

For users of

Amorest 28[®]

(norgestimate + ethinylestradiol)



This is Amorest 28

Amorest 28 is a contraceptive which prevents you from becoming pregnant, provided you use it correctly. Amorest 28 is a so-called combined contraceptive tablet, which means that it contains two types of hormone, oestrogen (ethinylestradiol) and progestogen (norgestimate).

Amorest 28 prevents pregnancy as follows:

- Ovulation does not take place.
- The endometrium remains thin and does not fill with blood, which means that an egg is not able to attach.
- The secretion in the cervix thickens, making it difficult for sperm to penetrate.

Before taking Amorest 28:

- Carefully read the package leaflet in the packaging.
- Contact your midwife or doctor if you have any questions.

Your normal menstrual cycle

In order to understand how Amorest 28 works, it is also important that you know how your normal menstrual cycle works. Once a month an egg is released from one of your ovaries. The endometrium prepares itself to receive the egg by filling with blood and becoming stronger in order for the egg, if fertilised, to get the nourishment it needs to grow into a foetus. If the egg is not fertilised, it will be ejected after 14 days together with the newly formed endometrium in the womb. The bleeding that arises is called a period.

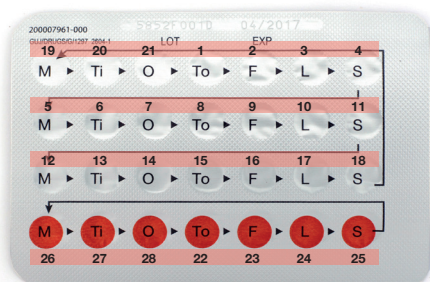
A normal period lasts 3-8 days. The entire menstrual cycle, from the beginning of the bleed to the next bleed, is usually 28 days, but varies among women from 21 up to 35 days. Ovulation can take place between days 9 and 20 in a 28-day cycle.

Positive effects of contraceptive tablets

When you use combined contraceptive tablets, menstrual flow is reduced compared to your usual menstruation. Menstrual cramping and ovulation pain are also reduced. The thickened secretion in the cervix can make it harder for bacteria to pass through. Women who use contraceptive tablets have fewer instances of salpingitis. On the other hand, contraceptive tablets do not give protection against sexually transmitted diseases.

Note:

Contraceptive tablets do not provide protection against sexually transmitted diseases, so you should use condoms as extra protection if you meet a new partner.



If the first day of your period is a Thursday, for example, you should start with the tablet marked "To".



Amorest 28 packaging contains 3, 6 or 13 blister packs with 28 tablets each. The first 21 blue tablets (rows 1-3) contain hormones, while the 7 green tablets (row 4) are free of hormones.

How to use Amorest 28

- If you take the first blue tablet on the first day of your menstruation, you will be immediately protected from pregnancy. You can also begin taking Amorest 28 on day 2-5 of your menstrual cycle, but you will then have to use an extra contraceptive method (such as a condom) for the first 7 days.
- You should take the tablets with a little liquid at about the same time each day.
- Start with a tablet from the top row with the current day's weekly marking. For example, if you start on a Tuesday, take a tablet that has a Ti marking.
- Follow the direction of the arrows until you have taken all 28 tablets. You will typically experience bleeding that resembles a period (withdrawal bleed) 2 to 3 days after taking the last blue hormone tablet.
- The day after emptying a blister pack, begin a new one, even if you are still bleeding. This means that you always begin a new blister pack on the same day of the week and that you will have your period on about the same days each month.

The illustration below, to the left, shows how to take your tablets from day 1 to day 28. In the example, the first day of the period is a Thursday.

1. Begin by taking the first tablet on the first day of bleeding. If it is a Thursday, for instance, you take the tablet under "To" (tablet marked "1" in the image on the left).
2. Follow the direction of the arrow on the foil until you have taken all the 21 blue tablets, i.e. tablet "1" to tablet "21".
3. Next, start immediately with the green tablets on the same weekday on which you started taking the blue tablets – in this example, on "To" (marked "22" in the image). Take all the 7 green tablets until the blister is empty.
4. Start immediately on a new pack.

