

Package Leaflet: Information for the user

Loestrin* 20 Tablets Loestrin* 30 Tablets (norethisterone acetate and ethinylestradiol)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Loestrin is and what it is used for
2. What you need to know before you take Loestrin
3. How to take Loestrin
4. Possible side effects
5. How to store Loestrin
6. Contents of the pack and other information

1. What Loestrin is and what it is used for

The name of your medicine is Loestrin tablets. Loestrin contains two types of medicine:

- Norethisterone acetate – this is a hormone known as a ‘progestogen’
- Ethinylestradiol – this is a hormone known as an ‘estrogen’.

These hormones are similar to those produced naturally by your body during pregnancy.

What Loestrin is used for

Loestrin is a contraceptive pill used to stop you becoming pregnant.

- It is called a ‘combined contraceptive pill’
- This is because it contains two types of medicine.

How Loestrin works

The hormones in your pill help stop you from getting pregnant in the following ways:

- Stopping eggs being released for fertilisation
- Thickening the fluid present in the neck of the womb. This makes it more difficult for sperm to enter the womb
- The lining of the womb does not thicken enough for a fertilised egg to become embedded in it.

2. What you need to know before you take Loestrin

Do not take Loestrin:

- if you are allergic to norethisterone acetate, ethinylestradiol or any of the other ingredients of this medicine (listed in section 6)
- if you are pregnant, think you might be pregnant or are trying to become pregnant
- if you are breast-feeding
- if you are very overweight
- if you have ever been told that you have breast cancer or cancer of the lining of the womb
- if you, or any member of your family, have ever had blood clots (including heart attack or stroke)
- if you have had bleeding from your vagina of unknown cause
- if you have ever had a problem with clotting of your blood, or high levels of fat or cholesterol in your blood
- if you have a problem with your red blood cells (called 'sickle cell anaemia')
- if you have ever had very high blood pressure (hypertension) or other problems of the heart and blood vessels
- if you have severe headaches (migraine) or have ever had a small stroke or transient ischemic attack (TIA)
- if you have had any of the following problems during a pregnancy:
 - a yellowing of the skin and the whites of your eyes (jaundice)
 - itching of the whole body (pruritus of pregnancy)
 - a nerve problem which causes jerky movements of the muscles (chorea)
 - a blister-like rash called pemphigoid gestationis
 - your deafness getting worse (otosclerosis)
- if you have ever had a yellowing of the skin and the whites of your eyes (jaundice) while taking an oral contraceptive in the past
- if you have liver problems including:
 - a type of jaundice (Dubin-Johnson or Rotor syndromes)
 - swelling of the liver (hepatitis)
 - high levels of blood fats such as cholesterol or triglycerides
 - porphyria, liver tumour or gallstones.
- if you have hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir (see also in section Other medicines and Loestrin).

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Loestrin.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Loestrin:

- if you have ever had depression
- if you have diabetes
- if you have asthma
- if you have kidney problems
- if you have epilepsy or any other problem that can cause fits (convulsions)
- if you have fibroids of the womb
- if you have a form of deafness called 'otosclerosis'

- if you have a muscle problem caused by lower than normal levels of the mineral calcium in the blood (tetany)
- if you have brown patches on your face and body (chloasma). You should keep out of direct sunlight to stop this problem getting worse
- if you have a problem of the nervous system called ‘multiple sclerosis’.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Loestrin.

Medical check-ups

- Before taking Loestrin, your doctor or a nurse will check your blood pressure
- Your doctor may decide to examine your breasts or your tummy and may do an internal examination. Your doctor will only do this if it is necessary for you
- Before you start Loestrin, you may also need to take a pregnancy test to confirm that you are not pregnant.

Other medicines and Loestrin

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Loestrin can affect the way some other medicines work. Also, some other medicines can affect the way Loestrin works.

Do not take the herbal medicine called St. John’s Wort while taking Loestrin. It may stop Loestrin working properly.

