

Read all of this leaflet carefully before you start using Gracial

Keep this leaflet. You may need to read it again. This leaflet will provide information about the benefits and risks of using oral contraceptives. It will also advise you about how to take Gracial properly and when to tell your doctor about health-related conditions. If you have further questions, please ask your doctor, professional health care provider or your pharmacist. This preparation has been prescribed for you personally and you should not pass it on to others. It may harm them.

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The name of your contraceptive pill is
Gracial, tablets for oral use

- **The active substance is:**
 blue tablets : desogestrel (0.025 mg) and ethinylestradiol (0.040 mg)
 white tablets: desogestrel (0.125 mg) and ethinylestradiol (0.030 mg)

blue tablets: silica colloidal anhydrous; alpha-tocopherol; indigo carmine (E132); lactose monohydrate; potato starch; povidone; stearic acid.

white tablets: silica colloidal anhydrous; alpha-tocopherol; lactose monohydrate; potato starch; povidone; stearic acid.

1.1 Type of Pill

Gracial is a combined oral contraceptive (‘the combined Pill’). Each tablet contains a small amount of two different female hormones. These are desogestrel (a progestogen) and ethinylestradiol (an estrogen). Because of the small amounts of hormones, Gracial is considered a low-dose oral contraceptive. As the two hormones in the blue tablets are combined in a different dose than in the white tablets, it is considered a combiphasic oral contraceptive.

Gracial is used to prevent pregnancy.

Oral contraceptives are a very effective method of birth control. When taken correctly (without missing tablets), the chance of becoming pregnant is very low.

Gracial is presented in strips of 22 tablets (7 blue and 15 white tablets) packed in a ply carton. The tablets are biconvex, round and 6 mm in diameter. Each tablet is marked TR above 8 (white tablets) or TR above 9 (blue tablets) on one side and Organon* on the reverse side.

Do not use the combined Pill if you have any of the conditions listed below. If any of these apply to you, tell your doctor before starting to use Gracial. Your doctor may advise you to use a different type of Pill or an entirely different (non-hormonal) method of birth control.

- If you have, or have ever had a disorder affecting the blood circulation: in particular, those conditions relating to thrombosis (the formation of a blood clot) in the blood vessels of the legs (deep vein thrombosis), the lungs (pulmonary embolism), the heart (heart attack), or other parts of the body. (See also the section later in this leaflet called *The Pill and Thrombosis*).
- If you have or have had a stroke (caused by a blood clot in or a rupture of a blood vessel in the brain).
- If you have or have ever had a condition that may be a first sign of a heart attack (such as angina pectoris or chest pain) or stroke (such as transient ischaemic attack or small reversible stroke).
- If you have a history of migraine accompanied by e.g., visual symptoms, speech disability, or weakness or numbness in any part of your body.
- If you have diabetes mellitus with blood vessel damage.
- If you have or have had a pancreatitis (an inflammation of the pancreas) associated with high levels of fatty substances in your blood.
- If you have jaundice (yellowing of the skin) or severe liver disease.
- If you have or have had a cancer that may grow under the influence of sex hormones (e.g., of the breast or the genital organs).
- If you have or have had a benign or malignant liver tumor.
- If you have any unexplained vaginal bleeding.
- If you are pregnant or think you might be pregnant.
- If you are hypersensitive (allergic) to ethinylestradiol or desogestrel or any of the other ingredients of Gracial.

If any of these conditions appear for the first time while using the Pill, stop taking it at once and consult your doctor. In the meantime, use non-hormonal contraceptive measures. See also 'General Notes' in the next section.

3.1 General notes

In this leaflet, several situations are described where you should stop taking the Pill, or where the reliability of the Pill may be decreased. In such situations you should not have sex or you should take extra non-hormonal contraceptive precautions, e.g., use a condom or another barrier method. Do not use rhythm or temperature methods. These methods can be unreliable because the Pill alters the usual changes in temperature and cervical mucus that occur during the menstrual cycle.

Gracial, like all contraceptive Pills, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

the combined Pill is used in the presence of any of the conditions listed below you may need to be kept under close observation. Your doctor can explain this to you. Therefore, if any of these apply to you, tell your doctor before starting to use Gracial.

- you smoke;
- you have diabetes;
- you are overweight;
- you have high blood pressure;
- you have a heart valve disorder or a certain heart rhythm disorder;
- you have an inflammation of your veins (superficial phlebitis);
- you have varicose veins;
- anyone in your immediate family has had a thrombosis, a heart attack or a stroke;
- you suffer from migraine;
- you suffer from epilepsy;
- you or someone in your immediate family has or has had high blood levels
- of cholesterol or triglycerides (fatty substances);
- anyone in your immediate family has had breast cancer;
- you have liver or gallbladder disease;
- you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease);
- you have systemic lupus erythematosus (SLE; a disease affecting the skin all over the body);
- you have haemolytic uraemic syndrome (HUS; a disorder of blood coagulation causing failure of the kidneys);
- you have sickle cell disease;
- you have a condition that occurred for the first time or worsened during pregnancy or previous use of sex hormones (e.g., hearing loss, a metabolic disease called porphyria, a skin disease called herpes gestationis, a neurological disease called Sydenham's chorea);
- you have or have had chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face); if so, avoid too much exposure to the sun or ultraviolet radiation.

