular, shorter and lighter periods - potentially resulting in a decrease in anaemia (iron deficiency)
- a decrease in period pain
- improvement in symptoms like bloating, swelling or weight gain related to fluid retention.

Some conditions such as pelvic inflammatory disease, ovarian cysts, ectopic pregnancy (where the foetus is carried outside of your womb), fibrocystic breast changes and cancer of the uterus (womb) and ovaries may be less common in women taking the Pill.

When taken correctly, it prevents you from becoming pregnant in several ways including:

- inhibiting the egg release by stopping it maturing
- changing the cervical mucus consistency, making it more difficult for the sperm to reach the egg.

BROOKE has 24 active (hormone) tablets and 4 inactive tablets, rather than the traditional 21 active tablets and 7 inactive tablets. This means that with BROOKE, you take the

active (hormone) tablets for three more days. This helps your hormone levels to stay even.

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, or may not be absorbed due to vomiting and diarrhoea.

Like all oral contraceptives, BROOKE is intended to prevent pregnancy. It does not protect against HIV infection (AIDS) and other sexually transmitted infections.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

## **Before you take BROOKE**

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

**Do not take BROOKE if you have an allergy to:**

- drospirenone and/or ethinylestradiol, the active ingredients in BROOKE
- 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 BROOKE if you are taking antiviral medicines which contain glecaprevir, pibrentasvir, sofosbuvir, velpatasvir, voxilaprevir, ombitasvir, paritaprevir or dasabuvir, and combinations of these. These antiviral medicines are used to treat chronic (long-term) hepatitis C (an infectious disease that affects the liver, caused by the hepatitis C virus).**

**Do not take BROOKE if you have or have had a blood clot in:**

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

**Do not take BROOKE if you have or 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.

You are more at risk of having a blood clot when you take the Pill. But the risk of having a blood clot when taking the Pill is less than the risk during pregnancy.

**Do not take BROOKE 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 BROOKE if you have, or have had:**

- any blood clotting disorders such as Protein C deficiency, Protein S deficiency, Leiden Factor V mutation, Antithrombin III deficiency or other inherited blood clotting conditions
- a confirmed blood test showing:
  - increased levels of homocysteine
  - antiphospholipid antibodies (APLAs) e.g. anticardiolipin-antibodies and lupus anticoagulant. These may increase your risk for blood clots or pregnancy losses (miscarriage)
- major surgery after which you have not been able to move around for a period of time
- angina (chest pain)

- mini stroke (also known as TIA or transient ischaemic attack)
- severe kidney insufficiency or an acute failure of your kidney
- migraine, accompanied by visual symptoms, speech disability, or weakness or numbness in any part of your body
- high risk of blood clots due to conditions such as diabetes mellitus with blood vessel damage, severe high blood pressure or severe high or low level of fats in your blood
- pancreatitis (an inflammation of the pancreas) associated with high levels of fatty substances in your blood
- severe liver disease and your liver function has not returned to normal
- cancer that may grow under the influence of sex hormones (e.g. of the breast or the genital organs)
- benign or malignant liver tumour
- 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 this medicine if you are pregnant or think you might be pregnant.**

**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 have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you smoke.**

**Tell your doctor if you or anyone in your immediate family has had blood clots in the legs (deep vein thrombosis - DVT) or lungs (PE), a heart attack, a stroke, breast cancer or high cholesterol.**

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

- diabetes
- high blood pressure
- heart valve disorders or certain heart rhythm disorders

- inflammation of your veins (superficial phlebitis)
- varicose veins
- migraine
- epilepsy
- an increased potassium blood level (e.g. due to problems with your kidney/s) and also use diuretics or other drugs that may increase the potassium in your blood
- cancer
- hyperhomocysteinaemia, a condition characterised by high levels of the amino acid homocysteine in the blood.

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

- are overweight
- have any hereditary or acquired conditions that may make it more likely for you to get blood clots
- have high cholesterol or triglycerides
- have liver disease
- have kidney disease
- have high potassium in your blood

- have jaundice (yellowing of the skin) and/or pruritus (itching of the skin) related to cholestasis (condition in which the flow of bile from the liver stops or slows)
- have gall bladder disease
- have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- have systemic lupus erythematosus (SLE – a disease affecting the skin all over 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 angioedema – you should see your doctor immediately if you experience symptoms of angioedema, 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, recur or worsen while taking BROOKE, you should contact your doctor.**

**Tell your doctor if you are breastfeeding.**

BROOKE is generally not recommended if you are breastfeeding.