Some medicines can reduce the effect of Loestrin

Tell your doctor if you are taking:

- Medicines for epilepsy such as carbamazepine, phenobarbital, phenytoin or primidone
- Medicines for infections such as griseofulvin or rifampicin.

You will need to use an additional method of contraception, such as a condom, while taking any of these medicines. You will also need to do this for at least 7 days after stopping them. If these 7 days run beyond the end of the pack, a new pack should be started immediately without a break (see Section 3: ‘How to take Loestrin’).

If you are taking rifampicin, you will need to use an additional method of contraception, such as a condom, while you are taking this medicine, and for at least 4 weeks after stopping it.

Do not take Loestrin if you have Hepatitis C and are taking the medicinal products containing ombitasvir/paritaprevir/ritonavir and dasabuvir as this may cause increases in liver function blood test results (increase in ALT liver enzyme).

Your doctor will prescribe another type of contraceptive prior to start of the treatment with these medicinal products.

Loestrin can be restarted approximately 2 weeks after completion of this treatment. See section “Do not take Loestrin”.

Some medicines can increase the effect of Loestrin

Tell your doctor if you are taking any of the following medicines:

- Atorvastatin for high cholesterol

- Paracetamol
- Vitamin C preparations.

Although these medicines will not stop Loestrin from working properly, you should talk to your doctor before taking Loestrin with these medicines.

Loestrin can affect the way some medicines work

Tell your doctor if you are taking any of the following medicines:

- Ciclosporin
- Paracetamol
- Prednisolone
- Theophylline.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Loestrin.

Operations or being unable to get around (immobilisation)

You should stop taking Loestrin:

- Six weeks before any planned operations
- If you are unable to move freely (immobilised) for a long time.

Loestrin with food and drink

Food and drink have no effect on the way Loestrin works.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- Do not take this medicine if you are pregnant or think you may be pregnant.
- Do not take this medicine if you are breast-feeding or planning to breast-feed.

Driving and using machines

Loestrin is not likely to affect you being able to drive or use any tools or machines.

Loestrin 20 and Loestrin 30 contain lactose and sucrose

Loestrin 20 and Loestrin 30 contain lactose and sucrose (types of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Loestrin 30 contains sunset yellow FCF (E110)

Loestrin 30 contains the colouring agent sunset yellow FCF (E110). This may cause an allergic reaction.

The pill and blood clots

Research suggests that women who take the combined pill are more likely to get blood clotting problems than women who do not take the pill. Rarely, a blood clot can develop in a vein (venous thrombosis) or artery (arterial thrombosis). This can cause a blockage.

In rare cases, a blood clot can form in the deep veins of the legs (deep vein thrombosis). If this clot breaks off from where it forms in the vein, it can travel in the blood back to the heart. It can

then travel into the arteries of the lungs where it may cause a blockage. This is called pulmonary embolism or PE.

In very rare cases blood clots can form in the:

- Blood vessels of the heart - causing a heart attack
- Brain - causing a stroke.

In extremely rare cases, blood clots can happen in other places such as the liver, gut, kidney or eye.

You are more likely to get a blood clot:

- if you are very overweight
- if you have a problem of the heart or blood vessels
- if you have diabetes
- if you have migraines
- if you are older
- if you smoke. When taking the pill, stop smoking, especially if you are over 35 years of age.

If you are worried about any of these things, talk to your doctor to see if you should take the combined pill.

How likely is a blood clot?

A blood clot can develop whether or not you are taking the pill. However, the risk is higher in people who take the pill than those who do not. The risk is even higher during pregnancy.

