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Due to regulatory changes, the content of the following Patient Information Leaflet may vary from the one found in your medicine pack. Please compare the 'Leaflet prepared/revised date' towards the end of the leaflet to establish if there have been any changes.

If you have any doubts or queries about your medication, please contact your doctor or pharmacist.



Package booklet: Information for the user

Microgynon[®] 30 ED

Levonorgestrel

Ethinylestradiol

Five important things to know about the Pill.

- The Pill is a reliable contraceptive and may reduce your risk of cancer of the ovary and womb if used in the long term.
- The Pill will not protect you against sexually transmitted diseases.
- This medicine can increase your risk of problems such as blood clots and breast cancer.
- Some women should not take the Pill because of current medical problems or illnesses. Please read this booklet to make sure Microgynon 30 ED is right for you.
- To prevent pregnancy it is important to take Microgynon 30 ED as instructed and start each pack on time. Please make sure that you understand what to do if you miss a pill or if you think you are pregnant.

Read all of this booklet carefully before you start taking this medicine.

- Keep this booklet. You may need to read it again.
- If you have any questions or need more advice, ask your doctor, family planning nurse or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them.
- **If any of the side effects get severe**, or if you notice any not listed in this booklet, please tell your doctor, family planning nurse or pharmacist.

In this booklet:

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1. What Microgynon 30 ED does

Microgynon 30 ED is a combined oral contraceptive pill ('the Pill'). **You take it to stop you getting pregnant.**

This contraceptive contains two types of female sex hormones, oestrogen and progestogen. These hormones stop you getting pregnant by working in three ways: by preventing an egg being released from your ovaries; by making the fluid (mucus) in your cervix thicker, which makes it more difficult for sperm to enter the womb; and by preventing the lining of your womb thickening enough for an egg to grow in it.

Microgynon 30 ED is taken every day without a break. You take an 'active pill' each day for 21 days, followed by an 'inactive pill' each day for 7 days.

The benefits of taking the Pill include:

- it is one of the most reliable reversible methods of contraception if used correctly
- it doesn't interrupt sex
- it usually makes your periods regular, lighter and less painful
- it may help with pre-menstrual symptoms.

Microgynon 30 ED will not protect you against sexually transmitted infections, such as Chlamydia or HIV. Only condoms can help to do this.

Microgynon 30 ED needs to be taken as directed to prevent pregnancy.

2. Make sure Microgynon 30 ED is OK for you

It's important that you understand the benefits and risks of taking the Pill before you start taking it, or when deciding whether to carry on taking it. Although the Pill is suitable for most healthy women it isn't suitable for everyone.

→ **Tell your doctor** if you have any of the illnesses or risk factors mentioned in this booklet.

Before you start taking the Pill

- Your doctor will ask about you and your family's medical problems, check your blood pressure and exclude the likelihood of you being pregnant. You

may also need other checks, such as a breast examination, but only if these examinations are necessary for you, or if you have any special concerns.

While you're on the Pill

- You will need **regular check-ups** with your doctor or family planning nurse, usually when you need another prescription of the Pill.
- You should go for **regular cervical smear** tests.
- **Check your breasts** and nipples every month for changes – tell your doctor if you can see or feel anything odd, such as lumps or dimpling of the skin.
- **If you need a blood test** tell your doctor that you are taking the Pill, because the Pill can affect the results of some tests.
- **If you're going to have an operation**, make sure your doctor knows about it. You may need to stop taking the Pill about 4–6 weeks before the operation. This is to reduce the risk of a blood clot (see section 2.1). Your doctor will tell you when you can start taking the Pill again.

2.1 The Pill and blood clots

The Pill may slightly increase your risk of having a blood clot (called a *thrombosis*).

A clot in a leg vein – a *deep vein thrombosis* (or DVT) – is not always serious. However, if it moves up the veins and blocks an artery in the lungs, it can cause chest pain, breathlessness, collapse or even death. This is called a *pulmonary embolism* and is very rare.

Your chances of having a blood clot are only increased slightly by taking the Pill.

