

MONOFEME[®]

Levonorgestrel and Ethinylestradiol Tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Monofeme.

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 Monofeme against the benefits this medicine is expected to have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Monofeme is used for

Monofeme is an oral contraceptive, commonly known as a "birth control pill" or "the Pill". Monofeme tablets contain two hormones (levonorgestrel and ethinylestradiol), which prevent you from becoming pregnant if taken correctly. They are similar to the hormones that your body normally produces.

Monofeme prevents pregnancy in several ways:

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

Ask your doctor if you have any questions about why Monofeme has been prescribed for you.

Your doctor may have prescribed Monofeme for another reason.

This medicine is available only with a doctor's prescription.

Monofeme is not habit-forming.

This medicine is not expected to affect your ability to drive a car or operate machinery.

Before you take Monofeme

When you must not take Monofeme

Do not take Monofeme if you have an allergy to:

- **Any medicine containing ethinylestradiol or levonorgestrel**
- **Any of the ingredients listed at the end of this leaflet**
- **Any other similar medicines (such as other oral contraceptives).**

Some of the symptoms of an allergic reaction may include:

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

Do not take Monofeme if you have or have had any of the following medical conditions:

- Venous thromboembolism (VTE) and are on medicines called anticoagulants which are used to "thin the blood"
- Blood clots or a history of blood clots in the:
 - Legs (thrombophlebitis or deep vein thrombosis (DVT)),
 - Lungs (pulmonary embolism)
 - Eyes.
- Hereditary or an acquired disposition for venous thromboembolism
- Multiple risk factors VTE including obesity, age above 35 years, smoking
- Major surgery and have been confined to bed for long periods of time
- Arterial thromboembolism (ATE) or a past history of these that include:
 - Stroke
 - Angina
 - Transient ischaemic attack or "mini stroke".
- Hereditary or an acquired disposition for ATE
- History of migraine, accompanied by blurred vision, difficulty in speaking, muscle weakness, or increased sensitivity to light, sound, or noise
- Multiple risk factors for ATE or a serious risk factor for ATE that include:
 - High blood pressure
 - Diabetes with blood vessel damage
 - Severe lipid disease

- Sickle cell anaemia.
- Disease in any blood vessel(s)
- Inflammation of the pancreas, which is associated with very high blood levels of triglycerides (fatty substances)
- Breast cancer or cancer of the lining of the womb, cervix or vagina, or you think you have or have had these conditions
- Unexplained vaginal bleeding
- Liver tumour or liver disease
- Yellowing of the whites of the eyes or of the skin (jaundice) during pregnancy or during previous use of an oral contraceptive.

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

If you are not certain whether these may apply to you, or you are worried by anything in this list, tell your doctor.

Do not take this medicine if you are pregnant or you think you are pregnant.

Pregnancy must be excluded before you start taking Monofeme.

Do not give this medicine to a child.

Do not take this medicine if you have already experienced menopause.

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

If it is expired or damaged, return it to your pharmacist for disposal.

Before you start to take Monofeme

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

You must tell your doctor if you or anyone in your immediate family has, or has had blood clots in the legs or lungs.

Blood clots are a rare occurrence when taking an oral contraceptive.

The risk of a blood clot is highest during the first year of taking an oral contraceptive for the first time or if you are re-starting the "pill" after a break of 4 weeks or more.

The risk of having a blood clot is higher in oral contraceptive users than in non-users, but is not as high as during pregnancy.

Tell your doctor about any of the following conditions as these are risk factors for developing blood clots:

- Cancer
- Systemic lupus erythematosus (SLE)
- Haemolytic uraemic syndrome (HUS) - a disorder of blood coagulation causing failure of the kidneys)
- Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- Sickle cell disease
- Smoking particularly if you are heavy smoker (15 or more cigarettes per day) and are aged over 35 years
- Have had any recent surgery or trauma
- Recently had a baby
- Lost a baby in the second trimester
- Are pregnant
- Had major surgery and have been confined to bed for long periods of time

- Also tell your doctor if you are planning a long haul plane flight (greater than 4 hours).

You must tell your doctor if you or anyone in your immediate family has, or has had a stroke or heart attack.

Taking oral contraceptives is linked with an increased risk of having a heart attack, angina, stroke or a "mini stroke".

Tell your doctor if you have any of the following conditions:

- Heart disease including heart valve disorders or certain heart rhythm disorders
- High blood pressure, a history of high blood pressure or high blood pressure during pregnancy
- High cholesterol
- Diabetes
- Migraine or other headaches
- Hyperhomocysteinemia.

