

Package leaflet: Information for the user

Atazor R Tablets

Atazanavir 300 mg/ritonavir 100 mg tablets

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you or your child.

- **Keep this leaflet. You may need to read it again.**
- **If you have any further questions, ask your doctor or pharmacist.**
- **This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.**
- **If you get any side effects talk to your doctor, or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.**

What is in this leaflet

1. What Atazor R Tablet is and what it is used for
2. What you need to know before you or your child takes Atazor R Tablets
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6. Contents of the pack and other information

1. What Atazor R Tablet is and what it is used for

Atazor R Tablets is a fixed dose combination product of atazanavir 300 mg and ritonavir 100 mg.

Atazor-R is an antiviral (or antiretroviral) medicine from the group of medicines called HIV-1 protease inhibitors (PI). This medicine controls Human Immunodeficiency Virus (HIV) infection by stopping a protein that the HIV needs for its multiplication. They work by reducing the amount of HIV in your body and this in turn, strengthens your immune system. In this way Atazor-R reduces the risk of developing illnesses linked to HIV infection.

Atazor R tablets is used in combination with other anti-HIV medicines to control your HIV infection.

2. What you need to know before you or your child takes Atazor R Tablets

Do not take Atazor R Tablets

- If you are allergic to atazanavir or ritonavir or any of the other ingredients of this medicine (listed in section 6)
- If you have moderate to severe liver problems. Your doctor will evaluate how severe your liver disease is before deciding whether you can take Atazor R Tablets
- If you are taking any of these medicines: see also Other medicines and Atazor R Tablets
 - Alfuzosin (used to treat enlarged prostatic gland)
 - Piroxicam, pethidine, propoxyphene (Used to relieve pains)
 - Ranolazine (Used to treat chest pain)
 - Amiodarone, dronedarone, bepridil, encainide, flecainide, propafenone, quinidine (used to correct irregular heartbeats);
 - Fusidic Acid (used to treat bacterial infections)
 - Voriconazole (used to treat fungal infections)
 - Astemizole or terfenadine (commonly used to treat allergy symptoms, these medicines may be available without prescription);
 - Colchicine (an anti-gout used to treat attacks of gout, condition is caused by too much uric acid in the blood which leads to inflammation (pain, redness, swelling, and heat) in a joint) if you have kidney and/or liver problems
 - Rifabutin, rifampicin (used to prevent/treat certain infections);
 - Lurasidone (used to treat depression)
 - Clozapine, pimozide, (used to treat abnormal thoughts or feelings);
 - Quetiapine (used to treat schizophrenia, bipolar disorder and major depressive disorder)
 - Ergotamine, dihydroergotamine, (used to treat headaches);
 - ergonovine, methylergonovine ((used to stop excessive bleeding that may occur following childbirth or an abortion);
 - Cisapride (used to treat gastric reflux, sometimes called heartburn);
 - Simvastatin and lovastatin (used to lower blood cholesterol)
 - Neratinib (used to treat breast cancer)
 - Lomitapide (used to lower blood cholesterol)
 - Sildenafil if you suffer from a lung disease called pulmonary arterial hypertension that makes breathing difficult. Patients without this disease may use sildenafil for impotence (erectile dysfunction) under their doctor's supervision
 - Avanafil or vardenafil (used to treat erectile dysfunction);
 - Clorazepate, diazepam, estazolam, flurazepam, triazolam or oral (taken by mouth) midazolam (used to help you sleep and/or to relieve anxiety)
 - Medicines containing St. John's wort (*Hypericum perforatum*, an herbal preparation)
 - grazoprevir-containing products, including elbasvir/grazoprevir fixed dose combination and glecaprevir/pibrentavir fixed dose combination (used to treat chronic hepatitis C infection)

If you are currently taking any of these medicines, ask your doctor about switching to a different medicine while you are taking Atazor-R tablets.

Tell your doctor at once if any of these apply to you.

Warnings and precautions

Talk to your doctor or pharmacist before taking Atazor-R tablets:

- If you suffer from allergy, or if you have had allergy problems in the past;
- Atazor R tablets is not a cure for HIV infection.
- You may continue to develop infections or other illnesses linked to HIV infection. You can still pass on HIV when taking this medicine, although the risk is lowered by effective antiretroviral therapy. Discuss with your doctor the precautions needed to avoid infecting other people.
- Some people will need special care before or while taking Atazor R Tablets. Talk to your doctor or pharmacist before taking Atazor R Tablets and make sure your doctor knows:
 - If you have hepatitis B or C
 - if you develop signs or symptoms of gall stones (pain at the right side of your stomach)
 - if you have type A or B hemophilia
 - if you require haemodialysis

Atazor R may affect how well your kidneys work.

Talk to your doctor if you have/had:

- a history of liver disease
- **Hepatitis B or C** and are being treated with a combination of antiretroviral agents, as you are at a greater risk of a severe and potentially life threatening reaction because of the effect on the liver. Regular blood tests may be required to check your liver is working properly.
- **Haemophilia**, as there have been reports of increased bleeding in patients with haemophilia who are taking this type of medicine (protease inhibitors). The reason for this is not known. You may need additional medicine to help your blood clot (factor VIII), in order to control any bleeding.
- **Erectile dysfunction**, as the medicines used to treat erectile dysfunction can cause hypotension and prolonged erection.
- **Diabetes**, as there have been reports of worsening of or the development of diabetes (diabetes mellitus) in some patients taking protease inhibitors.
- **Kidney (renal) disease** since your doctor may need to check the dose of your other medicines (such as protease inhibitors).

