

GRACIAL TABLET

Desogestrel / Ethinylestradiol (25 mcg / 40 mcg & 125 mcg / 30 mcg)

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What GRACIAL Tablet is used for

GRACIAL Tablet is used for contraception, to prevent pregnancy. When taken correctly (without missing tablets), the chance of becoming pregnant is very low.

How GRACIAL Tablet works

GRACIAL Tablet is a combined oral contraceptive. Each tablet contains a small amount of two different female hormones. These are desogestrel (a progestogen) and ethinylestradiol (an estrogen). Because of small amounts of hormones, GRACIAL Tablet 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 combiphase oral contraceptive.

GRACIAL Tablet prevents the release of egg cell from the ovaries and causes changes in the cervical secretion, thus prevent pregnancy.

Before you use GRACIAL Tablet

- When you must not take it

Do not take GRACIAL Tablet if you have the following conditions listed below. If anything on this list applies to you, tell your doctor before starting GRACIAL Tablet.

- If you have or had in the past of blood clots (thrombosis) in blood vessel of the leg, lung (embolus) or other organs.
- If you have or had in the past a heart attack or stroke.
- If you have or 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 disturbance of blood clotting (e.g. protein C deficiency).
- If you have major surgery (e.g. an operation) and your ability to move around is limited for a long period of time.
- If you have (had) a type of migraine called 'migraine with aura'.
- If you have diabetes mellitus with blood vessel damage.
- If you have a serious risk factor or several risk factors for developing thrombosis.
- If you have or had in the past a pancreatitis (an inflammation of pancreas) associated with high levels of fatty substances in your blood.
- If you have jaundice (yellowing of the skin) or had in the past severe liver disease and your liver is not yet working normally.
- If you have or had in the past a liver tumour.
- If you have or suspected cancer that may grow under the influence of sex hormones (e.g. genital organs or breasts).
- If you have any unexplained vaginal bleeding.
- If you are pregnant or may think you might be pregnant.
- If you are allergic to any of the ingredients of GRACIAL Tablet.
- If you have Hepatitis C and are taking the medicinal products containing ombitasvir / paritaprevir / ritonavir with or without dasabuvir, glecaprevir / pibrentasvir and sofosbuvir / velpatasvir / voxilaprevir.

Before you start to use it

If GRACIAL Tablet is used in the presence of any of the conditions listed below you may need to be kept under close observation. If any of these apply to you, tell your doctor before starting to use GRACIAL Tablet.

- you smoke / overweight
- you have diabetes
- 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, heart attack or a stroke.
- you suffer from migraine
- you suffer from epilepsy
- you or someone in your immediately family have or had high cholesterol or triglycerides (fats in the blood)
- anyone in your immediate family has had breast cancer
- you have liver or gallbladder disease
- you have Crohn's disease and ulcerative colitis (chronic inflammatory bowel disease)
- you have systemic lupus erythematosus (SLE: a chronic connective tissue disease affecting the skin all over the body)
- you have haemolytic uraemic syndrome (HUS: a disorder of blood clotting causing failure of the kidneys)
- you have sickle cell disease (a rare blood disease)
- you have an operation, or if your ability move around is limited for a long period of time
- if you have recently given birth you are at an increased risk of blood clots.
- you have condition that occurred for the first time or got worse during pregnancy or previous use of sex hormones (e.g. hearing loss, a disease called porphyria, a skin disease called herpes gestations, a disease called Sydenham's chorea, hereditary / acquired angioedema).

- you have or had chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face); if so, avoid too much exposure to the sun or ultraviolet light.

- Taking other medicines

You **must** tell your doctor or pharmacist about all the medicines you are taking, even those which you have bought for yourself without a doctor's prescription. The other medicines that you may be taking may increase or decrease the effect of GRACIAL Tablet.

These include medicines used for the treatment of epilepsy (e.g., primidone, barbiturates, carbamazepine, oxcarbazepine, topiramate, felbamate); tuberculosis (e.g., rifampicin) and HIV infections (e.g., ritonavir); antibiotics (e.g. griseofulvin) for some other infectious diseases; and the herbal remedy St. John's wort (treatment of depressive moods).