Tell your doctor if over 35 years of age or are overweight.

If you are not certain whether any of the above may apply to you, check with your doctor.

Tell your doctor if you have any other health problems, especially:

- Breast lumps, abnormal breast X-ray or mammogram
- Epilepsy
- Depression
- Gallbladder disease
- Fluid retention or kidney disease
- Asthma
- Fibroids
- Yellowing of the whites of the eyes or skin (jaundice) during pregnancy or during previous oral contraceptive use
- Hereditary angioedema. (swelling of the face, lips, mouth, tongue or throat).

If you have any of these conditions you should have regular check-ups with your doctor to make sure that

taking Monofeme is not making the conditions worse.

Tell your doctor if you plan to become pregnant or are breastfeeding.

Your doctor can discuss the risks and benefits involved with you.

If you have not told your doctor about any of the above, tell him/her before you start taking Monofeme.

Monofeme contains lactose.

If you know that you are intolerant to some sugars, or your doctor has told you so, speak to your doctor before taking it.

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including:

- All prescription medicines
- All medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

Some medicines may be affected by Monofeme or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

Tell your doctor or pharmacist if you are taking any of the following:

- Rifampicin and rifabutin for the treatment of tuberculosis
- Antibiotics such as ampicillin, other penicillins and tetracyclines
- Anti-fungal agents such as griseofulvin
- Barbiturates (certain types of medicines prescribed for epilepsy, such as phenobarbitone)
- Medicines for epilepsy (such as phenytoin, primidone, carbamazepine and topiramate)

- Ritonavir for the treatment of HIV infection
- Modafinil used to treat excessive daytime sleepiness
- St. John's Wort, an ingredient in many medicines you can buy without a prescription from a pharmacy, health food shop or supermarket
- Corticosteroids such as dexamethasone.

While you are taking any of these medicines and for the next 7 days after stopping them, you must also use an additional non-hormonal method of contraception (such as condoms or a diaphragm, but not the rhythm or temperature methods). If you come to the end of the white tablets during these 7 days, start the next pack straight away. Skip the 7 red tablets.

If you take rifampicin and some other medicines, you may need to use additional non-hormonal contraception for four weeks after finishing the course of treatment.

Ask your doctor or pharmacist about how long you need to use additional non-hormonal contraception.

Tell your doctor or pharmacist if you are taking any of the following:

- Atorvastatin used to treat high cholesterol
- Indinavir for the treatment of HIV infection
- Anti-fungal agents such as itraconazole and fluconazole
- Paracetamol and ascorbic acid (Vitamin C).
- Cyclosporin used to prevent organ rejection
- Theophyllines used for asthma and other breathing difficulties
- Corticosteroids
- Lamotrigine used for seizures.

If you have not told your doctor or pharmacist about any of the above,

tell them before you start taking Monofeme.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while you are taking this medicine.

Do not take Monofeme, and tell your doctor if you are taking the combination drug regimen ombitasvir/paritaprevir/ritonavir and dasabuvir with or without ribarivin for the treatment of Hepatitis C. Treatment with Monofeme should be stopped when you are taking this combination of treatment regimen and can be restarted approximately 2 weeks after completion of this treatment.

How to take Monofeme

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How to take it

Swallow tablets whole with a full glass of water.

When to take Monofeme

You must take Monofeme every day, regardless of how often you have sex.

Monofeme will work best if you do not miss any tablets and take it at the same time each day. Taking Monofeme at the same time each day will also help you remember when to take the tablets.

It does not matter if you take Monofeme before or after food.

If you are concerned about this, please speak to your doctor or pharmacist.

Starting a hormonal contraceptive for the first time

To start taking Monofeme follow these steps:

1. On the first day of your menstrual bleed, take a white tablet that matches the day of the week from the green shaded section of the blister pack.

You must also use an additional non-hormonal method of contraception (such as condoms or a diaphragm, but not the rhythm or temperature methods) until a white tablet has been taken daily for 7 days without a break.

2. Then take one white tablet each day, following the arrows so that you are taking the correct tablet for the day of the week until all 21 white tablets have gone.
3. Then take one red tablet each day for the next 7 days.
4. You will have a 'withdrawal' bleed, similar to having a period, during the week of red tablets.

If you do not have a period while you are taking the red tablets, and there is any chance that you have not followed all the instructions in this leaflet, contact your doctor to check if you are pregnant.