**BROOKE contains lactose.**

If you have intolerance to some sugars, tell your doctor before you start taking BROOKE.

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

## **Taking other medicines**

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

Some medicines and BROOKE may interfere with each other. These include:

- medicines used to treat tuberculosis such as rifampicin, rifabutin
- macrolide antibiotics (e.g. clarithromycin, erythromycin) and antibiotics such as penicillin, ampicillin, tetracycline

- medicines used to treat HIV, such as ritonavir or nevirapine
- medicines used to treat epilepsy such as phenytoin, primidone, barbiturates (e.g. phenobarbitone), carbamazepine, oxcarbazepine, topiramate, felbamate, lamotrigine
- some medicines used to treat Hepatitis C Virus (HCV) such as boceprevir, telaprevir, glecaprevir, pibrentasvir, ombitasvir, paritaprevir, dasabuvir
- medicines used to treat fungal infections, such as griseofulvin, ketoconazole
- cyclosporin, an immunosuppressant medicine
- medicines used to treat high blood pressure, chest pain and/or irregular heartbeats such as diltiazem, verapamil
- etoricoxib, an anti-inflammatory medicine used to treat pain
- tizanidine, melatonin or midazolam which are medicines that relax the body
- theophylline, a medicine that helps with breathing
- herbal medicines containing St John's Wort
- grapefruit juice.

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

Some medicines

- can have an influence on the blood levels of BROOKE
- **can make it less effective in preventing pregnancy**
- can cause unexpected bleeding.

You might have an increase in potassium in the blood if you are taking BROOKE with medicines that may increase potassium levels in the blood. These include:

- medicines used to treat high blood pressure, such as ACE inhibitors, angiotensin-II-receptor antagonists and diuretics
- certain anti-inflammatory medicines, such as indomethacin
- aldosterone antagonists, such as spironolactone and eplerenone.

In a study of women taking drospirenone together with an ACE inhibitor, no significant differences were observed in the potassium levels when compared to the placebo.

**You may need to use additional barrier methods of contraception (such as condoms or a diaphragm) while you are taking any of these medicines and for some time after stopping them.**

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

## **How to take BROOKE**

**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 box, ask your doctor or pharmacist for help.**

## **How much to take**

Take one tablet daily at about the same time every day. This will help you remember when to take it. You must take BROOKE every day regardless of how often you have sexual intercourse.

## **How to take it**

**Swallow the tablet whole with water.**

It does not matter if you take it before or after food.

Each blister pack is marked with the day of the week.

**Take your first light pink (active) tablet from the green area on the blister pack corresponding to the day of the week.**

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

A period should begin 2-3 days after starting to take the white inactive tablets and may not have finished before the next pack is started.

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

## **Taking BROOKE for the first time**

If you are starting BROOKE 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 may also start on days 2-5 of your period, but in that case make sure you also use additional barrier contraceptive precautions (e.g. condom) for the first 7 days of tablet-taking.

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

- are taking BROOKE after having a baby
- have had a miscarriage or an abortion.

## **Switching from another contraceptive**

**Changing from a combined oral contraceptive:**

Start taking BROOKE on the day after taking the last active tablet in your previous Pill pack. Bleeding may not occur until the end of the first pack of BROOKE.

You can also switch to BROOKE after taking one or more inactive tablets in your previous Pill pack, but no later than the day after taking the last inactive tablet.

**If you are not sure which were the active/inactive tablets in your previous Pill pack, ask your doctor or pharmacist.**

Your previous Pill pack may have different colour tablets to those of BROOKE.

### **Changing from a progestogen-only pill ('minipill'):**

If you are switching from a progestogen-only Pill (minipill), stop taking the minipill on any day and start taking BROOKE at the same time the next day.

**You must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm) for the first 7 days of tablet-taking when having intercourse.**

### **Changing from a progestogen-only injection, implant or intrauterine system (IUS):**

Start taking BROOKE when your next injection is due, or on the day that your implant or IUS is removed.

**You must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm) for the first 7 days of tablet-taking when having intercourse.**

### **Changing from a vaginal ring:**

Start BROOKE on the day of removal of the vaginal ring but at the latest when the next application would have been due.