- Of 100,000 women who are **not on the Pill** and not pregnant, about **5** will have a blood clot in a year.
- Of 100,000 women **taking a Pill** such as Microgynon 30 ED, about **15** will have a blood clot in a year.
- Of 100,000 women who are **pregnant**, around **60** will have a blood clot in a year.

Very rarely, blood clots can also form in the blood vessels of the heart (causing a **heart attack**) or the brain (causing a **stroke**). In healthy young women the chance of having a heart attack or stroke is extremely small.

You are more at risk of having a blood clot:

- as you get **older**
- if you **smoke**
- if you or any of your close family have had **blood clots**
- if you are seriously **overweight**
- if you have a **disorder of blood fat** (*lipid*) **metabolism**, or other **very rare blood disorders**
- if you have **high blood pressure**
- if you suffer from **migraines**

- if you have a **heart valve disorder** or a particular type of **irregular heartbeat** (*atrial fibrillation*)
- if you have **recently had a baby**
- if you have **diabetes**
- if you have certain rare medical conditions such as **systemic lupus erythematosus, sickle cell disease, Crohn's disease or ulcerative colitis**
- if you're **off your feet for a long time** because of major surgery, injury or illness

→ **Tell your doctor if any of these apply to you.** Taking the Pill may add to this risk so Microgynon 30 ED may not be suitable for you.

Signs of a blood clot include:

- a **migraine** for the first time, a migraine that is worse than normal or unusually frequent or severe **headaches**
- any sudden **changes to your eyesight** (such as loss of vision or blurred vision)
- any sudden **changes to your hearing, speech, sense of smell, taste or touch**
- **pain or swelling in your leg**
- **stabbing pain when you breathe**
- **coughing** for no apparent reason
- **pain and tightness in the chest**
- sudden **weakness** or **numbness** in one side or part of your body
- **dizziness** or **fainting**.

→ **See a doctor as soon as possible. Do not take any more Microgynon 30 ED** until your doctor says you can. Use another method of contraception, such as condoms, in the meantime.

2.2 The Pill and cancer

While high dose Pills reduce your risk of cancer of the ovary and womb if used in the long term, it is not clear whether lower dose Pills like Microgynon 30 ED also provide the same protective effects. However, it also seems that taking the Pill slightly increases your risk of **cancer of the cervix** – although this may be due to having sex without a condom, rather than the Pill. All women should have regular **smear tests**.

If you have **breast cancer**, or have had it in the past, you should not take the Pill. The Pill slightly increases your risk of breast cancer. This risk goes up the longer you're on the Pill, but returns to normal within about 10 years of stopping it. Because breast cancer is rare in women under the age of 40, the extra cases of breast cancer in current and recent Pill users is small. For example:

- Of 10,000 women who have **never taken the Pill**, about **16** will have breast cancer by the time they are 35 years old.
- Of 10,000 women who **take the Pill for 5 years in their early twenties**, about **17–18** will have breast cancer by the time they are 35 years old.

- Of 10,000 women who have **never taken the Pill**, about **100** will have breast cancer by the time they are 45 years old.
- Of 10,000 women who **take the Pill for 5 years in their early thirties**, about **110** will have breast cancer by the time they are 45 years old.

Your risk of breast cancer is higher:

- if you have a close relative (mother, sister or grandmother) who has had breast cancer
- if you are seriously overweight

→ **See a doctor as soon as possible if you notice any changes in your breasts**, such as dimpling of the skin, changes in the nipple or any lumps you can see or feel.

Taking the Pill has also been linked to liver diseases, such as jaundice and non-cancer liver tumours, but this is rare. Very rarely, the Pill has also been linked with some forms of liver cancer in women who have taken it for a long time.

→ **See a doctor as soon as possible if you get severe pain in your stomach, or yellow skin or eyes (jaundice)**. You may need to stop taking Microgynon 30 ED.

2.3 Microgynon 30 ED should not be taken by some women

→ **Tell your doctor or family planning nurse** if you have any medical problems or illnesses.

Do not take Microgynon 30 ED if any of the following apply to you. Taking Microgynon 30 ED would put your health at risk.