The risks of getting a blood clot in your vein are as follows:

- In women who are **healthy, not pregnant and not taking the pill:**
 - about **5** cases per **100,000** women per year
- In women taking **combined oral contraceptive pills**, which contain the **progestogens levonorgestrel or norethisterone** - Loestrin is this type of pill:
 - about **15** cases per **100,000** women per year
- In women taking **combined oral contraceptive pills**, which contain the **progestogens gestodene or desogestrel:**
 - about **25** cases per **100,000** women per year
- In women who are **pregnant:**
 - about **60** cases per **100,000** pregnancies per year

The risk of getting a blood clot is highest during the first year you take a combined oral contraceptive. This increased risk applies to the first time ever a combined oral contraceptive is used, rather than each time you start a new type of combined oral contraceptive.

The possible signs of a blood clot (thrombosis) are **listed in Section 4** of this leaflet: **‘Possible side effects’**. If you notice any of the signs, stop taking Loestrin and **talk to your doctor straight away**. In the meantime, use another method of contraception, such as a condom.

The pill and cancer

Breast cancer

- Every woman is at risk of breast cancer, whether or not she takes the pill
- Breast cancer is rare under the age of 40 years. The risk increases as a woman gets older

- Breast cancer has been found slightly more often in women who take the pill. If you stop taking the pill, this risk reduces with time. This means that 10 years after stopping the pill, the risk is the same as for women who have never taken the pill
- Breast cancer seems less likely to spread in women who take the pill than in women who do not take the pill.

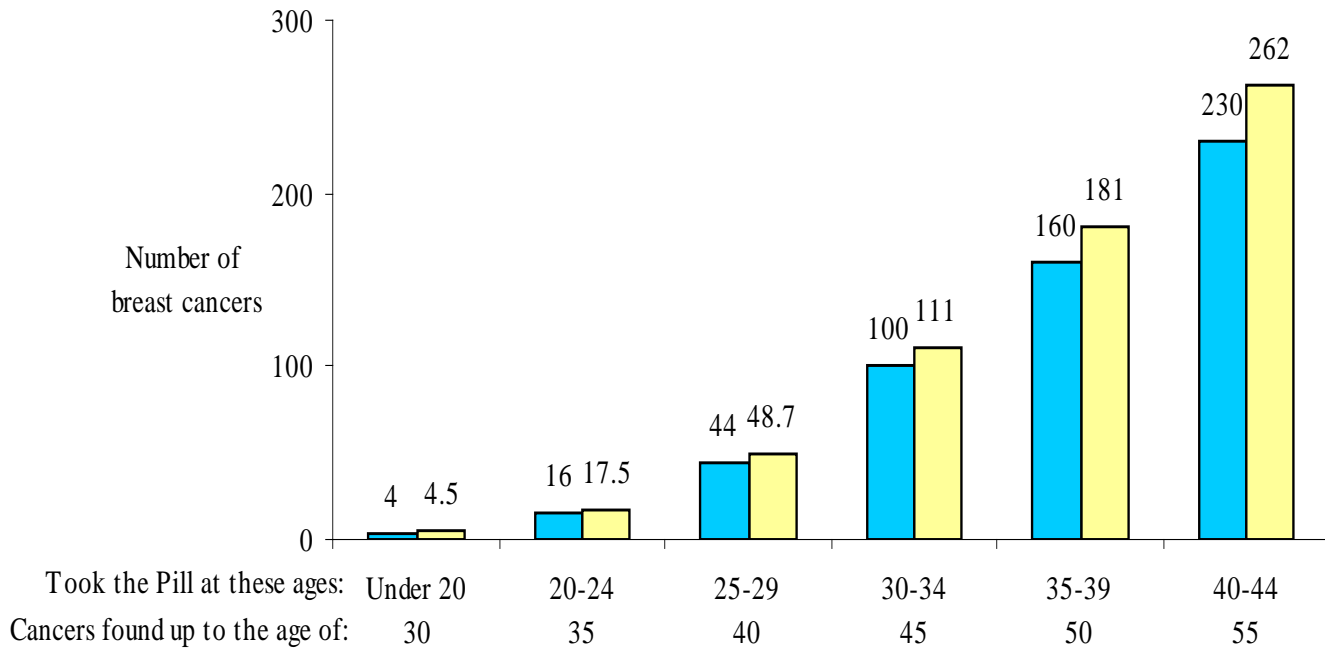
It is possible that the pill is not the cause of this increased risk of breast cancer. It may be that women taking the pill are examined more often. This might mean that the breast cancer is noticed earlier.

