

# Synphasic® 28 Day Tablets

**35mcg Ethinylloestradiol and 500mcg Norethisterone + 35mcg Ethinylloestradiol and 1mg Norethisterone**

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## What is in this leaflet

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This leaflet answers some common questions about Synphasic 28 day tablets. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Synphasic against the benefits it is expected to have for you. Use Synphasic as directed by your doctor and follow advice given in this leaflet. **If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Remember: This medicine is prescribed for you and should not be given to others.**

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## What Synphasic is used for

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Synphasic is a birth control pill commonly known as a “Combined Oral Contraceptive”, that contains both an oestrogen (ethinylloestradiol) and progestogen (norethisterone) hormone.

Oral contraceptives belonging to this group produce their birth control (or contraceptive) effect by preventing ovulation (or the release of an egg from the ovary) during each menstrual cycle. Combined Oral Contraceptives also cause changes to the mucus of the cervix and the lining of the womb which contribute to the contraceptive action.

If taken according to directions the combined oral contraceptives are very effective in preventing pregnancy. The failure rate of this type of contraceptive is such that for every 1,000 women using the pill for one year, two will become pregnant.

Synphasic 28 day is only available on a prescription from your doctor.

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## Before you start to take Synphasic

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

Synphasic 28 Day tablets are not suitable for some women. You must not take Synphasic if:

- you have or have had high blood pressure, stroke, heart attack or a clot in the lung.
- you have or have had inflammation, infection or clotting in any blood vessel(s).
- you have liver disease (including tumours of any type), a history of jaundice or cholestatic jaundice of pregnancy, or severe generalised itch in the body during pregnancy; Dubin-Johnson Syndrome or Rotor Syndrome.
- you have abnormal vaginal bleeding, the cause of which is unknown.
- you are pregnant or suspect that you may be pregnant.
- you are breast feeding.
- you have cancer or suspected cancer of the breast or sex organs (e.g. cervix, ovaries, endometrium, womb) and known or suspected oestrogen - dependent tumours.
- you have sickle cell anaemia.
- you have a lipid metabolism disorder.
- you have a history of herpes during pregnancy.
- you have otosclerosis (an ear disorder) which worsened in past pregnancies.
- you suffer from partial paralysis during migraine attacks (hemiplegic migraine).

**It is important to tell your doctor about any existing medical condition as this may be affected by taking the birth control pill.**

**Also if you have any special sensitivities or allergies, including sensitivity to any of the ingredients listed under “Ingredients”, you should tell your doctor.**

Do not take Synphasic after the expiry date (EXP) printed on the pack has passed. Do not take Synphasic if the packaging is torn or shows signs of tampering.

### ***Before you start to take it***

Before taking Synphasic tell you doctor if:

- you smoke
- you have uterine fibroids
- you have gall bladder disease
- you have diabetes
- you have high blood pressure
- you suffer from epilepsy, and which medicines you take to control it
- you suffer from migraine headaches
- you have asthma
- you have heart or kidney disease
- you have or have had any form of depression
- you have a disorder of calcium or phosphorus metabolism
- any member of your family has suffered from blood clots, a stroke, or heart attack.

### ***Taking other medicines***

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

Some medicines may interfere with the effectiveness of Synphasic. This is particularly important if you need to take antibiotics or medicines for epilepsy.

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## **How to take Synphasic**

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- To begin Synphasic 28 Day, take your first tablet on the first day of your next period, that is, the day your bleeding starts.
- From the first row of the green section of the strip (i.e. the row which contains all the blue tablets) take the tablet which corresponds to the appropriate day of the week. For example, if your first day of bleeding is on TUESDAY, you should take the tablet marked “TUE” from the first row of the green section of the strip. (Please note that the green section contains blue and white active tablets. Be sure to take a blue tablet corresponding to the day of the week from the first row of the green section).
- Continue to take one tablet every day, following the arrows around the strip until all 21 tablets in this green section are finished.
- You should then take one orange tablet daily for the next 7 days, following the arrows.
- You should take your tablet at approximately the same hour each day.
- When you have finished your first strip of tablets start the next strip the following day and continue taking the tablets even when you are having a period.
- Remember to start every new strip from the first row of the green section.
- This sequence of tablet taking is repeated for as long as birth control is required. This product is effective from the first day if taken as directed above.