- If you have or have ever had **breast cancer**
- If you have ever had a problem with your blood circulation. This includes a **blood clot (thrombosis)** in the legs (*deep vein thrombosis*), lungs (*pulmonary embolism*), heart (**heart attack**), brain (**stroke**) or any other parts of the body
- If you have any condition which makes you **more at risk of a blood clot (thrombosis)** – see section 2.1, *The Pill and blood clots*)
- If you have **very high or uncontrolled blood pressure**
- If you have any **symptoms of a blood clot**, such as **chest pain (angina pectoris)** or **'mini-stroke' (transient ischaemic attack)**
- If you have ever suffered from **migraine with visual disturbances**
- If you have ever had a **severe liver disease**, and you have been told by your doctor that your liver function test results are not yet back to normal
- If you have ever had **liver tumours**
- If you have **severe diabetes affecting your blood vessels**
- If you are **allergic (hypersensitive)** to any of the ingredients in Microgynon 30 ED.

→ **If you suffer from any of these**, or get them for the first time while taking Microgynon 30 ED, contact your doctor as soon as possible. Do not take Microgynon 30 ED.

2.4 Microgynon 30 ED can make some illnesses worse

Some of the conditions listed below can be made worse by taking the Pill. Or they may mean it is less suitable for you. You may still be able to take Microgynon 30 ED but you need to take special care and have check-ups more often.

- If you have **diabetes**
- If you or your close family have ever had problems with your heart, or circulation such as **high blood pressure**
- If you or your close family have ever had problems with **blood clotting**
- If you have the inherited disease called **porphyria**
- If you are **overweight** (*obese*)
- If you have **migraines**
- If you have **inflammation of the pancreas** (*pancreatitis*) or a history or family history of **high levels of fat in your blood** (*hypertriglyceridemia*), as you may be at risk of developing pancreatitis
- If you have **any illness that worsened during pregnancy or previous use of the Pill** (see section 4.2)

→ **Tell your doctor or family planning nurse if any of these apply to you.**

Also tell them if you get any of these for the first time while taking the Pill, or if any get worse or come back, because you may need to stop taking Microgynon 30 ED.

2.5 Taking other medicines

If you ever need to take another medicine at the same time as being on the Pill, always tell your doctor, pharmacist or dentist that you're taking Microgynon 30 ED. Also check the leaflets that come with all your medicines to see if they can be taken with hormonal contraceptives.

Some medicines can stop Microgynon 30 ED from working properly – for example:

- **some medicines used to treat epilepsy**
- **some medicines used to treat HIV**
- **griseofulvin** (an anti-fungal medicine)
- **certain antibiotics**
- **certain sedatives** (called *barbiturates*)
- **St. John's Wort** (a herbal remedy).

If you do need to take one of these medicines, Microgynon 30 ED may not be suitable for you or you may need to use extra contraception for a while. Your doctor, pharmacist or dentist can tell you if this is necessary and for how long.

Microgynon 30 ED can also affect how well other medicines work. Your doctor may need to adjust the dose of your other medicine.

In addition, Microgynon 30 ED can also interfere with the results of some blood tests, so always tell your doctor that you are taking Microgynon 30 ED if you have a blood test.

2.6 Taking Microgynon 30 ED with food and drink

There are no special instructions about food and drink while on Microgynon 30 ED.

2.7 Pregnancy and breast-feeding

Do not use Microgynon 30 ED if you are pregnant. If you think you might be pregnant, do a pregnancy test to confirm that you are before you stop taking Microgynon 30 ED.

If you are breast-feeding, your doctor or family planning nurse may advise you not to take Microgynon 30 ED. They will be able to suggest alternative contraception. Breast-feeding may not stop you getting pregnant.

2.8 Driving and using machines

Microgynon 30 ED has no known effect on the ability to drive or use machines.

2.9 Microgynon 30 ED contains lactose and sucrose

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before using Microgynon 30 ED.

3. Taking Microgynon 30 ED

3.1 How to take it

To prevent pregnancy, always take Microgynon 30 ED as described below. Check with your doctor or family planning nurse if you are not sure.

This pack is designed to help you remember to take your pills. Your pack contains 3 foil memo strips with 3 sets of 7 self-adhesive strips showing the days of the week. Each foil memo strip contains 28 tablets: 21 small active tablets in 3 rows and 7 larger inactive tablets in the last row.

