

Synphase Tablets

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INFORMATION FOR THE PATIENT

Synphase®

Please read this booklet carefully before you start to take Synphase

PHARMACIA

Synphase® tablets

This booklet gives you some information about how to take your pills. The booklet can't tell you everything about Synphase. So if you have any questions or are not sure about anything, ask your doctor, clinic or pharmacist.

Some information about Synphase

Synphase contains two hormones

- a progestogen hormone called norethisterone and an oestrogen hormone called ethinylestradiol. These two hormones act together to prevent pregnancy.

What is in Synphase?

Each Synphase foil strip contains:

- seven blue pills containing 500 micrograms of norethisterone and 35 micrograms ethinylestradiol (the 'active' ingredients);
- nine white pills containing 1 milligram of norethisterone and 35 micrograms ethinylestradiol (the 'active' ingredients);
- five blue pills containing 500 micrograms of norethisterone and 35 micrograms ethinylestradiol (the 'active' ingredients).

The 'inactive' ingredients in all the pills are:

- maize starch, polyvidone, lactose and magnesium stearate; and
- colouring E132 in the blue pills.

The blue and white Synphase pills are marked 'SEARLE' on one side and 'BX' on the other side.

They are packed in blister strips and come in packs of 21 pills.

One of the active ingredients in this medicine is ethinylestradiol. This is the new name for ethinyloestradiol. The ingredient itself has not changed.

Who supplies Synphase?

PHARMACIA

Synphase is supplied by:

Pharmacia Limited
Ramsgate Road
Sandwich
Kent
CT13 9NJ

Who makes Synphase?

Synphase is made by:

Pharmacia Limited
Morpeth
Northumberland
NE61 3YA
UK

What is Synphase for?

Synphase is a combined oral contraceptive pill you take to prevent you becoming pregnant.

Before you take Synphase

Synphase may not be suitable for all women. Before you take Synphase, make sure your doctor knows if you have ever had any of the following conditions.

- Blood clots in the legs, blood clots in varicose veins, the lungs, the brain or elsewhere (coronary and cerebral thrombotic disorders).
- A heart attack, angina or a stroke.
- High levels of fats in your blood (hyperlipidaemia or other disorders of body fats).
- Cancer of the breast, cervix, vagina or womb.
- If during pregnancy you had:

- pruritus (itching of the whole body);
- jaundice, for which your doctor could not find the cause; or
- pemphigoid gestationis (a rash previously known as herpes gestationis).
- Certain types of jaundice (Dubin-Johnson or Rotor syndrome).
- Bad migraines.
- Vaginal bleeding, for which your doctor could not find the cause.
- Liver tumours.
- Liver disease.

If you are pregnant or are trying to get pregnant, you should not take the pill.

What I should know before taking Synphase

If you had irregular periods or no periods in the past, you may stop ovulating (releasing eggs from your ovaries). You may also stop having normal periods after you have stopped using the combined pill. If you have any of these conditions you may find it better to use a different contraceptive method. You should ask your doctor or clinic for advice.

It is possible that sometimes certain long-term diseases may get worse while you are taking the pill. See the section, ‘Reasons for careful medical checks’.

The pill and thrombosis

Some evidence suggests that women who take the pill are more likely to develop various blood circulation disorders than women who don’t take the pill.

A thrombosis is a blood clot. A thrombosis can develop in veins or in arteries and can cause a blockage. The chance of a thrombosis forming in women taking the pill and women not taking the pill is rare. When blood clots form in arteries they can cause chest pain (angina), strokes (blood clots in or bleeding from the blood vessels in the brain) and heart attacks.

If blood clots form in veins they can often be treated, with no long-term danger. On rare occasions a piece of thrombosis may break off. It can travel to the lungs to cause a condition called pulmonary embolism. Therefore in rare cases a thrombosis can cause serious permanent disability or could even be fatal.

It is important to note that a thrombosis can form in people who are not taking the pill as well as those who are taking it. The risk is higher in women who take the pill than in women who don’t take the pill, but is not high as the risk during pregnancy. The excess risk of thrombosis is highest during the first year a woman ever uses a combined oral contraceptive pill.

For healthy non-pregnant women: the chance of having a blood clot is about 5 in 100,000 each year.

For women taking the pill containing either levonorgestrel or norethisterone (a second generation pill): the chance of having a blood clot is about 15 in 100,000 each year.