## **If you want to delay a period**

To delay your period,

- continue taking the light pink active tablets in the current blister,
- skip the white placebo tablets in the last row of the same blister, and
- start a new blister by taking the light pink active tablet from the green area corresponding to the day of the week (to ensure that you take your tablets on the corresponding day of the week as marked on the pack, you may have some extra tablets left over in your current blister which you can discard).

You can continue to delay your period by skipping the white placebo tablet in the second blister. The delay can be extended until the last light pink active tablet in the third blister is taken.

If you wish for your period to begin at any time during the extension, stop taking the light pink active tablets and start taking the white placebo tablets instead.

You should get your period approximately 2 – 3 days after you start taking the white placebo tablet. After taking the last white placebo tablet, start a new blister by taking the light pink active tablet.

During the extension, you may have some breakthrough bleeding or spotting on active tablet-taking days.

## **Stopping BROOKE**

You can stop taking BROOKE at any time. 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 BROOKE 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 are late taking a tablet but still take it within 24 hours, contraception is maintained. If you are more than 24 hours late, this is called a missed pill. Follow these detailed instructions:

**For BROOKE to be most effective, light pink active tablets need to be taken uninterrupted for 7 days.**

**If you have been taking the light pink active tablets for 7 uninterrupted days and miss a light pink 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.**

You will not need to use additional barrier contraceptive precautions.

The chance of pregnancy after missing a light pink 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 light pink 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 light pink active tablets of the second pack. You may have spotting or breakthrough bleeding on tablet-taking days.

**If you have been taking the light pink active tablets for less than 7 days and miss a light pink 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 light pink 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 miss a white inactive tablet, you do not need to take them later because they do not contain any active ingredients. However, it is important that you discard the missed white tablet(s) to make sure that the number of days between taking active tablets is not increased as this would increase the risk of pregnancy. Continue with the next tablet at the usual time.**

### **Summary of advice if you missed a light pink active tablet more than 24 hours ago:**

**Before missing your tablet, did you take light pink active tablets for the previous 7 days?**

**NO - Did you have sex in the 7 days before missing the tablet?**

- **NO - Take the tablet missed AND use extra barrier precaution for 7 days. If there are fewer than 7 light pink active tablets left in the pack, finish the active tablets and go straight to the light pink active tablets of the next pack. This means you skip the white inactive tablets.**
- **YES - See your doctor or pharmacist for advice**

**YES - Does your pack still have 7 active light pink tablets in a row to follow?**

- **NO - Take the tablet you missed AND complete taking the light pink active tablets. Skip the white inactive**

**tablets. Start your next pack with the light pink active tablets**

- **YES - Take the tablet you missed AND complete the pack as normal**

**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) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much BROOKE. Do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

If you take several light pink active tablets at once, you may feel sick or vomit or may bleed from the vagina. Even girls who have not yet started to menstruate but have accidentally taken this medicine may experience such bleeding.

## **While you are taking BROOKE**

### **Things you must do**

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking BROOKE.**

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

**Stop taking BROOKE and see your doctor immediately if you notice the following signs:**

- one-sided swelling of the leg and/or foot or along a vein in the leg
- pain or tenderness in the leg which may be felt only when standing or walking
- increased warmth in the affected leg; red or discoloured skin on the leg
- sudden onset of unexplained shortness of breath or rapid breathing
- sudden coughing or coughing up of blood
- sharp chest pain or sudden severe pain in the chest which may increase with deep breathing
- severe light headedness or dizziness
- rapid or irregular heartbeat
- sudden pain, swelling and slight blue discoloration of an extremity
- sudden numbness or weakness of the face, arm, leg or any part of your body especially on one side

- sudden trouble walking, dizziness, loss of balance or coordination
- sudden confusion, slurred speech or aphasia; sudden partial or complete loss of vision, double vision, painless blurring of vision which can progress to loss of vision
- sudden, severe or prolonged headache with no known cause or migraine attack
- loss of consciousness or fainting with or without seizure
- pain, discomfort, pressure, heaviness, sensation of squeezing or fullness in the chest arm, or below the breastbone
- discomfort radiating to the back, jaw, throat, arm, stomach
- feeling of being full, having indigestion or choking
- sweating, nausea, vomiting
- extreme weakness and anxiety
- sudden changes to your hearing, sense of smell, or taste
- severe pain in your abdomen.

**If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.**

The risk of having deep venous thrombosis (blood clots) is temporarily increased as a result of an operation including major surgery, any surgery to the legs or pelvis, neurosurgery,

or major trauma. In women who take BROOKE, the risk may be higher.