Going on to further blister packs

On the day after your last red tablet, begin the next pack with a white tablet from the green shaded section of the blister pack that matches the day of the week. Do this even if you are still bleeding.

Each new pack is started with a white tablet on the same day as the first pack, so that you have 21 days on white tablets, then 7 days on red tablets. There is no break between packs.

If you start taking your new pack late, you must also use an additional non-hormonal method of contraception (such as condoms

or a diaphragm, but not the rhythm or temperature methods) until a white tablet has been taken daily for 7 days without a break.

Switching from a different combined oral contraceptive

When changing from a different combined oral contraceptive to Monofeme, it is important to follow the instructions below carefully.

Monofeme works best if you do not miss any tablets and take it at the same time each day.

Follow these steps if your current oral contraceptive contains an estrogen and a progestogen:

1. Stop taking your current oral contraceptive after you have taken the last active tablet. If your current oral contraceptive pack also contains reminder tablets, do not take them.
2. The next day, take the first white Monofeme tablet from the green shaded section that matches the day of the week.

You must also use an additional non-hormonal method of contraception (such as condoms or a diaphragm, but not the rhythm or temperature methods) until a white tablet has been taken daily for 7 days without a break.

3. Then take one white tablet each day following the direction of the arrows until all 21 white tablets have gone.
4. Then take one red tablet each day for the next 7 days.
5. You will have a 'withdrawal' bleed, similar to having a period, during the week of red tablets.

If you do not have a period while you are taking the red tablets, and there is any chance that you have not followed all the instructions in this leaflet, contact your doctor to check if you are pregnant.

Switching from a progestogen-only contraceptive

You can stop taking a progestogen-only contraceptive tablet any day and start taking Monofeme the next day, at the same time.

If you have been using a progestogen-only implant, start taking Monofeme on the day the implant is removed.

If you have been using a progestogen-only injection, start taking Monofeme on the day the next injection would be due.

In all cases start Monofeme by taking a white tablet from the green shaded section that matches the day of the week.

You must also use an additional non-hormonal method of contraception (such as condoms or a diaphragm, but not the rhythm or temperature methods) until a white tablet has been taken daily for 7 days without a break.

After having a baby

If you have just had a baby, talk to your doctor before you start taking Monofeme.

After a miscarriage or abortion

Your doctor will advise you how to take Monofeme after a miscarriage or abortion.

How long to take Monofeme

Continue taking your medicine for as long as your doctor tells you.

Your doctor may prescribe Monofeme for long periods, until you no longer need or want contraception.

If you are not sure how long you should be taking Monofeme, ask your doctor.

If you forget to take your tablets

If you forget to take Monofeme every day, it may not work as well in protecting you from becoming pregnant.

Do not try to make up for missed doses by taking more than one tablet at a time.

Forgetting one white tablet:

If you forget one white tablet but it is less than 12 hours late, take the missed tablet immediately. Take the next tablet at your usual time, even if this means taking two white tablets in one day.

If you do not take the missed tablet within 12 hours, Monofeme may not work as well in protecting you from becoming pregnant.

If one white tablet is missed and is remembered more than 12 hours late, take the last tablet as soon as you remember and the next tablet at the usual time.

Continue to take tablets at your usual time but you must also use an additional non-hormonal method of contraception (such as condoms or a diaphragm but not the rhythm or temperature methods) until a white tablet has been taken daily for 7 days without a break. If you come to the end of the white tablets during the 7 days after a missed tablet, start the next pack straight away. Skip the 7 red tablets.

Forgetting two white tablets:

If you forget two white tablets, take the last missed tablet as soon as you remember and the next tablet at the usual time.

Continue to take tablets at your usual time but you must also use an additional non-hormonal method of contraception (such as condoms or a diaphragm but not the rhythm or temperature methods) until a white tablet has been taken daily for 7 days without a break. If you come to the end of the white tablets during the 7 days

after the missed tablets, start the next pack straight away. Skip the 7 red tablets.

You may not have a withdrawal bleed until the end of this new pack, but you may have spotting or breakthrough bleeding when taking the white tablets. If you don't have a withdrawal bleed at the end of the new pack, contact your doctor, who must make sure that you are not pregnant before you start the next pack.

Forgetting three or more white tablets:

Contact your doctor for advice on what to do.

Forgetting a red tablet:

If you miss one or more red tablets, leave them in the pack and do not worry.