For women taking the pill containing desogestrel or gestodene (a third generation pill): the chance of having a blood clot is about 25 in 100,000 each year.

For women who are pregnant: the chance of having a blood clot is about 60 in 100,000 pregnancies.

The risk of heart attacks and strokes for women who use the combined pill increases with age and smoking. Other conditions also increase the risk of blood clots in the arteries. These include being greatly overweight, having diseased arteries (atherosclerosis), high blood pressure during pregnancy (pre-eclamptic toxæmia), high blood levels of cholesterol, and diabetes. If you have any of these conditions, you should check with your doctor or clinic to see if the pill is suitable for you. Smokers over 35 are usually told to stop taking these pills.

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, but the risk increases as a woman gets older.

Breast cancer has been found slightly more often in women who take the pill than in women of the same age who do not take the pill. If women stop taking the pill, this reduces the risk so that 10 years after stopping the pill, the risk of finding breast cancer is the same as for women who have never taken the pill. Breast cancer seems less likely to have spread when found in women who take the pill than in women who do not take the pill.

It is not certain whether the pill causes the increased risk of breast cancer. It may be that women taking the pill are examined more often, so that 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.

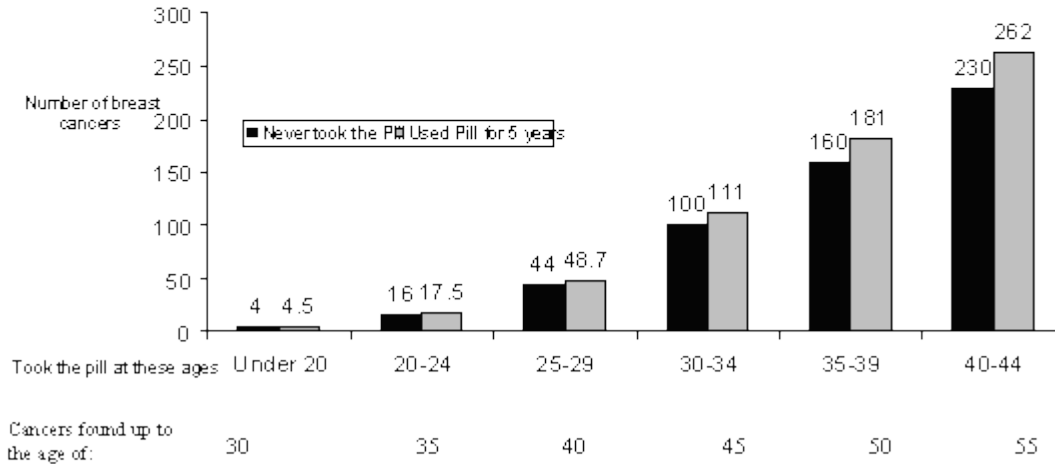
The chart on pages 22 and 23 shows the background chances of breast cancer at various ages for 10,000 women who have never taken the pill (black bars) and for 10,000 women whilst taking the pill and during the 10 years after stopping it (grey bars). The small extra risk of finding breast cancer can be seen for each age group. This small possible additional risk in women who take the pill has to be balanced against the fact that the pill is a very effective contraceptive and it helps prevent cancer of the womb or ovary.

Taking any medicine carries some risk. You can use the information in this booklet, and the advice your doctor or clinic has given you to weigh up the risks and benefits of taking the pill. Don't be embarrassed, ask as many questions as you need to.

Reasons for careful medical checks

Your doctor or clinic will give you regular checkups while you are taking Synphase. Your blood pressure will be checked before you start the pill and then at regular intervals whilst you are on the pill. If your blood pressure goes up, your doctor may tell you to stop taking Synphase. They may also check your breasts and reproductive organs, including taking a cervical smear at regular intervals, if this is considered necessary by the doctor.

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



Tell your doctor if you have any of the following conditions.

- Migraine, asthma, epilepsy, heart or kidney disease, high blood pressure (hypertension) or you have a previous history of these conditions. This is because the pill may cause fluid retention which can make these conditions worse.
- Diabetes.

If you have any of the following conditions and they appear to get worse or they appear for the first time, your doctor or clinic may tell you to stop taking the pill.

- High blood pressure
- Diabetes
- Multiple sclerosis.
- Tetany (muscle twitches).
- Breast problems.
- Varicose veins.
- Migraine.
- Epilepsy.
- Kidney disease.
- Severe depression.
- Fibroids in your uterus.
- Gallstones.
- Liver problems.
- Sickle-cell anaemia.
- Diseases of the heart and blood vessels (cardiovascular disease).
- Otosclerosis (an inherited form of deafness).
- Porphyria (a metabolic disease).