**Although spotting and break-through bleeding may occur in some women, these tend to disappear in the majority of patients after the first three to four cycles.**

**Always ensure that you have a new strip of tablets available**, so that you can continue to take the tablets without interruption.

**If you are switching to Synphasic 28 Day from another 21 or 28 Day oral contraceptive**, please see your doctor or pharmacist for directions.

### ***When to use it***

You should take your tablet at approximately the same hour each day.

### ***If you forget to take a tablet***

Tablets should be taken at about the same hour each day. If you are less than 12 hours late in taking your tablet, you should take that tablet at once and then take the next one at your usual time.

If you are more than 12 hours late in taking your tablet you should continue to take your tablets as usual, but ignore the missed tablet or tablets and take extra contraceptive precautions (other than the rhythm or temperature method) for the next seven days.

If these seven days extend into the inactive orange tablet section, start a new pack on the next day after having taken the last active tablet of the current pack, that is, skip the orange inactive tablets. This will mean that you will not have a period until the end of two packs.

**If you miss an orange (inactive) tablet**, take it as soon as you remember and continue on as before. An additional birth control method is not necessary in this case.

If your doctor has prescribed the taking of Synphasic any differently, or you are unclear about the above directions, then you should discuss this with him or her.

If you have trouble remembering to take Synphasic, ask your pharmacist for some hints.

### ***If you miss a period***

If you have missed a period you may be pregnant and should contact your doctor immediately.

### ***If you take too much (overdose)***

Overdosage may cause nausea. This may be followed by vaginal bleeding in some women.

Serious ill effects **have not** been reported in young children who have taken large doses of birth control pills. However, in the case of overdosage or accidental ingestion, **immediately telephone your doctor or pharmacist or the National Poisons Centre (telephone 03 474 7000) or go to Accident and Emergency at your nearest hospital. Do this even if there are no signs of discomfort or poisoning.**

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## **While you are using Synphasic**

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**Women who use oral contraceptives should not smoke. Cigarette smoking increases the risk of blood clotting and damage to the heart and blood vessels from birth control pills. The risk increases with age and with heavy smoking (15 or more cigarettes per day) and is quite marked in women over 35 years of age.**

**If you develop unexplained or persistent pains in the head, chest, stomach or legs, you should stop taking the tablets and see your doctor.** In the meantime, use another method of birth control. If you are in any doubt, see your doctor.

**Stop taking Synphasic Tablets if you develop gradual or sudden, partial or complete loss of vision; double vision or symptoms of severe vision impairment, eye protrusion,**

**swelling of the eye or eye lesions, aggravation of migraine or development of severe headache of a new pattern.** See your doctor immediately and use another birth control method in the meantime.

Slight breast tenderness or a feeling of sickness may occur in the first few months of use. This usually improves or stops with continued use.

If a full monthly period or slight spotting starts before all tablets have been taken, do not stop taking your tablets. Slight spotting during tablet taking is normally of no significance. However, **if such bleeding persists, or if heavier bleeding occurs, you should see your doctor.**

If vaginal irritation or discharge occurs, it may be an indication of a yeast infection for which treatment is available from your doctor.

If you suffer from a **stomach upset which results in vomiting or diarrhoea**, the effectiveness of Synphasic may be reduced. Tablet taking should continue as normal, and a non-hormonal method of contraception (other than the rhythm or temperature method) should be used during the period of vomiting or diarrhoea and continued for seven days following the episode of vomiting or diarrhoea. If these seven days extend into the inactive orange tablet section you should start a new pack on the next day after having taken the last active tablet from the green section of the current pack (i.e. skip the orange inactive tablets).

If you **need to have an operation**, or go to **hospital in an emergency**, you should tell the hospital doctor that you are taking Synphasic birth control pills. Surgery and prolonged periods of bed rest increase the risk of developing blood clots.

Delays in becoming pregnant may occur after Synphasic therapy is stopped. This is more likely to occur in women whose periods were irregular before using birth control pills. If you continue to experience difficulties in falling pregnant, see your doctor.

Synphasic may affect the amount and quality of breast milk as the components of Synphasic are found in breast milk. If you are breast-feeding you should talk to your doctor.

Tell your doctor if you feel depressed, think you are retaining water or your eyes are uncomfortable whilst wearing contact lenses. Your doctor will make an assessment of your condition and advise whether or not you should continue to take Synphasic.