In women at risk of prolonged immobilisation (including major surgery, any surgery to the legs or pelvis, neurosurgery, major trauma or when you have your leg or legs in plaster or splints), your doctor may tell you to stop taking BROOKE several weeks before surgery, or at the time of immobilisation, and when you can start taking BROOKE again. In the case of elective surgery at least four weeks in advance and not resume until two weeks after complete remobilisation.

Another method of contraception should be used to avoid unintentional pregnancy. Your doctor may prescribe other treatment (e.g. treatment for blood clots) if BROOKE has not been discontinued in advance.

Other risk factors for blood clotting as a result of temporary immobilisation include air travel of greater than 4 hours, particularly in women with other risk factors. Consult your doctor if you plan to air travel for greater than 4 hours.

If you notice possible signs of a thrombosis, stop taking BROOKE and consult your doctor immediately.

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

**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 Cervical Screening Test. Your doctor will advise how often you need a Cervical Screening Test. A Cervical Screening Test can detect abnormal cells lining the cervix. Sometimes abnormal cells can progress to cancer.

**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 light pink 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 light pink active tablets at the right time
- you have not been taking medicine(s) that may interfere with BROOKE
- you have not vomited or had severe diarrhoea during this cycle.

If this is so, continue to take BROOKE 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 BROOKE 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.**

If you choose to delay your period while taking BROOKE, your regular bleeding is not expected to occur during the extension period when the intake of the light pink active tablet is uninterrupted. Therefore, the absence of regular bleeding cannot be used as a sign of an unexpected pregnancy and as such, unexpected pregnancy may be difficult to recognise.

Although pregnancy is unlikely if BROOKE is taken as directed, if for any reason you think you might be pregnant, contact your doctor and do a pregnancy test. This may be of particular importance if you are also using other medications, since some medications are known to be harmful to the foetus.

BROOKE 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 take BROOKE to treat any other conditions unless your doctor tells you to.**

**Do not give your medicine to anyone else.**

**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 BROOKE, or do not take a tablet every day.

## **Side effects**

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

This medicine helps most people, but it may have unwanted side effects in some people.

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

**Do not be alarmed by the following list of side effects.**

You may not experience any of them.

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

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

- nausea
- stomach pain
- changes in weight
- headache, including migraines
- mood changes, including depression
- unscheduled vaginal bleeding
- abnormal periods
- irregular bleeding between periods
- breast tenderness or pain.

The above list includes the more common side effects of your medicine. They are usually mild and lessen with time.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency 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 your speech, understanding or eyesight.

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

- jaundice (yellowing skin or yellowing eyes)
- you cough up blood
- breast lump
- unexplained vaginal bleeding.

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

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

Other side effects not listed above may also occur in some people.

## **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 blood vessels 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 excess risk of a blood clot is highest during the first year of taking the Pill for the first time or when re-starting after having a break from the Pill for 4 weeks or 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 blood clot, stop taking BROOKE and consult your doctor immediately.**

**To prevent pregnancy, you must also use additional barrier contraceptive precautions (e.g. condoms or a diaphragm).**

**If you are concerned about an increased risk of blood clots while on BROOKE, speak to your doctor.**

## **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.

## **After taking BROOKE**

### **Storage**

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

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

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

**Do not store BROOKE or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.**

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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

**Return any unused medicine to your pharmacist.**

## **Product description**

### **What it looks like**

BROOKE active tablets are round, light pink, uncoated biconvex tablet with '420' debossed on one side and other side plain.

BROOKE inactive tablets are round, white to off-white, uncoated biconvex tablet with '303' debossed on one side and other side plain.

BROOKE is available in a carton of 1 or 3 blister packs. Each blister pack contains 24 light pink active tablets and 4 white inactive tablets.

## **Ingredients**

Each BROOKE light pink active tablet contains:

Active ingredients:

- 3 mg of drospirenone
- 20 micrograms of ethinylestradiol

Inactive ingredients:

- lactose monohydrate
- maize starch

- crospovidone
- povidone
- magnesium stearate
- iron oxide red

Each BROOKE inactive tablet contains:

- lactose monohydrate
- polacrillin potassium
- magnesium stearate

BROOKE contains lactose.

## **Supplier**

BROOKE is supplied in Australia by:

**Alphapharm Pty Ltd trading as Viatris**

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone: 1800 274 276

Australian registration numbers:

BROOKE: AUST R 219081

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