

Marvelon® 28

(mar-ve-lon)

Ethinylestradiol and Desogestrel

Consumer Medicine Information

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This leaflet answers some common questions about Marvelon 28. 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 Marvelon 28 against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Read this information carefully before you start taking Marvelon 28 tablets.

Keep this leaflet.

You may need to read it again.

1. What Marvelon 28 is used for

Marvelon 28 is an oral contraceptive, commonly known as a "Birth Control Pill" or "The Pill" that has been prescribed to prevent you from getting pregnant.

Marvelon 28 prevents pregnancy in several ways:

- It inhibits the egg release by stopping it maturing.
- Changing the cervical mucus consistency making it difficult for the sperm to reach the egg.
- Changing the lining of the uterus making it less suitable for implantation.

Marvelon 28 consists of 21 large white tablets, each containing 2 active ingredients: 30 micrograms of ethinylestradiol (an estrogen) and 150 micrograms of desogestrel (a progestogen) and 7 small white inactive tablets (first row of the blister pack).

Because of the small amounts of different female hormones in the active tablets, Marvelon 28 is considered a low-dose combined oral contraceptive.

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

The following non-contraceptive health benefits have been associated with the combined Pill:

- Your periods may be lighter and shorter. As a result, the risk of anaemia may be lower.
- Your period pains may become less severe or may completely disappear.
- In addition, some serious disorders have been reported to occur less frequently in users of Pills containing 50 micrograms of ethinylestradiol ('high-dose Pills'). These are benign breast disease, ovarian

cysts, pelvic infections (pelvic inflammatory disease), ectopic pregnancy (pregnancy in which the embryo implants outside of the womb) and cancer of the endometrium (lining of the womb) and ovaries. This may also be the case for low-dose Pills but so far this has only been confirmed for endometrial and ovarian cancer.

Marvelon 28 is available only with a doctor's prescription.

2. When you must not use Marvelon 28

Do not take Marvelon 28 if you have an allergy to:

- any medicine containing (desogestrel or ethinylestradiol)
- any ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or troubled breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not use the combined Pill if you have or have had any of the conditions listed below. If any of these conditions apply to you, tell your doctor before starting to use Marvelon 28. Your doctor may advise you to use a different type of Pill or an entirely different (non-hormonal) method of birth control.

- 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')
- a stroke (caused by a clot in or a rupture of a blood vessel in the brain)
- a condition that may be the first sign of a heart attack (such as angina pectoris or chest pain) or stroke (such as transient ischaemic attack or small reversible stroke)
- a serious risk factor or several risk factors for developing a blood clot
- very high blood pressure
- a very high level of fat in the blood (cholesterol or triglycerides)
- if you have major surgery (e.g., an operation) and your ability to move around is limited for a long period of time (see also the section later in this leaflet called "The Pill and Thrombosis")
- a disorder affecting your blood clotting - for instance Activated Protein C resistance, antithrombin-III, protein C or protein S deficiencies
- a history of migraine accompanied by e.g. visual symptoms, speech disability, or weakness or numbness in any part of the body
- diabetes mellitus with blood vessel damage

- pancreatitis (an inflammation of the pancreas) associated with high levels of fatty substances in your blood
- jaundice (yellowing of the skin) or severe liver disease and your liver is not yet working normally
- a cancer that may grow under the influence of sex hormones (e.g. of the breast or of the genital organs)
- a benign or malignant liver tumour
- any unexplained vaginal bleeding
- you are pregnant or think you might be pregnant.

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

Do not use Marvelon 28 if you have Hepatitis C and are taking the combination drug regimen ombitasvir/paritaprevir/ritonavir, with or without dasabuvir (see "Taking Other Medicines").

Do not take Marvelon 28 if the expiry date printed on the pack has passed.

Do not take Marvelon 28 if the packaging is torn or shows signs of tampering.

3. What you need to know before using Marvelon 28

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.

If you are concerned about contracting a sexually transmitted infection (STI), ask your partner to wear a condom when having sexual intercourse with you.

Marvelon 28 will not protect you from HIV (AIDS) or any other sexually transmitted infections. To help protect yourself from STIs, you need to use a barrier contraceptive such as a condom, but even barrier contraceptives may not protect you against human papilloma virus (HPV).

Before you start to use Marvelon 28

You should have a thorough medical check-up, including a Pap smear, breast check, blood pressure check and urine check.

You must tell your doctor if you are allergic to any foods, dyes, preservatives or any other medicines.