Take Microgynon 30 ED every day for 28 days

- Find the set of self-adhesive strips. Each strip starts with a different day of the week. Peel off a strip that starts with your starting day.
- For instance, if you start the tablets on a Wednesday, use a strip that starts with 'Wed'.
- Stick the strip along the top of the foil memo-strip so that the first day is above the pill marked 'start'.
- You can now see on which day you have to take each tablet.
- Take your pill at the same time every day.
- Follow the direction of the arrows on the strip. Take one pill each day, until you have finished all 28 pills.
- Swallow each pill whole, with water if necessary. Do not chew the pill.

Then start your next strip

Start taking your next strip of Microgynon 30 ED the next day. Do not leave a gap between packs.

As long as you take Microgynon 30 ED correctly, you will always start each new strip on the same day of the week.

3.2 Starting Microgynon 30 ED

As a new user or starting the Pill again after a break

It is best to take your first Microgynon 30 ED pill on the first day of your next period. By starting in this way, you will have contraceptive protection with your first pill.

Changing to Microgynon 30 ED from another contraceptive Pill

- **If you are currently taking a 21-day Pill:** start Microgynon 30 ED the next day after the end of the previous strip. You will have contraceptive protection with your first pill. You will not have a bleed until after your first strip of Microgynon 30 ED.
- **If you are taking a 28-day Pill:** start taking Microgynon 30 ED the day after your last active pill. You will have contraceptive protection with your first pill. You will not have a bleed until after your first strip of Microgynon 30 ED.
- **Or, if you are taking a progestogen-only Pill (POP or 'mini Pill'):** start Microgynon 30 ED on the first day of bleeding, even if you have already taken the progestogen-only Pill for that day. You will have contraceptive cover straight away.

Starting Microgynon 30 ED after a miscarriage or abortion

If you have had a miscarriage or an abortion **during the first three months** of pregnancy, your doctor may tell you to start taking Microgynon 30 ED straight away. This means that you will have contraceptive protection with your first pill.

If you have had a miscarriage or an abortion **after the third month** of pregnancy, ask your doctor for advice. You may need to use extra contraception, such as condoms, for a short time.

Contraception after having a baby

If you have just had a baby, your doctor may advise you that Microgynon 30 ED should be started 21 days after delivery provided that you are fully mobile. You do not have to wait for a period. You will need to use another method of contraception, such as a condom, until you start Microgynon 30 ED and for the first 7 days of pill taking.

3.3 A missed pill

If you are less than 12 hours late with an active pill, take it straight away. Keep taking your pills at the usual time. This may mean taking two pills in one day. Don't worry – your contraceptive protection should not be reduced.

If you are more than 12 hours late with an active pill, or you have missed more than one active pill, your contraceptive protection may be reduced.

- **Take the most recently missed pill** as soon as you remember, even if it means taking two at once. Leave any earlier missed pills in the pack.

- **Continue to take a pill every day for the next seven days** at your usual time.
- If these 7 days run beyond the last active (small) tablet, finish taking the small active tablets, throw away the large white inactive tablets and start a new pack of Microgynon 30 ED the next day. Start with the tablet marked 'start' and use the self-adhesive strips to help you to see on which day you have to take each tablet (see section 3.1, *How to take it*). If you have to miss the large white inactive tablets you may see some bleeding on the days you take the active pills, but do not worry. If you do not have a period after the second pack, you must talk to your doctor before you start the next pack.
- **Use extra contraception for the next seven days**, such as condoms.
- If you have missed one or more pills from the first week of your strip (days 1 to 7) and you had sex in that week, you could become pregnant. Contact your doctor, family planning nurse or pharmacist for advice as soon as possible. They may recommend you use emergency contraception.

If you forget to take one of the large white inactive pills, take it straight away. Keep taking your pills at the usual time. This may mean taking two pills in one day. Don't worry – your contraceptive protection should not be reduced.

If you have missed any of the pills in a strip, and you do not bleed while taking the large white inactive pills, you may be pregnant. Contact your doctor or family planning clinic, or do a pregnancy test yourself.