However, if you miss red tablets and then forget to start the next pack on time, start as soon as you remember by taking a white tablet that matches the day of the week from the green shaded section. You must also use an additional non-hormonal method of contraception (such as condoms or a diaphragm but not the rhythm or temperature methods) until a white tablet has been taken daily for 7 days without a break.

If you are not sure what to do, ask your doctor or pharmacist.

If you are having trouble remembering to take Monofeme, ask your pharmacist for some hints.

If you vomit or have diarrhoea after taking Monofeme

If you have vomiting or diarrhoea within 3 to 4 hours after taking a white tablet, you must use an additional non-hormonal method of contraception (such as condoms or a diaphragm, but not the rhythm or temperature methods) until a white tablet has been taken daily for 7 days without a break. If you come to the end of the white

tablets during these 7 days, start the next pack straight away. Skip the 7 red tablets.

The tablet may not have time to be absorbed properly and may not protect you from becoming pregnant.

If you have vomiting or diarrhoea after taking a red tablet, do not worry.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Australia telephone 13 11 26, New Zealand telephone 0800 764 766) for advice, or go to Accident and Emergency at your nearest hospital if you think you or anyone else may have taken too much Monofeme.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include:

- Feeling sick or vomiting
- Dizziness
- Feeling sleepy or tired
- Women may also experience menstrual bleeding.

While you are taking Monofeme

Things you must do

Tell any other doctors, dentists and pharmacists who are treating you that you are taking Monofeme.

If you are about to start taking any new medicines, tell the doctor or pharmacist that you are taking Monofeme.

If you become pregnant while taking Monofeme, see your doctor immediately.

If you are about to have any blood tests, tell your doctor you are taking Monofeme.

It may interfere with the results of some tests.

If you miss a period and you have taken your tablets correctly, continue taking your tablets as you would normally.

Sometimes you might not have a menstrual period while taking Monofeme.

If you miss a period and you have not taken your tablets correctly, keep taking your tablets and see your doctor immediately.

Not taking your tablets correctly includes missing one or more tablets or starting a new pack later than you should have.

If you miss two menstrual periods, stop taking your tablets and see your doctor, even if you have taken the tablets correctly. You must use a non-hormonal method of contraception, (such as condoms or a diaphragm) during this time.

Your doctor should make sure you are not pregnant before you start taking Monofeme again.

Have regular check-ups from your doctor, including a Pap smear.

Oral contraceptives should not be prescribed for longer than one year without your doctor carrying out a check-up. Your doctor will advise you how often you need a Pap smear. A Pap smear can detect abnormal cells lining the cervix. Sometimes abnormal cells can progress to cervical cancer. The most important risk factor for cervical cancer is persistent human papillomavirus (HPV) infection. However, cervical cancer has been reported to occur more often in women using an oral contraceptive for a long time. This finding may not be caused by the oral contraceptive, but may be related to sexual behaviour and other reasons.

Perform regular breast self-examination.

Risk factors for the development of breast cancer include increasing age, family history, obesity, never having had a baby, and late age for first full-term pregnancy. Breast cancer has also been found slightly more often in women who use oral contraceptives than in women of the same age who do not use them. This slight increase in the number of breast cancer cases gradually disappears during the course of the 10 years after stopping use of oral contraceptives. It is not known whether the oral contraceptive causes the difference. It may be that the women were examined more often, so that the breast cancer was noticed earlier.

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

Monofeme will not protect you from HIV-AIDS or any other sexually transmitted diseases (STDs) such as chlamydia, genital herpes, genital warts, gonorrhoea, hepatitis B, human papilloma virus and syphilis. To help protect yourself from STDs, you need to use a barrier contraceptive such as a condom.

Tell your doctor you are using Monofeme at least 4 weeks before any planned hospitalisation or surgery.

Your doctor may tell you to stop taking Monofeme several weeks before surgery or at the time of immobilisation. Your doctor will tell you when you can start taking Monofeme after you are back on your feet.

To avoid pregnancy during this time you must use a non-hormonal method of contraception such as condoms or a diaphragm.

Things you must not do

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

Do not give your medicine to anyone else even if they have the same condition as you.

Do not stop taking Monofeme, or change the dosage, without checking with your doctor.

If you stop taking Monofeme or do not take a tablet every day, without using another form of contraception, you may become pregnant.

Side Effects

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get certain side effects.

It can be difficult to tell whether side effects are the result of taking Monofeme or are side effects of another medicine you are taking.

Do not be alarmed by the list of side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you have.

Tell your doctor if...