You must tell your doctor if you smoke. 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.

You must tell your doctor if you have any of the conditions listed below. You may need to be kept under close observation. Your doctor can explain this to you. Tell your doctor if:

- 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 levels of cholesterol or triglycerides (fatty substances) in the blood
- anyone in your immediate family has had breast cancer
- you have liver or gall bladder 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 (yellow brownish pigmentation patches on the skin, particularly of the face); if so, avoid too much exposure to the sun or ultraviolet radiation.
- You need an operation or if your ability to move around is limited for a long period of time. This includes travelling by plane for greater than 4 hours.
- if you have recently given birth you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start using Marvelon 28 (see also the section in this leaflet called 'The Pill and Thrombosis');
- you are lactose intolerant.

Tell your doctor if any of the above conditions appear for the first time, recur or worsen while using the Pill.

The Pill and Thrombosis

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 during the first year

after you start using the Pill for the very first time. The risk is also higher if you restart using the Pill (the same product or a different product) after a break of 4 weeks or more. Thrombosis can also happen if you become pregnant.

The risk of getting a blood clot in the deep veins of the legs for women using Pills with desogestrel (in Marvelon 28) may be slightly higher than for women using Pills with levonorgestrel, norgestimate or norethisterone. The absolute numbers remain very small.

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.

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 immobilisation (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 hospitalisation or surgery. Your doctor may tell you to stop taking the Pill several weeks before surgery or at the time of immobilisation. 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?').

The Pill and Cancer

Regularly examine your breasts.

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 this is caused by the Pill. It may be that the women were examined more often, so that the breast cancer was noticed earlier.

Tell your doctor immediately if you have severe pain in your stomach.

In rare cases benign liver tumours and even more rarely, malignant liver tumours have been reported in users of the Pill. These tumours may lead to internal bleeding.

Chronic infection with Human Papilloma Virus (HPV) is the single most important risk factor for cervical cancer. HPV is a sexually transmitted infection. In women who use combined oral contraceptives 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 behaviour and other factors.

The Pill and Pregnancy

Tell your doctor immediately if you are pregnant or think you are pregnant while you are using Marvelon 28.

Like most medicines, Marvelon 28 must not be used during pregnancy.

The Pill and Breastfeeding

Marvelon 28 is generally not recommended for use during breastfeeding. If you wish to

take the Pill while breastfeeding, please seek the advice of your doctor.

The Pill and Ability to Drive

There are no observed effects.

Taking 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 your pharmacist) that you use Marvelon 28.

Some medicines may stop Marvelon 28 from working properly. These include:

- medicines for epilepsy (such as phenytoin, primidone, phenobarbital, carbamazepine, oxcarbazepine, topiramate, felbamate)
- medicines for tuberculosis (e.g. rifampicin and rifabutin)
- medicines for HIV infections (e.g. ritonavir, nelfinavir, nevirapine, efavirenz)
- medicines for Hepatitis C virus infection (e.g. boceprevir, telaprevir);
- antifungals (e.g. griseofulvin)
- medicines for high blood pressure in the blood vessels of the lungs (bosentan);
- herbal medicines containing St. John's Wort primarily for the treatment of depressive moods

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

Your doctor will tell you how long you need to take additional contraceptive precautions or whether you should use another contraceptive method altogether.

Marvelon 28 may also interfere with how other medicines work, causing either an increase in effect (e.g., ciclosporin) or a decrease in effect (e.g lamotrigine).

Do not use Marvelon 28 if you have Hepatitis C and are taking the combination drug regimen ombitasvir/paritaprevir/ritonavir, with or without dasabuvir as this may cause increases in liver function blood test results (increase in ALT liver enzyme). Marvelon 28 can be restarted approximately 2 weeks after completion of treatment with the combination drug regimen. (See "When you must not use Marvelon 28").