If you are taking medicines or herbal products that might make GRACIAL Tablet less effective, a barrier contraceptive method should also be used. Since the effect of another medicine on GRACIAL may last up to 28 days after stopping the medicine, it is necessary to use the additional barrier contraceptive method for that long.

GRACIAL Tablet may also interfere with how other medicines work, causing either an increase in effect (e.g. cyclosporine) or a decrease in effect (e.g. lamotrigine).

Do not use GRACIAL Tablet if you have Hepatitis C and are taking the medicinal products containing ombitasvir / paritaprevir / ritonavir with or without dasabuvir, glecaprevir / pibrentasvir and sofosbuvir / velpatasvir / voxilaprevir. Your doctor will prescribe another type of contraceptive before starting the treatment with these medicinal products.

How to use GRACIAL Tablet

- How much to use

GRACIAL Tablet 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 breaking the aluminium cover of the corresponding indicator pocket in the green part of the strip. In this way you can easily check whether you took your daily tablet. Follow the direction of the arrows until all 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 roughly the same days, each month.

- When to use it

No preceding hormonal contraceptive use [in the past month]

Start taking Gracial on the first day of your cycle, i.e. the first day of menstrual bleeding. Gracial will work immediately. You do not need to use an additional contraceptive method. You may also start on days 2-5 of your cycle, but if you do, make sure you also use an additional contraceptive method (barrier method) for the first 7 days of tablet-taking in the first cycle.

Changing from a combined hormonal contraceptive (combined oral contraceptive (COC), vaginal ring, or transdermal patch)

You should start with GRACIAL Tablet preferably on the day after the last active tablet (the last tablet containing the active substances) of your previous COC, but at the latest on the day following the usual tablet-free or placebo tablet interval of her

previous COC. In case a vaginal ring or transdermal patch has been used, you should start using GRACIAL Tablet preferably on the day of removal, but at the latest when the next application would have been due.

If you have been using her previous method consistently and correctly and if it is reasonably certain that you are not pregnant you may also switch from your previous combined hormonal contraceptive on any day of the cycle.

The hormone-free interval of the previous method should never be extended beyond its recommended length.

Changing from a progestogen-only-method (minipill, injection, implant) or from a progestogen-releasing intrauterine system (IUS)

You may switch any day from the minipill (from an implant or the IUS on the day of its removal, from an injectable when the next injection would be due), but make sure you use additionally barrier method for the first 7 days of tablet-taking.

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 Tablet. Sometimes it is possible to start sooner. Your doctor will advise you. If you are breast-feeding and want to take GRACIAL Tablet, you should talk to your doctor first.

After a miscarriage or an abortion

Your doctor will advise you.

- How long to use it

Continue taking GRACIAL Tablet for as long as your doctor recommends.

- If you forget to use it

- 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.

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 the week before missing the tablets, it's possible that you could be pregnant. So tell your doctor immediately.

1 tablet missed in week 2

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.

1 tablet missed in week 3

You may choose either of the following options, without the need for extra contraceptive precautions.

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. Start the next pack as soon as the current pack is finished so that **no gap is left between packs**. You may not have a withdrawal bleed until the end of the second pack but you may have spotting or breakthrough bleeding on tablet-taking days.

Or

2. Stop taking tablets from your current pack, have a tablet-free break of 6 days or less (**including the day you missed your tablet**) and then start the next pack. If you do this, you can always start your next pack on the same day of the week as you usually do.

If you have forgotten tablets in a pack and you do not have your period in the first normal tablet-free break, you may be pregnant. Tell your doctor before you start with the next pack.

- If you suffer from gastro-intestinal disturbances (e.g. vomiting, severe diarrhoea)

If you vomit, or have severe diarrhoea, the active ingredients of your GRACIAL Tablet may not have been completely absorbed. If you vomit within 3 to 4 hours after taking your tablet, this is like missing a tablet. You must follow the advice of missed tablets. If you have severe diarrhoea, please tell your doctor.

- If you want to delay your period

You can delay your period if you start with the white tablets in your next pack of Gracial immediately after finishing your current pack. You can continue with this pack for as long as you wish, until the end of the second pack (maximally 15 days). When you wish your period to begin, just stop tablet-taking. While using the second pack you may have some breakthrough bleeding or spotting on tablet-taking days. Start with your next pack after the usual 6-day tablet-free break.