Chloasma (brown patches on your skin which can happen during pregnancy but may not fade completely).

- Any disease that is likely to get worse during pregnancy.

If you use any combined pill you may retain fluid which can make it uncomfortable to wear contact lenses.

Other medicines and Synphase

Several medicines can interfere with the way the pill works. These include some drugs that treat epilepsy, arthritis, tuberculosis and some antibiotics or sedatives. Other less common medicines may also have this effect. You may have to use another contraceptive method, such as a condom, while you are taking these medicines and during the next seven days. In some situations, your doctor or clinic may tell you to use extra precautions for longer. If while using these extra precautions you run beyond the end of the blister strip, start the next blister strip without a break. Always mention you are on the pill if a doctor, dentist or hospital prescribes you any medicine.

The herbal remedy St John's wort (*Hypericum perforatum*) should not be taken at the same time as this medicine. If you already take a St John's wort preparation, stop taking the St John's wort and mention it to your doctor.

Blood tests

The pill may affect the results of certain blood tests, so tell your doctor that you are on the pill if you need any blood tests.

How to take Synphase

A blister strip contains different colour pills.

- 7 blue ones.
- 9 white ones.
- 5 more blue ones.

The different coloured pills contain different amounts of hormones. When you take them in the correct order they imitate the natural rise and fall of your body's hormone levels during your monthly cycle. The pills are in numbered bubbles in a specially designed blister strip. Take one pill every day, in the right order. This is explained clearly below.

There is also a way to record the day you take the first pill. You will see there is a row of bubbles on the blister strip marked with the correct days of the week. When you take your first pill, press the bubble for the day of the week you have started taking the pills, for example, if you take your first pill on a Tuesday, press the bubble marked 'Tue'.

This will remind you when you started taking the pills. By counting from number one, you can work out if you have taken your pill that day. Another way of checking is, you should always take pill number eight and pill number 15 on the same day of the week as the day you took your first pill on.

Starting your first blister strip

- Take pill number one, marked 'start here' on your first day of bleeding. This is the day when your period starts. If you are not having periods, ask your doctor or clinic when you should start taking your pills.
- You will be protected at once as long as you take a pill every day.
- You can take the pill at a time that suits you, **but you must take it at about the same time every day.**
- Take a pill every day until you finish a blister strip.
- If you cannot start the pill on the first day of your period you may start to take it on any day up to the fifth day. However, if you do this, you may not be protected for the first seven days, so you should use another method of contraception such as a condom during those days.

Starting the next blister strip

- Once you have finished all 21 pills, **stop for seven days.** You will probably bleed during some or all of these seven days.
- Then, start the next blister strip. Do this whether or not you are still bleeding. You will always start the next blister strip on the same day of the week.
- You are protected during the seven day break, but only if you start the next blister strip on time. The first pill in your blister strip is the worst pill of all to miss or take late.

What do I do if I have a stomach upset or I am sick?

Synphase may not work if you are sick or have severe diarrhoea. You should carry on taking your pills as normal, but use a condom while you are ill and for the next seven days. If these seven days run beyond the end of the blister strip, start the next pack without a break.

What do I do if I miss a period?

If you have taken all your pills properly, it is very unlikely that you are pregnant. Take your next blister strip as normal. If you have not taken them correctly, see your doctor or clinic at once. You should do the same if you miss a second period. If you do get pregnant whilst you are taking this type of pill there may be a very small increased risk that your baby will have an abnormality. Ask your doctor to discuss this risk with you.

What do I do if my periods are different?

This is normal when you start the pill. You will probably have less bleeding. You may also have a little bleeding while you are taking the pills (this is called 'break-through bleeding'). If this happens, do not stop taking your pills. This should stop within two or three months. If the bleeding is heavy, do not stop taking the pill but talk to your doctor or clinic. If your periods seem different, do not stop taking the pills and just mention it to your doctor or clinic at your next visit.

What do I do if I am having an operation?

If you are planning to have an operation, which will mean lying in bed for more than a whole day, or any operation on your legs, it is best that you stop taking this type of pill **at least** four

weeks before your operation. This does not apply to some minor operations. You can usually start to take the pill again two weeks after the operation. Talk to your doctor or clinic about another method of contraception you can use until the operation.