4. When should you contact your doctor?

Regular check-ups

When you are using the Pill, your doctor will tell you to return for regular check-ups. You should have a check-up at least once a 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 (see also "When you must not use Marvelon 28?" and "Before you start to use Marvelon 28"); do not forget about the items related to your immediate family

- you feel a lump in your breast
- you are going to use other medicines (see also Taking Other Medicines)
- your ability to move around is limited for a long period of time or you are to have surgery (consult your doctor at least 4 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 such as:

- an unusual cough
- severe pain in the chest which may reach the left arm - this discomfort may include the back, jaw, throat, arm, stomach
- feeling of being full, having indigestion or choking
- sweating, nausea, vomiting, anxiety
- breathlessness or rapid breathing
- any unusual, sudden, severe or prolonged headache or migraine attack
- partial or complete loss of vision, or double vision
- confusion, slurring or speech disability
- sudden changes to your hearing, sense of smell or taste
- dizziness or fainting
- fast or irregular heartbeat
- weakness or numbness in any part of your body
- severe pain in your stomach
- severe pain or swelling in either of your legs
- pain or tenderness in the leg which may be felt only when standing or walking
- warmth, red or discoloured skin on the leg
- sudden pain, swelling and slight blue discoloration of an extremity
- sudden trouble walking, loss of balance or coordination

The situations and symptoms mentioned above are described and explained in more detail in the following section 'What do you need to know before using Marvelon 28'.

5. How to use Marvelon 28

Marvelon 28 pack contains 28 tablets: 21 large white tablets with active substances and 7 small tablets that do not contain active substances. On the blister each tablet is marked with the day of the week on which it is to be taken. Take your tablet about the same time each day, with some liquid if necessary. Follow the direction of the arrows on the pack until all 28 tablets have been taken. A period should begin during the 7 days that you use the inactive tablets (the withdrawal bleed). Usually it will start on day 2-3 after the last large tablet.

Start taking your next pack immediately after the last small inactive tablet, even if your period continues. This means you will

always start new packs on the same day of the week, and also means that you have your period on about the same days, each month.

When no hormonal contraception has been used in the past month

Start taking Marvelon 28 on the first day of your cycle, i.e. the first day of menstrual bleeding. Take a tablet from the green section marked with that day of the week.

For example, if your period starts on a Friday, then take a tablet marked Friday. Then follow the days in order. Marvelon 28 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 1st cycle.

When changing from another combined hormonal contraceptive (combined oral contraceptive (COC), vaginal ring, or transdermal patch)

You can start taking Marvelon 28 the day after you take the last tablet from your present Pill pack. If your present Pill pack contains inactive tablets (placebo) tablets you can start Marvelon 28 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 the 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 Marvelon 28 preferably on the day of removal, but at latest when the next ring or patch would have been applied.

When changing from a progestogen-only method (minipill)

You can stop taking the minipill any day and start taking Marvelon 28 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 changing from an injectable, an implant or a progestogen-releasing intrauterine device (IUD)

Start using Marvelon 28 when your next injection is due or on the day that your implant or your IUD is removed. Make sure you also use an additional contraceptive method (a 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 Marvelon 28. Sometimes it is possible to start sooner. Your doctor will advise you. If you are breast-feeding and want to take Marvelon 28, you should discuss this first with your doctor.

After a miscarriage or abortion

Your doctor will advise you.

Additional contraceptive precautions

When additional contraceptive precautions are required you should either abstain from vaginal sex, or use a barrier method of contraception, a condom or a cap (diaphragm) plus spermicide. Rhythm methods are not advised as the Pill disrupts the cyclical changes associated with the

natural menstrual cycle e.g. changes in temperature and cervical mucus.

6. What to do if...

You forget to take your tablets

- If you are less than 12 hours late in taking any tablet, take the tablet as soon as you remember and take further tablets at the usual time.
- If you are more than 12 hours late in taking a large (active) 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 large (active) tablets at the beginning of the pack or in the 3rd week (the week before you start taking the small tablets). Therefore you should follow the rules given below.

More than one tablet forgotten in a pack

Ask your doctor for advice.

One 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, there is a possibility of becoming pregnant. So tell your doctor immediately.

One 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. The reliability of the Pill is maintained. You need not use extra contraceptive precautions.

One 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 large (active) tablets in the current pack are finished, so skip the smaller placebo tablets. You may not have a withdrawal bleed until you take the placebo tablets at the end of the second pack but you may have spotting or breakthrough bleeding on active tablet-taking days.
Or
2. Stop taking the large (active) tablets from your current pack and immediately continue with the smaller placebo tablets (a maximum of 6 days, the total number of placebo plus missed tablets may not be more than 7). Then continue with the next pack. When following this method, you can always start your next pack on the same day of the week as you usually do.

One tablet missed in week 4

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 have forgotten tablets in a pack and you do not have the expected period in the first normal placebo tablet interval, you may be pregnant. Consult your doctor before you start with the next pack.