- If you want to change the starting day of your period

If you take your tablets correctly, you will have your period on about the same day every 4 weeks. If you want to change this day, just shorten, (never lengthen) the next tablet-free break. For example, if your period usually starts on a Friday and in future you want it to start on Tuesday (3 days earlier) start your next pack 3 days sooner than you usually do. If you make your tablet-free break very short (e.g., 3 days or less), you may not bleed during the break. You may have some breakthrough bleeding or spotting while using the next pack.

- If you have an unexpected bleeding

With all Pills, for the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding) between your periods. You may need to use sanitary protection, but keep taking your tablets as usual. Irregular vaginal bleeding usually stops once your body has adjusted to GRACIAL Tablet (usually after about 3 months). If bleeding continues, becomes heavy or starts again, tell your doctor.

- If you have a missed period

If you have taken all of your tablets at the right time, and you have not vomited, or used other medicines then you are very unlikely to be pregnant. Keep taking GRACIAL Tablet as usual.

If you miss your period twice in a row, you may be pregnant. Tell your doctor.

- If you use too much (overdose)

Contact your doctor immediately or go to Emergency Department of your nearest hospital if you think that you or anyone else may have taken too much GRACIAL Tablet.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking too many tablets may cause nausea, vomiting or vaginal bleeding.

While you are using GRACIAL Tablet

- Things you must do

Regular check-ups

When you are taking GRACIAL Tablet, you should usually have a check-up every year.

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 ('When you must not take it' and 'Before you start to take it'; do not forget about changes in the health of your immediate family)
- you feel a lump in your breast
- you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives together with difficulty breathing
- you are going to use other medicines ('Taking Other Medicines')
- your ability to move around is limited for a long period of time or you are to have surgery (tell 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 your doctor tells you).

- Things you must not do

Do not stop taking GRACIAL Tablet without first checking with your doctor.

Do not take any new medicines without consulting your doctor.

Do not take GRACIAL Tablet to treat any other complaints unless your doctor tells you to.

Do not give GRACIAL Tablet to anyone else, even if they have the same condition as you.

- Things to be careful of

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

Stop taking tablets and see your doctor immediately if you notice possible signs of thrombosis:

- 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.

Side effects

Like all medicines, GRACIAL Tablet can cause side effects. However, many of these occur because the dose is too high. Therefore your doctor may need to adjust this.

Common effects:

- Depressed mood, mood changes
- Headache
- Nausea, abdominal pain
- Breast pain / tenderness
- Weight increased

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [*Consumers* → *Reporting Side Effects to Medicines (ConSERF)* or *Vaccines (AEFI)*].

Storage and Disposal of GRACIAL Tablet

- Storage

Keep out of the reach and sight of children.

Store below 30°C. Protect from light.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Each strip of GRACIAL Tablet contains 7 (blue) tablets of Desogestrel / Ethinylestradiol 25mcg/40mcg and 15 (white) tablets of Desogestrel / Ethinylestradiol 125mcg/30mcg.

Desogestrel / Ethinylestradiol 25mcg/40mcg (Blue Tablet)

- Blue, round and flat tablets with bevelled edges with a diameter of 6 mm, coded TR/9 on one side and blank on the other side.

Desogestrel / Ethinylestradiol 125mcg/30mcg (White Tablet)

- White, round and flat tablets with bevelled edges with a diameter of 6 mm, coded TR/8 on one side and blank on the other side.

- Ingredients

Desogestrel / Ethinylestradiol 25mcg/40mcg (Blue Tablet)

Active ingredients:

- Desogestrel 25 mcg
- Ethinylestradiol 40 mcg

Inactive ingredients:

- Potato Starch
- Silica, colloidal anhydrous
- All-rac-alpha-tocopherol
- Indigo Carmine E132
- Stearic acid
- Povidone
- Lactose monohydrate

Desogestrel / Ethinylestradiol 125mcg/30mcg (White Tablet)

Active ingredients:

- Desogestrel 125 mcg
- Ethinylestradiol 30 mcg

Inactive ingredients:

- Potato Starch
- Silica, colloidal anhydrous
- All-rac-alpha-tocopherol
- Stearic acid
- Povidone
- Lactose monohydrate

- MAL number

MAL20076018ACZ

Manufacturer

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Product Registration Holder

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