If any of the above conditions appear for the first time, recur or worsen while using the Pill, you should contact your doctor.

A thrombosis is the formation of a blood clot which may block a blood vessel. A thrombosis sometimes occurs in the deep veins of the legs (deep venous thrombosis). If this blood clot breaks away from the veins where it is formed, it may reach and block the arteries of the lungs, causing a so-called 'pulmonary embolism'. Deep venous thrombosis is a rare occurrence. It can develop whether or not you are taking the Pill. The risk is higher in Pill-users than in non-users. The chance of getting a thrombosis is highest after you started using the Pill for the very first time. Thrombosis can also happen if you become pregnant. The risk of getting a deep venous thrombosis for women using Pills with desogestrel may be slightly higher than for women using Pills with levonorgestrel. The absolute numbers remain very small. If 10 000 women use a Pill with levonorgestrel for one year, 2 women would get a thrombosis. If 10 000 women use a Pill with desogestrel for a year approximately 3 to 4 women would get a thrombosis. For comparison, if 10 000 women get pregnant, approximately 6 would get a thrombosis. These findings are based on the results of some studies. Other studies did not find a higher risk for Pills with desogestrel.

Blood clots can also occur very rarely in the blood vessels of the heart (causing a heart attack) or the brain (causing a stroke).

Extremely rarely blood clots can occur in the liver, gut, kidney or eye.

Very occasionally thrombosis may cause serious permanent disabilities or may even be fatal.

The risk of having a heart attack or stroke increases as you get older. It also increases the more you smoke. **When using the Pill you should stop smoking, especially if you are older than about 35 years of age.**

If you develop high blood pressure while using the Pill, you may be told to stop using it.

The risk of having deep venous thrombosis is temporarily increased as a result of an operation or immobilization (for example, when you have your leg or legs in plaster or splints). In women who use the Pill, the risk may be yet higher. Tell your doctor you are using the Pill well in advance of any expected hospitalization or surgery. Your doctor may tell you to stop taking the Pill several weeks before surgery or at the time of immobilization. Your doctor will also tell you when you can start taking the Pill again after you are back on your feet.

If you notice possible signs of a thrombosis, stop taking the Pill and consult your doctor immediately (See also *'When should you contact your doctor?'*).

Breast cancer has been diagnosed slightly more often in women who use the Pill than in women of the same age who do not use the Pill. This slight increase in the numbers of breast cancer diagnoses gradually disappears during the course of the 10 years after stopping use of the Pill. It is not known whether the difference is caused by the Pill. It may be that the women were examined more often, so that the breast cancer was noticed earlier.

In rare cases benign liver tumors and even more rarely, malignant liver tumors have been reported in users of the Pill. These tumors may lead to internal bleeding. Contact your doctor immediately if you have severe pain in your abdomen.

Chronic infection with the Human Papilloma Virus (HPV) is the single most important risk factor for cervical cancer. In women who use COCs for a long time the chance of getting cervical cancer may be slightly higher. This finding may not be caused by the Pill itself but may be related to sexual behavior and other factors.

Gracial must not be used by women who are pregnant, or who think they may be pregnant. If you suspect that you are pregnant while you are already using Gracial, you should consult your doctor as soon as possible.

Gracial is generally not recommended for use during breastfeeding. If you wish to take the Pill while breastfeeding, please seek the advice of your doctor.

There are no observed effects.

Some medicines may stop the Pill from working properly. These include medicines used for the treatment of epilepsy (e.g., primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate, felbamate); tuberculosis (e.g., rifampicin, rifabutin) and HIV infections (e.g., ritonavir); antibiotics (e.g., penicillins, tetracyclines, griseofulvin) for some other infectious diseases; and the herbal remedy St. John's wort (primarily used for the treatment of depressive moods). The Pill may also interfere with the working of other medicines.

Please inform your doctor or pharmacist if you are taking or have recently taken any other medicines or herbal products, even those not prescribed.

Also tell any other doctor or dentist who prescribes another medicine (or the dispensing pharmacist) that you use Gracial. They can tell you if you need to take additional contraceptive precautions and if so, for how long.

Regular check-ups
When you are using the Pill, your doctor will tell you to return for regular check-ups.

Contact your doctor as soon as possible if:

- you notice any changes in your own health, especially involving any of the items mentioned in this leaflet (see also 'When should you not use Gracial and 'Before you start to use Gracial'; do not forget about the items related to your immediate family);
- you feel a lump in your breast;
- you are going to use other medications (see also 'The Pill and Other Medicines');
- you are to be immobilized or are to have surgery (consult your doctor at least four weeks in advance);
- you have unusual, heavy vaginal bleeding;
- you forgot tablets in the first week of the pack and had intercourse in the seven days before;
- you have severe diarrhoea;
- you miss your period twice in a row or suspect you are pregnant (do not start the next pack until told to by your doctor).