If you start a new strip of pills late, you may not be protected from pregnancy. If you had sex in the last seven days, ask your doctor, family planning nurse or pharmacist for advice. You may need to consider emergency contraception. You should also use extra contraception, such as a condom, for seven days.

3.4 A lost pill

If you lose an **active pill**,

Either take the last active pill of the strip in place of the lost pill. Then take all the other pills on their proper days. Your cycle will be one day shorter than normal, but your contraceptive protection won't be affected. After taking the large white inactive pills you will have a new starting day, one day earlier than before.

Or if you do not want to change the starting day of your cycle, take a pill from a spare strip. Then take all the other pills from your current strip as usual. You can then keep the opened spare strip in case you lose any more pills.

If you lose an **inactive pill**, don't worry, just continue taking the remaining tablets at the correct time. Your contraceptive protection won't be affected.

3.5 If you are sick or have diarrhoea

If you are sick (*vomit*) or have very bad diarrhoea within 4 hours of taking the Pill, your body may not get its usual dose of hormones from that pill. If you are **better within 12 hours of taking Microgynon 30 ED**, follow the instructions in section 3.4 *A lost pill*, which describes how to take another pill.

If you are still sick or have diarrhoea **more than 12 hours after taking Microgynon 30 ED**, see section 3.3, *A missed pill*.

→ **Talk to your doctor if your stomach upset carries on or gets worse.** He or she may recommend another form of contraception.

3.6 Missed a period – could you be pregnant?

Occasionally, you may miss a withdrawal bleed. This could mean that you are pregnant, but that is very unlikely if you have taken your pills correctly. Start your next strip at the normal time. If you think that you might have put yourself at risk of pregnancy (for example, by missing pills or taking other medicines), or if you miss a second bleed, you should do a pregnancy test. You can buy these from the chemist or get a free test at your family planning clinic or doctors surgery. If you are pregnant, stop taking Microgynon 30 ED and see your doctor.

3.7 Taking more than one pill should not cause harm

It is unlikely that taking more than one pill will do you any harm, but you may feel sick, vomit or have some vaginal bleeding. Talk to your doctor if you have any of these symptoms.

3.8 When you want to get pregnant

If you are planning a baby, it's best to use another method of contraception after stopping Microgynon 30 ED until you have had a proper period. Your doctor or midwife relies on the date of your last natural period to tell you when your baby is due. However, it will not cause you or the baby any harm if you get pregnant straight away.

4. Possible side effects

Like all medicines, Microgynon 30 ED can cause side effects, although not everybody gets them.

→ **Tell your doctor, pharmacist or family planning nurse** if you are worried about any side effects which you think may be due to Microgynon 30 ED.

4.1 Serious side effects – see a doctor straight away

Signs of a blood clot:

- a **migraine** for the first time, a migraine that is worse than normal or unusually frequent or severe **headaches**
- any sudden **changes to your eyesight** (such as loss of vision or blurred vision)
- any sudden **changes to your hearing, speech, sense of smell, taste or touch**
- **pain or swelling in your leg**
- **stabbing pain when you breathe**
- **coughing** for no apparent reason
- **pain and tightness in the chest**
- sudden **weakness** or **numbness** in one side or part of your body

- **dizziness or fainting.**

Signs of a severe allergic reaction or worsening of hereditary angioedema:

- **swelling of the hands, face, lips, mouth, tongue or throat.** A swollen tongue/throat may lead to **difficulty swallowing and breathing**
- a red bumpy rash (*hives*) and itching.

Signs of breast cancer include:

- **dimpling** of the skin
- **changes in the nipple**
- any **lumps** you can see or feel.

Signs of cancer of the cervix include:

- **vaginal discharge** that smells and/or contains blood
- unusual **vaginal bleeding**
- **pelvic pain**
- **painful sex.**

Signs of severe liver problems include:

- severe **pain in your upper abdomen**
- **yellow skin or eyes** (*jaundice*)
- **inflammation of the liver** (*hepatitis*)
- your whole body starts **itching.**

→ **If you think you may have any of these, see a doctor straight away.** You may need to stop taking Microgynon 30 ED.