Read more on the package leaflet about how to start using Amorest 28 after childbirth or if you have previously used a different hormonal contraceptive.

Frequently asked questions

What if I forget to take Amorest 28?

The risk of pregnancy is greatest if you forget a tablet in connection with the hormone-free period, i.e. if the hormone-free period is longer than 7 days.

- If **less than 12 hours** have passed since you should have taken your tablet, you are still protected against pregnancy. Take the tablet as soon as you remember to do so, and take the next tablet at the usual time.
- If **more than 12 hours** have passed, the effect of the contraceptive tablet may be reduced. Follow the instructions below:

You have forgotten more than 1 tablet in the blister pack:
Contact your doctor/midwife for advice.

1 tablet forgotten in week 1:

Take the missed tablet as soon as you remember, even if it means taking two tablets at the same time. Take the next tablets at the usual time, but do not forget to use extra contraceptive protection (such as a condom) for the next 7 days. If you had intercourse in the week prior to the forgotten tablet, there is a risk that you may be pregnant. Tell your doctor/midwife immediately.

1 tablet forgotten in week 2:

Take the missed tablet as soon as you remember, even if it means taking two tablets at the same time. Take the next tablets at the usual time. The contraceptive tablet still has the desired effect and you do not need any extra contraceptive protection. If you forget more than 1 tablet, supplementary contraception should be used for 7 days.

1 tablet forgotten in week 3:

If you choose one of the following two options, you do not need extra contraceptive protection:

1. Take the forgotten tablet as soon as you remember, even if it means taking two tablets at the same time. Take the remaining tablets at the usual time. Skip the 7 green tablets and start immediately on the next blister pack. You will probably not have any real withdrawal bleeding until the end of the second blister pack. However, you may have spotting and breakthrough bleeding on the days when you take tablets.
2. Immediately stop taking the active blue tablets in row 3 and begin taking the hormone-free (green) tablets in the last row. Then continue with a new blister pack.

1 tablet forgotten in week 4:

Forgetting to take a green hormone-free tablet does not affect the contraceptive effect. Throw away the forgotten green tablet and take the next tablet at the usual time.

Note: If you forgot to take tablets from a blister pack and do not experience withdrawal bleeding while taking the hormone-free green tablets, you may be pregnant. Consult your doctor/midwife before starting on the next blister pack.

What if I want to switch the starting day of my period?

Do not take all of the tablets in row 4 before starting on the next blister pack. For example, if your bleeding usually starts on a Friday and you want to have it on a Tuesday instead, you can begin a new blister pack 3 days earlier than normal. Start at the top row with the blue tablets. Throw the excess tablets from the first pack away.

What if I want to delay my period?

When you have taken the last tablet in row 3, you can delay your period by skipping the green hormone-free tablets and instead immediately starting with a new blister pack at row 1. Continue to take your blue hormone tablets for as long as you want to avoid bleeding. After that, take the green tablets for 7 days and then begin a new blister pack with 28 tablets and a new starting day.

What if I experience small bleeds?

Small bleeds can occur and are most common when you start taking contraceptive tablets. The risk of irregular bleeding increases if you do not take your contraceptive tablets regularly or if you take your tablets for a long stretch of time. If the bleeding becomes uncomfortable or only appears after a few months, contact your midwife/doctor.

What if I have vomited or had diarrhoea?

If you have vomited within 3-4 hours after taking a blue tablet and/or had bad diarrhoea, it is possible that your body has not been able to absorb the hormones correctly. After vomiting or diarrhoea, you must take a new blue tablet from another blister pack (spare pack) as soon as possible. If this is not possible, or if 12 hours have already passed from when you normally take your tablet, you should follow the advice under "*What if I forget to take a tablet*".