Stop taking tablets and see your doctor immediately if you notice possible signs of thrombosis, myocardial infarction or a stroke:

- an unusual cough;
- severe pain in the chest which may reach the left arm;
- breathlessness;
- any unusual, severe, or prolonged headache or migraine attack;
- partial or complete loss of vision, or double vision;
- slurring or speech disability;
- sudden changes to your hearing, sense of smell, or taste;
- dizziness or fainting;
- weakness or numbness in any part of your body;
- severe pain in your abdomen;
- severe pain or swelling in either of your legs

The situations and symptoms mentioned above are described and explained in more detail in Section 3 of this leaflet.

5.1 When and how to take the tablets?
The Gracial pack contains 22 tablets: 7 blue (numbered 1-7) and 15 white tablets (numbered 8-22). Take your tablet at about the same time each day, with some liquid if necessary. Each time you start a new pack of Gracial, take the number 1 blue tablet in the left-hand top corner. Mark your starting day by drawing a checkmark on the aluminium cover of the corresponding injection pocket in the green part of the strip. In this way, you can easily check whether you have your daily tablet. Follow the direction of the arrows until 22 tablets have been taken. When doing that, you will take all the blue tablets first, followed by all the white tablets. During the next 6 days you take no tablets. A period should begin during these 6 days (the withdrawal bleed). Usually it will start on day 2-3 after the last Gracial tablet. Start taking your next pack on the 7th day even if your period continues. This means that you will always start new packs on the same day of the week, and also that you have your withdrawal bleed on about the same days, each month.

- *When no hormonal contraceptive has been used in the past month.*
Start taking Graciel on the first day of your cycle, i.e. the first day of menstrual bleeding. Graciel will work immediately, it is not necessary to use an additional contraceptive method.
You may also start on days 2-5 of your cycle, but in that case make sure you also use an additional contraceptive method (barrier method) for the first 7 days of tablet-taking in the first cycle.
- *When changing from another combined hormonal contraceptive (combined oral contraceptive pill (COC), vaginal ring, or transdermal patch).*
You can start taking Graciel the day after you take the last tablet from your present Pill pack (this means no tablet-free break). If your present Pill pack also contains inactive tablets you can start Graciel on the day after taking the last **active** tablet (if you are not sure which this is, ask your doctor or pharmacist). You can also start later, but never later than the day following the tablet-free break of your present Pill (or the day after the last inactive tablet of your present Pill). In case you use a vaginal ring or transdermal patch, you should start using Graciel preferably on the day of removal, but at the latest when the next ring or patch would have been applied.
If you follow these instructions, it is not necessary to use an additional contraceptive method

- You can stop taking the minipill any day and start taking Gracial the next day, at the same time. But make sure you also use an additional contraceptive method (a barrier method) for the first 7 days of tablet taking when having intercourse
- When changing from an injectable, an implant or a progestogen-releasing intrauterine device (IUD). Start using Gracial when your next injection is due or on the day that your implant or your IUD is removed. But make sure you also use an additional contraceptive method (a barrier method) for the first 7 days of tablet taking when having intercourse
- After having a baby. If you have just had a baby, your doctor may tell you to wait until after your first normal period before you start taking Gracial. Sometimes it is possible to start sooner. Your doctor will advise you. If you are breastfeeding and want to take Gracial, you should discuss this first with your doctor.

3.5 If too many Gracial tablets are taken (overdose)
There have been no reports of serious harmful effects from taking too many Gracial tablets at one time. If you have taken several tablets at a time, you may have nausea, vomiting or vaginal bleeding. If you discover that a child has taken Gracial, ask your doctor for advice.

You can stop taking Gracial at any time you want. If you stop because you want to get pregnant, it is generally recommended that you wait until you have had a natural period before trying to conceive. This helps you to work out when the baby will be due.

If you do not want to become pregnant, ask your doctor about other methods of birth control.

WHAT TO DO IF you forget to take your tablets

- If you are less than 12 hours late in taking a tablet, the reliability of the Pill is maintained. Take the tablet as soon as you remember and take the next tablets at the usual times.
- If you are more than 12 hours late in taking any tablet, the reliability of the Pill may be reduced. The more consecutive tablets you have missed, the higher the risk that the contraceptive efficacy is decreased. There is a particularly high risk of becoming pregnant if you miss tablets at the beginning or at the end of the pack. Therefore you should follow the rules given below (see also the diagram below).

More than one tablet forgotten in a pack
Ask your doctor for advice.

1 tablet missed in week 1
Take the missed tablet as soon as you remember (even if this means taking two tablets at the same time) and take the next tablets at the usual time. Use extra contraceptive precautions (barrier method) for the next 7 days.

If you had sexual intercourse in this week before missing the tablets, there is a possibility of becoming pregnant. So let your doctor immediately.