The risk of finding breast cancer is not affected by how long a woman takes the pill, but by the age at which she stops. This is because the risk of breast cancer strongly increases as a woman gets older.

The chart below shows the background chances of breast cancer at various ages for 10,000 women who have never taken the pill (black bars) and for 10,000 women whilst taking the pill and during the 10 years after stopping it (grey bars). The small extra risk of finding breast cancer can be seen for each age group. The small possible additional risk in women who take the pill should be balanced against the benefit of effective contraception and that evidence suggests that it helps prevent cancer of the womb or ovary.

Estimated number of breast cancers found in 10,000 women who took the pill for 5 years then stopped, or who never took the pill

- Never took the pill
- Used pill for 5 years



Endometrial and ovarian cancer

Research shows that oral contraceptives protect against cancer of the ovary and cancer of the lining of the womb (endometrium).

Cervical cancer

Some research suggests that there is an increased risk of getting cervical cancer (cancer of the neck of the uterus or womb) in women who take combined oral contraceptives for a long time. However, this may be due to other causes, such as sexual behaviour and higher rates of detection, as a result of regular cervical screening. The most important risk factor for cervical cancer is persistent HPV (Human Papilloma Virus) infection.

Liver cancer

Very rarely, tumours of the liver have been seen in women taking combined oral contraceptives, especially if they have been taken for a long time.

If you are worried about any of these things or if you have had cancer in the past, talk to your doctor to see if you should take the combined pill.

3. How to take Loestrin

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

Taking this medicine

- Take this medicine by mouth
- Swallow the tablets whole with a drink of water
- Do not crush or chew your tablets.

How much to take

The recommended dose is one Loestrin tablet taken once a day.

- Take the tablet at about the same time of day, for 21 days in a row
- The packet of tablets is marked with the day of the week when you should take each tablet. This will help you remember to take one tablet for these 21 days
- If you are not sure whether you have taken your tablet, look at the day on the pack to see.

Once you have taken all 21 tablets, stop taking Loestrin for 7 days

- A few days after you have taken the last tablet, you should have a period
- You do not need to use any additional contraceptive protection during the 7 days' break, provided all of the tablets have been taken correctly.

After the 7 days' break, start the next pack of Loestrin

- Start on the same day of the week that you started your previous pack
- Start taking Loestrin on that day, whether or not you are still bleeding.

Starting your first course of Loestrin

- You can start Loestrin anytime in your menstrual cycle if you are sure you are not pregnant
- If you start Loestrin on the first day of your period you will be protected from pregnancy immediately
- You can also start Loestrin up to, and including, the fifth day of your period and you will be protected from pregnancy immediately
- If you start Loestrin at any other time in your menstrual cycle you will need to use additional contraception, such as condoms, for the first seven days of taking Loestrin. However, you can switch from another hormonal contraceptive, such as a different combined oral contraceptive (COC) or a progestogen-only pill (POP), at any time in your menstrual cycle and additional contraception is not required. Speak to your doctor or pharmacist if you are not sure what type of contraceptive you were using.

Taking Loestrin after having a baby

You can start taking Loestrin 21 days after the delivery:

- if you are not breast-feeding
- if you do not have any complications
- if you are able to get up and move around without any problems
- By starting this way you will have contraceptive protection straight away.

If you start taking Loestrin more than 21 days after the delivery:

- You should use an additional method of contraception, such as a condom
- Keep doing this until you start to take Loestrin, and for 7 days after you start.

Taking Loestrin after a miscarriage or an abortion

After a miscarriage or abortion, Loestrin can normally be started straight away.