Tell your doctor if you notice any of the following and they worry you:

- Changes in bleeding patterns, including breakthrough bleeding/spotting
- Painful periods
- Missed periods, but if you have not taken Monofeme as directed you should check whether you are pregnant
- Changes in mucus from the vagina
- Changes in the cervix
- Vaginal thrush (candida)

- Breast pain, tenderness, enlargement, possible milk secretion
- Changes in sex drive
- Nausea or vomiting
- Abdominal pain, cramps or bloating
- Mood changes, including depression
- Headache, including migraines
- Nervousness
- Dizziness
- Contact lenses becoming uncomfortable to wear
- Weight change (increase or decrease)
- Changes in appetite
- Swelling of the hands, ankles or feet
- Acne
- Rash
- Darkening of the skin, which may persist after stopping your medicine
- Loss of scalp hair
- Increase in body hair.

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible if...

Tell your doctor as soon as possible if you notice any worsening of conditions that you may already have such as:

- Chorea (involuntary muscle spasm)
- Porphyria
- Systemic lupus erythematosus (Lupus)
- Varicose veins
- Gallbladder disease
- Hereditary angioedema (swelling of the face, lips, mouth, tongue or throat).

Go to hospital if...

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- Unexplained or persistent pains in the head, chest, arm or below the breastbone
- Severe pain, swelling or discolouration in either of your legs
- Shortness of breath
- Rapid or irregular heartbeat
- Blurred or double vision
- Partial or complete loss of sight
- Eye protrusion, swelling of the eye or eye lesions
- Dizziness or fainting, sometimes with loss of balance
- Sweating, nausea or vomiting
- An unusual cough
- Weakness or numbness in any part of your body
- Discomfort radiating to the back, jaw, throat or stomach
- Confusion, trouble speaking or understanding
- Bloody diarrhoea
- Abdominal pain
- Fever
- Feeling of indigestion or choking
- Rectal bleeding
- Feeling tired
- Lose your appetite or lose weight
- Breast lumps
- Jaundice or a yellowing of the skin or eyeballs, often with fever, fatigue, loss of appetite, dark coloured urine or light coloured bowel movements. Taking oral contraceptives has been associated with an increased risk of having a benign liver tumour and, in very rare cases, liver cancer. The risk appears to increase the longer oral contraceptives are taken

- Migraine headaches for the first time
- More frequent migraines if you already suffer from them
- Itchy rash
- You are an epileptic and your fits become more frequent
- Rise in blood pressure. You may experience headache, blurred vision or palpitations. Sometimes your blood pressure may rise without you experiencing any of these symptoms. It is important to keep your routine doctor's appointments so that your blood pressure can be checked
- Swelling around the eyes or mouth.

Whilst these side effects are rare, they are serious. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

After stopping Monofeme

If your periods do not return within 2 to 3 months of stopping Monofeme tell your doctor.

Some women have short-term problems getting pregnant after stopping Monofeme, especially if they had irregular menstrual cycles before starting to use an oral contraceptive.

If you are planning to become pregnant after stopping Monofeme, use a non-hormonal method of contraception such as condoms or a diaphragm for 3 months before trying to fall pregnant.

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

After taking Monofeme

Storage

Keep your tablets in the blister pack until it is time to take them.

If you take the tablets out of the blister pack they may not keep well.

Keep your tablets in a cool, dry place where the temperature stays below 25°C and is away from light.

Do not store Monofeme or any other medicine, in a bathroom or near a sink. Do not leave Monofeme in the car on hot days or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Monofeme, or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Monofeme comes in a 12-week box containing 3 blister packs. Each blister pack contains 21 white hormone tablets and 7 red non-hormonal tablets. The blister pack is marked with days of the week next to each tablet.

Ingredients

Each white tablet contains 150 micrograms of levonorgestrel and 30 micrograms of ethinylestradiol as the active ingredients.

Red tablets do not contain active ingredients.

The white and red tablets also contain the following inactive ingredients:

- Lactose monohydrate
- Maize starch
- Povidone
- Talc
- Magnesium stearate
- Sucrose
- Macrogol 6000
- Calcium carbonate
- Glycol montanate (red tablets only)
- White beeswax (white tablets only)
- Carnauba Wax (white tablets only)

The red tablets also contain the colouring agents:

- Brilliant scarlet 4R
- Erythrosine

Monofeme does not contain gluten, tartrazine or any other azo dyes.

Supplier

Monofeme is supplied in New Zealand by:

Pfizer New Zealand Limited

PO Box 3998

Auckland, New Zealand

Toll Free number: 0800 736 363.

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