**See your doctor if you notice any unusual physical changes or discomfort while using oral contraceptives. Women who use oral contraceptives should visit their doctor regularly for medical check-ups, which may include blood tests. Your doctor will advise you of the type and frequency of any tests required.**

Synphasic (like all oral contraceptives) is intended to prevent pregnancy. It does not protect against HIV infection (AIDS) and other sexually transmitted diseases.

**Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Synphasic. If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking Synphasic.**

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## Side effects

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects. **Ask your doctor or pharmacist to answer any questions you may have.**

**Side effects most commonly reported** in early cycles of therapy include break-through bleeding, spotting, nausea, vomiting and other gastric or stomach discomforts. These often decrease with continued use.

**Other common side effects include:** change in menstrual flow, change in weight, dark discolouration of the skin, blotchy discolouration on the face (which may persist after the tablets have been stopped), absence of periods, and breast changes (tenderness, enlargement and secretion).

**In addition to the above,** the following side effects have also been reported in some women using Synphasic tablets: headache, migraine, drowsiness, mental depression, fatigue or tiredness, change in appetite, hair growth, loss of scalp hair, acne, rashes, itching, eye lesions, dizziness, vaginal thrush, change in cervical secretions, suppression of milk production and intolerance to contact lenses.

**The most serious known side effect with Combined Oral Contraceptive use is abnormal blood clotting which may have serious consequences. Deaths have occurred in some women as a result of blood clots carried by the blood stream causing obstruction of blood vessels in the lungs or in the brain.** The risk of developing blood clotting disorders and other blood vessel diseases in oral contraceptive users **increases with age from 30 years onwards. Cigarette smoking also increases the risk.** These problems may persist after a woman has stopped taking the birth control pill.

**The use of a Combined Oral Contraceptive can increase the risk of a woman having a heart attack.** Other risk factors for a heart attack include cigarette smoking; high blood pressure; high cholesterol; obesity; diabetes; a history of pre-eclamptic toxæmia in pregnancy and age over 40 years.

**Some women may experience a rise in blood pressure** whilst taking oral contraceptives.

**The association between the use of Combined Oral Contraceptives and the development of breast cancer** has not been firmly established to date. Breast cancer has been diagnosed slightly more often in women taking the pill. This increased risk seems to be related to use at a young age, and duration of use.

**Rarer side effects** associated with the use of combined oral contraceptives are not listed here. You may wish to discuss these, or any of the side effects listed above, with your doctor if you are concerned.

**Side effects not previously reported with Synphasic may also occur.** If you notice anything unusual while you are taking Synphasic, see your doctor.

**Do not be alarmed by this list of possible side effects.** You may not experience any of them.

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## After taking Synphasic

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### **Storage**

Keep your Synphasic Tablets in a safe place away from the sight and reach of children. Keep your Synphasic tablets in a dry place, at a temperature below 25 °C. Do not keep your tablets in the refrigerator.

Do not take any tablets past the expiry date shown on the label.

Do not store Synphasic or any other medicine in the bathroom or near a sink. Do not leave it in the car on hot days or on window sills. Heat and dampness can destroy some medicines.

## ***Disposal***

If your doctor tells you to stop taking Synphasic or if the tablets have passed their expiry date, **ask your pharmacist what to do with any that are left over.**

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## **Product description**

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### ***What it looks like***

Synphasic 28 Day is available in calendar packs consisting of three strips of tablets (3 months' supply) each with 12 blue active tablets marked "SEARLE" on one side and "BX" on the other, and 9 white active tablets marked "SEARLE" on one side and "BX" on the other and 7 orange inactive tablets.

### ***Ingredients***

Each blue tablet contains the hormones "norethisterone" 500 micrograms (mcg) and "ethinyloestradiol" 35 micrograms (mcg). These blue tablets also contain magnesium stearate, povidone, maize starch, lactose and indigo carmine CI 73015. Each white tablet contains the hormones "norethisterone" 1.0 milligram (mg) and "ethinyloestradiol" 35 micrograms (mcg). These white tablets also contain magnesium stearate, povidone, maize starch and lactose. The orange inactive tablets contain magnesium stearate, cellulose microcrystalline, lactose & sunset yellow FCF (CI No. 15985).

### ***Supplier***

Pharmacia  
PO Box 11-282  
Ellerslie  
Auckland

This leaflet was prepared in November 2001