If you have a stomach upset

Being sick (vomiting) and/or having diarrhoea may stop Loestrin from working properly. If you have a stomach upset, you should:

- Keep taking Loestrin as usual
- Use another method of contraception, such as a condom
- Keep doing this during the upset and for 7 days after recovery.

If the 7 days goes past when the pack has run out, you should:

- Start the next pack, the next day, without taking the 7 days' break.

If you do not get a period after finishing the second pack, talk to your doctor straight away before starting your next pack.

If you have no bleeding or irregular bleeding with Loestrin

Ask your doctor for advice before you start a new course of Loestrin if you have no bleeding at all in the 7 days after a course of tablets. Your doctor may want to check you, to see if you are pregnant.

If bleeding occurs during the 21 days in which you are taking Loestrin, do not stop taking the tablets. The bleeding should stop in a day or two. However, if the bleeding is troublesome, very heavy, lasts a long time or keeps happening, talk to your doctor.

If bleeding does occur while taking Loestrin, it is usually only in the first 2 or 3 months, while your body is adjusting itself to Loestrin.

If you take more Loestrin than you should

If you take more Loestrin than you should, talk to a doctor straight away.

If you forget to take Loestrin or start a pack late

Missing tablets or starting the pack late may make Loestrin less effective. The chance of pregnancy after missing tablets depends on **when** tablets are missed and **how many** tablets are missed. A Loestrin tablet is late when you have forgotten to take it at the usual time. A tablet has been missed when it is more than 24 hours since the time you should have taken it.

If you miss one Loestrin tablet anywhere in your pack or start the new pack one day late, you will still have contraceptive cover. However, missing **two or more Loestrin tablets** or starting the pack **two or more days late** (more than 48 hours late) may affect your contraceptive cover. As soon as you realise you have missed any Loestrin tablets, take the last tablet you missed immediately. In particular, during the seven day pill free break your ovaries are not getting any effects from Loestrin. If you make this pill free break longer by forgetting two or more Loestrin tablets, your ovaries might release an egg and there is a real risk of becoming pregnant.

Follow the advice below. If you are not sure what to do, continue to take Loestrin and use additional contraception, such as condoms, and seek advice as soon as possible.

If you have missed **one Loestrin tablet**, anywhere in the pack:

- Take the last tablet you missed now even if it means taking two tablets in one day
- Continue taking the rest of the pack as usual
- No additional contraception needed
- Take your 7 day break as normal

If you have missed **two or more Loestrin tablets (more than 48 hours late)**, anywhere in the pack:

- Take the last tablet you missed now even if it means taking two tablets in one day
- Leave any earlier missed tablets
- Continue taking the rest of the pack as usual and use an extra method of contraception for the next seven days
- You may need emergency contraception – see below
- You may need to start the next pack of Loestrin without a break – see below.

Emergency contraception

If you have had unprotected sex in the previous seven days and you have missed two or more Loestrin tablets (more than 48 hours late) **in the first week of a pack**, you may need emergency contraception. Get advice from your contraception clinic, family doctor, or a pharmacist about this.

Starting the next pack of Loestrin after missing two or more tablets (more than 48 hours late)

If **seven or more** tablets are left in the pack after the last missed tablet:

- Finish the pack
- Have the usual seven-day break.

If **less than seven** tablets are left in the pack after the missed tablet:

- Finish the pack and begin new one the next day (this means missing out the break)

If you stop taking Loestrin

To make sure you have contraceptive protection, it is important that you take Loestrin as directed by your doctor. If you stop taking Loestrin, this will result in the loss of contraceptive protection and the risk of pregnancy.

If you wish to become pregnant, you should contact your doctor about stopping the tablets.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking Loestrin and see a doctor straight away if you notice any of the following serious side effects. You may have a serious blood clot (thrombosis) and may need urgent medical treatment:

- The very first attack of migraine that you have ever had (usually sight problems followed by a throbbing headache and feeling sick)
- Any bad headaches which are worse than normal or more often than normal
- Migraines you already have which get worse
- Pain, tingling or feeling numb in any part of the body
- Chest or stomach pain
- Painful breathing, feeling breathless or unexplained cough
- Speech problems
- Feeling dizzy or faint
- Sudden sight problems
- Swelling of the veins (phlebitis) or limbs.