4.2 Less serious side effects

Common side effects (between 100 and 1000 in every 10,000 users may be affected)

- **feeling sick**
- **stomach ache**
- **putting on weight**
- **headaches**
- **depressive moods or mood swings**
- **sore or painful breasts**

Uncommon side effects (between 10 and 100 in every 10,000 users may be affected)

- **being sick and stomach upsets**
- **fluid retention**
- **migraine**
- **loss of interest in sex**
- **breast enlargement**
- **skin rash, which may be itchy**

Rare side effects (between 1 and 10 in every 10,000 users may be affected)

- **poor tolerance of contact lenses**
- **losing weight**
- **increase of interest in sex**

- **vaginal or breast discharge**

Other side effects reported

- **Bleeding and spotting between your periods** can sometimes occur for the first few months but this usually stops once your body has adjusted to Microgynon 30 ED. If it continues, becomes heavy or starts again, contact your doctor (see section 4.3).
- **Chloasma** (yellow brown patches on the skin). This may happen even if you have been using Microgynon 30 ED for a number of months. Chloasma may be reduced by avoiding too much sunlight and/or UV lamps
- Occurrence or deterioration of the movement disorder **chorea**
- **Crohn's disease or ulcerative colitis**
- **Conditions that may worsen during pregnancy or previous use of the Pill:**
 - **yellowing of the skin** (*jaundice*)
 - **persistent itching** (*pruritus*)
 - **kidney or liver problems**
 - **gall stones**
 - certain rare medical conditions such as **systemic lupus erythematosus**
 - **blister-like rash** (*herpes gestationis*) whilst pregnant
 - an inherited form of deafness (*otosclerosis*)
 - a personal or family history of a form of **sickle cell disease**
 - **swelling of body parts** (*hereditary angioedema*)
 - an inherited disease called **porphyria**
 - **cancer of the cervix**

→ **Tell your doctor, pharmacist or family planning nurse** if you are worried about any side effects which you think may be due to Microgynon 30 ED. Also tell them if any existing conditions get worse while you are taking Microgynon 30 ED.

4.3 Bleeding between periods should not last long

A few women have a little unexpected bleeding or spotting while they are taking Microgynon 30 ED, especially during the first few months. Normally, this bleeding is nothing to worry about and will stop after a day or two. Keep taking Microgynon 30 ED as usual. The problem should disappear after the first few strips.

You may also have unexpected bleeding if you are not taking your pills regularly, so try to take your pill at the same time every day. Also, unexpected bleeding can sometimes be caused by other medicines.

→ **Make an appointment to see your doctor** if you get breakthrough bleeding or spotting that:

- carries on for more than the first few months
- starts after you've been taking Microgynon 30 ED for a while
- carries on even after you've stopped taking Microgynon 30 ED.

5. How to store Microgynon 30 ED

Keep all medicines out of the reach and sight of children.

Do not use Microgynon 30 ED after the expiry date shown on the strip.

Do not throw away any medicines down a drain or into a bin. Ask your pharmacist what to do with any medicines you do not want. This will help to protect the environment.

6. What is in Microgynon 30 ED and who makes it

What is in Microgynon 30 ED

Each box of Microgynon 30 ED contains three strips of 28 tablets, and each strip of tablets has its own set of 7 self-adhesive strips showing the days of the week.

Each strip of Microgynon 30 ED contains 21 beige sugar-coated tablets containing 150 micrograms of the progestogen levonorgestrel and 30 micrograms of the oestrogen ethinylestradiol and 7 larger, white, inactive tablets.

Microgynon 30 ED also contains the inactive ingredients:

Lactose, maize starch, povidone, magnesium stearate (E572), sucrose, macrogol 6000, calcium carbonate (E170), talc, montan glycol wax, titanium dioxide (E171), glycerin (E422), ferric oxide, pigment yellow (E172).

The company that holds the product licence for Microgynon 30 ED is:

Bayer plc, Bayer House, Strawberry Hill, Newbury, Berkshire, RG14 1JA.

Microgynon 30 ED is made by:

Bayer Pharma AG, Berlin, Germany

or

Bayer Weimar GmbH & Co KG, Weimar, Germany

or

Delpharm Lille SAS, Lys-Lez-Lannoy, France.

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