For example, you may use a progestogen-only pill.

If you are having treatment for varicose veins, stop taking the combined pill four weeks before your treatment and stay off it until 3 months after your last treatment.

What do I do if I have an accident or I am ill?

If you have an accident or illness which means that you will have to stay in bed, it is best to stop taking the pill until you are active again.

Smoking

Smoking increases the risks to your health and some of the risks of taking the pill. It is always best to stop smoking. If you do smoke, your doctor or clinic may tell you to change your method of contraception when you are 35 or over.

What do I do if I want a baby?

If you want to have a baby it is best to wait until you have stopped taking the pill for three months or at least until your regular periods have returned. You can always use another contraceptive method such as a condom. Only rarely do regular periods take some time to return. Once you have had one period, it is easier to work out when your baby is due. However, if you do get pregnant as soon as you stop taking Synphase, this is not harmful.

What do I do if I am changing pill brands?

Take the first pill of your new blister strip on the day immediately after you have finished your old blister strip. Your period will usually be delayed until the new blister strip is finished, but you may have some breakthrough bleeding during the first few days of the new blister strip. This is quite normal and you will still be protected against pregnancy. If you do have a break, ask your doctor or clinic whether you need an extra contraceptive method such as a condom.

What do I do if I have just had a baby?

- If you are breast feeding, you should not take the combined pill. This is because the oestrogen in the pill may reduce the amount of milk you produce. You should be able to take the progestogen-only pill instead. Ask your doctor or clinic for advice.
- If you are not breast feeding, you may start taking the pill 21 days after your baby is born. This will protect you immediately. If you start later than this, you may not be protected until you have taken the pill for seven days.

What do I do if I have just had a miscarriage or abortion?

You may be able to start taking the pill immediately. If you can, you will be protected straight away. Ask your doctor or clinic if you should do so.

Overdose

If you take more than the recommended number of pills, or if you discover someone has taken a lot of pills, contact your doctor immediately.

What do I do if I forget to take a pill?

- If you forget to take a pill take it as soon as you remember and take the next one at your normal time. This may mean taking two pills on the same day.
- If you are 12 or more hours late in taking one or more pills, it may not work. As soon as you remember, take your last missed pill and carry on taking your pills normally. However, you may not be protected for the next seven days, so either avoid sexual intercourse or use an extra contraceptive method, such as a condom.
- If you have fewer than seven pills in your blister strip after you have missed taking your pill, you should complete the blister strip and start the next blister strip without a break. This will give you protection from when you took the last missed pill. You may not have a period until the end of two blister strips, but this will not harm you. You may also have some bleeding on days when you take the pill.

Does Synphase have side effects?

All medicines can sometimes cause problems. If you are worried about side effects, talk to your doctor.

These effects should become less of a problem as your body becomes used to the pills.

You may notice a change in your sex drive, and have irregular vaginal bleeding or changes in your period.

Other side effects that you might have include nausea, stomach upsets, tender breasts, weight gain, changes in appetite, headaches, depression, high blood pressure, and changes in the way your body breaks down sugars, fats or vitamins.

If you have fibroids in your uterus, these may also get worse.

Reasons to get medical help immediately

The cause of these symptoms may have nothing to do with the pill but you may need treatment. Stop taking your pills at once and tell your doctor if you have:

- a sudden sharp or severe pain in the chest;
- suddenly become short of breath or breathing is painful;
- coughed up blood;
- painful or inflamed veins in your legs;
- a crushing type of chest pain or your chest feels heavy;
- a very first attack of migraine (a bad headache with sickness);

- migraines which get worse, especially if your sight is affected, you see flashing lights, your limbs feel weak, you lose the sensation or feel a different sensation in your limbs, or you have a fit;
- sudden and unusual severe headaches;
- dizziness or you faint;
- a problem with your sight or speech;
- swollen arms or legs;
- jaundice (your skin or the whites of your eyes look yellow);
- a severe rash; or
- swelling or tenderness in your stomach.

How to store Synphase

Store your Synphase pills in a dry place, away from direct sunlight and below 25 °C. Make sure children cannot see or reach them.

Don't take Synphase after the 'expiry date' shown on the box. If your pack is out of date, take it to your pharmacist who will get rid of the pills safely.

If you have any comments on the way this booklet is written, please write to Medical Information at Pharmacia.

This booklet was written in April 2007