Your doctor may stop you taking Loestrin:

- if you develop a yellowing of the skin and the whites of your eyes (jaundice)
- if your blood pressure goes up
- if you get a condition listed in the section ‘Warnings and precautions’ or you have one of these listed conditions and it gets worse.

The following side effects have also been reported:

- Allergy-type rash
- Infection of the vagina (thrush)
- Being less able to tolerate sugar and starches (carbohydrates)
- Low mood (depression)
- Rise in blood pressure
- Stomach upset, bloating or cramps, feeling sick (nausea) or being sick (vomiting)
- Water retention or changes in body weight
- Yellowing of the skin or whites of the eyes (jaundice)
- Brown patches on the face or body
- Headaches
- Painful breasts or increase in breast size or leaking from breasts
- Reduced breast milk after birth
- Missed periods during and after treatment
- Breakthrough bleeding or spotting, heavier or lighter bleeding
- Changes in the cervix (neck of the uterus or womb)
- Temporary infertility after stopping the tablet
- Loss of interest in sex
- Changes to the shape of your cornea (a part of the eye). This can cause irritation or discomfort when wearing contact lenses. If you wear contact lenses and this happens, see an optician.

Other side effects reported but not thought to be connected with oral contraceptive treatment:

- Changes in appetite
- Blood problem (porphyria)

- Feeling tired, nervous or dizzy
- Inflamed vagina
- Pre-menstrual like syndrome
- Cloudy lenses in the eye (cataracts)
- Bad diarrhoea
- Increased hair growth or hair loss
- Acne, serious skin rashes or itching
- Back pain
- Kidney problems or pain when passing water (cystitis-like syndrome)
- Missed periods for some time after stopping the pill
- Liver problem (Budd Chiari syndrome). This causes pain and swelling in the right side of the stomach area, yellowing of the skin and whites of the eyes, feeling sick, fever, vomiting blood and swelling of the legs.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Loestrin

Keep this medicine out of the sight and reach of children.

Store in the original packaging below 30°C.

Do not use this medicine after the expiry date, which is stated on the carton and blister foil. The expiry date refers to the last day of that month.

Do not use this medicine if you notice that the pack or any of the tablets are damaged.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Loestrin 20 contains

The active substances in Loestrin 20 are norethisterone acetate 1.0mg and ethinylestradiol 0.02mg. **The other ingredients** in the tablet are: sugar (sucrose), lactose, maize starch, talc, spray-dried acacia and magnesium stearate.

The tablet coating contains hypromellose 15, hydroxypropylcellulose, carnauba wax and the colourings quinoline yellow (E104), erythrosine FD&C Red (E127), indigo carmine (E132) and titanium dioxide (E171).

What Loestrin 30 contains

The active substances in Loestrin 30 are norethisterone acetate 1.5mg and ethinylestradiol 0.03mg. **The other ingredients** in the tablet are: sugar (sucrose), lactose, maize starch, talc, spray-dried acacia, magnesium stearate and the colourings quinoline yellow (E104) and patent blue V (E131).

The tablet coating contains hypromellose 15, hydroxypropylcellulose, carnauba wax and the colourings quinoline yellow (E104), sunset yellow FCF (E110), indigo carmine (E132), brilliant blue FCF (E133) and titanium dioxide (E171).

What Loestrin looks like and contents of the pack

Loestrin 20 is a pale blue convex film-coated tablet.
Loestrin 30 is a pale green convex film-coated tablet.
Both strengths are available in packs of 63 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Galen Limited
Seagoe Industrial Estate
Craigavon
BT63 5UA
UK

Manufacturer

Recipharm Limited
Vale of Bardsley
Ashton-under-Lyne
Lancashire
OL7 9RR
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