What if I am taking other medication?

Always inform your midwife or doctor if you are taking any other medication. Using contraceptive tablets in combination with other medication can lead to reduced protection. Some antibiotics, medicine for epilepsy, charcoal tablets and the natural medicine St. John's wort are examples of this. You should also avoid drinking grapefruit juice, as it can diminish the effect of the contraceptive tablet.

What if I want to become pregnant?

If you want to become pregnant, you should finish the pack you are taking, but not begin a new one. In most women, ovulation returns immediately after they stop taking their contraceptive tablets. But it can also take some time, depending on the ovaries' own activity. Keep in mind that all women who wish to become pregnant should avoid tobacco and alcohol and take folic acid supplements, e.g. Natalben Gravid (read more on the next page).

What side effects might I experience?

Typical side effects which can occur include tenderness in the breasts, feeling sick, headache, breakthrough bleeding or mood swings. These side effects are usually mild and normally disappear within a few months. There are side effects which are rare yet serious. Among other things, there is a slightly higher risk of blood clots in veins or arteries, particularly in the first year or when combined contraceptive tablets are used following a break of 4 or more weeks. The risk of blood clots also increases if you have a major operation or are bedridden for a prolonged period. In these instances you should take a break from your contraceptive tablets.

Be alert and contact a doctor immediately if you experience any of the following symptoms:

Sudden swelling or pain in your calves, skin discolouration on the legs (e.g. pale, red or blue), sudden change in vision, migraine-like headaches that you have not had before, pain in the chest or difficulty breathing, severe pain in the abdomen, dizziness or impaired balance, severe itching or rash.

Important to remember:

If you experience any side effects, especially if they are serious or prolonged, or if your health changes and you think that it might be due to Amorest 28, contact a doctor or midwife.

If you have any other questions or doubts, contact your midwife or doctor. For further information read the patient information leaflet in the packaging.

What if I want to prevent bleeding?

There are general recommendations that you can take your contraceptive tablets without any break, but these do not specifically concern Amorest 28. There is no contraceptive that can guarantee that you will be entirely free of bleeding. However, if you take your active blue tablets continuously, without any break, your bleeding episodes may be fewer. You can continue with the blue tablets until you bleed (breakthrough bleeding). Then you take a break for no more than 7 days and start again with the active blue tablets.

Start taking folic acid if you stop taking your contraceptive tablets and wish to become pregnant

Folic acid is necessary for normal cell division and development of the brain and nervous system in the foetus. Inadequate intake of folic acid can increase the risk of having a child with spina bifida.

The Swedish National Food Administration and the National Board of Health and Welfare recommend a supplement of 400 micrograms of folic acid daily. To achieve the right effect, it is a good idea to begin approximately one month before conception.

Natalben Gravid is a nutritive tablet specially adapted for women who are or who plan to get pregnant. Natalben Gravid contains active folic acid that all women can benefit from, plus iron, iodine, vitamin D, omega-3 and another 14 carefully selected nutrients for pregnancy. Dietary supplements do not replace a healthy diet, but should be combined with a varied and balanced diet and a healthy lifestyle.

Consult your midwife or read more at www.natalben.se

Amorest 28 (250 micrograms norgestimate, 35 micrograms ethinylestradiol), tablets, combined contraceptive tablets. Rx. F. ATC code G03AA11.

Indication: Contraceptive for women.

Warnings and restrictions: When deciding whether to prescribe Amorest 28, the individual woman's risk factors must be taken into consideration, especially for venous thromboembolism (VTE) with Amorest 28 compared to other combined hormonal contraceptives.

Packaging: 3x28, 6x28 and 13x28. blister packs with 28 tablets. Each pack contains 21 active blue tablets and 7 green placebo tablets. Product summary updated 14 June 2017. For further information, see www.fass.se www.campuspharma.se