You want to delay your period

You can delay your period if you continue with the large (active) tablets in your next pack of Marvelon 28 immediately after finishing the large tablets in your current pack. You can continue with this pack for as long as you wish, until this pack is empty. 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 active tablet-taking days. Start your next pack after the usual 7 day inactive tablet interval.

You want to change the starting day of your period

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

If you vomit or have diarrhoea

If you vomit, or have severe diarrhoea, the active ingredients of your Marvelon 28 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. Therefore, follow the advice for missed tablets. If you have severe diarrhoea, please contact your doctor.

If you have 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 continue to take your tablets as normal. Irregular vaginal bleeding usually stops once your body clock has adjusted to the Pill (usually after about 3 tablet-taking cycles). Tell your doctor if it continues, becomes heavy or starts again.

If you have missed a period

If you have taken all of your tablets at the right time, and you have not vomited, or had severe diarrhoea or used other medicines then you are very unlikely to be pregnant. Continue to take Marvelon 28 as usual.

If you miss your period twice in a row, you may be pregnant. Do not start the next pack of Marvelon 28 until your doctor has checked you are not pregnant.

If you take too much (overdose)

There have been no reports of serious harmful effects from taking too many Marvelon 28 tablets at one time. If you take too much Marvelon 28 you may feel sick, vomit or have vaginal bleeding.

If you discover a child has taken Marvelon 28, ask your doctor for advice.

If you are not sure what to do, telephone your doctor or the Poisons Information Centre on 13 11 26 for advice.

7. Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while taking Marvelon 28.

Like all medicines, Marvelon 28 can have side effects. Sometimes they are serious, most of the time they are not.

Serious side effects

Serious reactions associated with the use of the Pill, as well as the related symptoms, are described in the following sections: 'The Pill and Thrombosis/ The Pill and Cancer'. Please read these sections for additional information and consult your doctor at once where appropriate.

Other possible side effects

The following side effects have been reported by users of the Pill, although they may not be caused by the Pill. These side effects may occur in the first few months that you are using the Pill and usually lessen with time.

Common/uncommon (occurring in more than one per 1000 users):

- nausea, vomiting, abdominal pain, diarrhoea
- increase in body weight, fluid retention
- headache, migraine
- decreased sexual drive, depressed mood, mood changes
- breast pain, breast tenderness, breast enlargement
- rash, hives.

Rare (occurring in less than one per 1000 users):

- contact lens intolerance
- hypersensitivity reactions
- decrease in body weight
- increased sexual drive
- breast secretion
- vaginal secretion
- acne
- erythema nodosum, erythema multiforme (these are skin conditions)
- hair loss
- excessive hair growth

You should stop taking Marvelon if you experience any signs of thrombosis (headache or pain elsewhere in your body, dizziness, fainting, disturbances in vision, swollen ankles), or jaundice (yellowing of the eyes or skin).

Tell your doctor or pharmacist if you notice any side effects not mentioned in this leaflet.

8. After taking Marvelon 28

If you want to stop taking Marvelon 28

You can stop taking Marvelon 28 any time you want to.

If you do not want to get pregnant, use another reliable birth control method after stopping Marvelon 28. Ask your doctor for advice.

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

Ask your doctor or pharmacist for advice about taking folate if you plan to become pregnant.

Storage

Do not use after the expiry date stated on the blister and outer box.

Store your tablets below 30°C in a dry place and protect them from light.

Do not store Marvelon 28 or any other medicine in the bathroom or near a sink. Do not leave it in the car or on a window sill.

Heat and dampness can destroy some medicines.

Do not use the product if you notice, for example, colour change in the tablet, crumbling of the tablet or any other visible signs of deterioration.

Keep it where children cannot reach it.

A locked cupboard at least 1.5 meters above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using Marvelon 28 or the tablets have passed their expiry date, ask your pharmacist what to do with any left over.

9. Product description

What it looks like

Marvelon 28 is presented in a PVC/Aluminium backed blister containing 28 tablets (21 active tablets) and 7 smaller (inactive) tablets packed in a sealed sachet. The sachet is packed in a carton together with the package leaflet.

Active Substance

In the large tablets:

- ethinylestradiol 30 micrograms
- desogestrel 150 micrograms

In the smaller (inactive) tablets:

- no active ingredients

Other ingredients

In the large tablets:

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

In the smaller (inactive) tablets:

- lactose monohydrate; potato starch; magnesium stearate

Supplier

Merck Sharp & Dohme (Australia) Pty Limited
Level 1, Building A,
26 Talavera Road,
Macquarie Park, NSW 2113
Australia

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