Tell your doctor if you experience:

Diarrhoea or vomiting that is not improving (persistent), as this may reduce how well the medicines you are taking work.

Feeling sick (nausea), **vomiting** or have **stomach pain**, because these may be signs of inflammation of the pancreas (pancreatitis). Some patients taking Atazor R can develop serious problems with their pancreas. Tell your doctor as soon as possible if this applies to you

Symptoms of infection –In some patients with advanced HIV infection (AIDS) and a history of opportunistic infection, signs and symptoms of inflammation from previous infections may

occur soon after anti-HIV treatment is started. It is believed that these symptoms are due to an improvement in the body's immune response, enabling the body to fight infections that may have been present with no obvious symptoms. If you notice any symptoms of infection, please inform your doctor immediately.

In addition to the opportunistic infections, autoimmune disorders (a condition that occurs when the immune system attacks healthy body tissue) may also occur after you start taking medicines for the treatment of your HIV infection. Autoimmune disorders may occur many months after the start of treatment. If you notice any symptoms of infection or other symptoms such as muscle weakness, weakness beginning in hands and feet and moving up towards the trunk of the body, palpitations, tremor or hyperactivity, please inform your doctor immediately to seek necessary treatment.

Some patients taking combination antiretroviral therapy may develop a bone disease called **osteonecrosis** (death of bone tissue caused by loss of blood supply to the bone). The length of combination antiretroviral therapy, corticosteroid use, alcohol consumption, severe immunosuppression, higher body mass index, among others, may be some of the many risk factors for developing this disease. Signs of **osteonecrosis are joint stiffness, aches and pains** (especially of the hip, knee and shoulder) and difficulty in movement. If you notice any of these symptoms please inform your doctor.

Hyperbilirubinaemia (an increase in the level of bilirubin in the blood) has occurred in patients receiving Atazor R Tablets. The signs may be a mild yellowing of the skin or eyes. If you notice any of these symptoms please inform your doctor.

Joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty moving, tell your doctor, as this may be a sign of a problem that can destroy bone (osteonecrosis). Some patients taking a number of antiretroviral medicines may develop this disease.

Serious skin rash, including Stevens-Johnson syndrome, has been reported in patients taking Atazor R Tablets. If you develop a rash inform your doctor immediately.

Dizziness, lightheadedness, fainting spells or abnormal heartbeat, some patients taking Atazor R may experience changes in the electrocardiogram (ECG). Tell your doctor if you have a heart defect or conduction defect.

Muscle pain, tenderness or weakness, particularly in combination with antiretroviral therapy including protease inhibitors and nucleoside analogues. On rare occasions these muscle disorders have been serious.

If you notice a change in the way your heart beats (heart rhythm changes), please inform your doctor. Children receiving Atazor R Tablets may require their heart to be monitored. Your child's doctor will decide this.

Children

Do not give this medicine to children with a body weight of at least 35 kg.

Other medicines and Atazor R tablets

You must not take Atazor R tablets with certain medicines. These are listed under Do not take Atazor R tablets, at the start of Section 2.

There are other medicines that may not mix with Atazor R tablets. Tell your doctor if you are taking, have recently taken, or might take any other medicines, including medicines obtained without a prescription.

Tell your doctor if you are taking any of the medicines listed below, as special care should be taken.

- Other medicines to treat HIV infection (e.g. indinavir, nevirapine and efavirenz)
- Boceprevir and sofosbuvir/velpatasvir/voxilaprevir (used to treat hepatitis C)
- Sildenafil, vardenafil, or tadalafil (used by men to treat impotence (erectile dysfunction)). The dose and/or frequency of use of these medicines may need to be reduced to avoid hypotension and prolonged erection
- if you are taking an oral contraceptive ("the Pill") with Atazor R tablets to prevent pregnancy, be sure to take it exactly as instructed by your doctor and not miss any doses
- Any medicines used to treat diseases related to the acid in the stomach (e.g. antacids to be taken 1 hour before taking Atazor R tablets or 2 hours after taking Atazor R tablets, H2-blockers like famotidine and proton pump inhibitors like omeprazole)
- Medicines to lower blood pressure, to slow heart rate, or to correct heart rhythm (amiodarone, diltiazem, systemic lidocaine, verapamil)
- Atorvastatin, pravastatin, rosuvastatin and fluvastatin (used to lower blood cholesterol) as atazanavir 300 mg and ritonavir 100 mg may raise the blood levels of these medicines. Talk to your doctor before you take any cholesterol-reducing medicines.
- Salmeterol (used to treat asthma)
- Hormonal contraceptives containing ethinyl estradiol, norgestimate, norethindrone (drug to prevent pregnancy) as this medicine may reduce the effectiveness of these medicines. It is recommended that a condom or other non-hormonal method of contraception is used instead. You may also notice irregular uterine bleeding if you are taking this type of hormonal contraceptive with atazanavir 300 mg and ritonavir 100 mg
- Cyclosporin, tacrolimus, and sirolimus (medicines to decrease the effects of body's immune system)
- tenofovir (anti-AIDS medicine-Nucleoside Reverse Transcriptase Inhibitor)
- Digoxin (heart medicine). Your doctor may need to adjust the dose of digoxin and monitor you while you are taking digoxin and this medicine in order to avoid heart problems.
- Trazodone (a medicine for depression) as, unwanted effects like nausea, dizziness, low blood pressure and fainting can occur

- Rifampicin and saquinavir (used for tuberculosis and HIV, respectively) as serious liver damage can occur when taken with this medicine
- Bosentan, riociguat (used for pulmonary arterial hypertension) as the blood levels may increase of these medicines
- Steroids (e.g. dexamethasone, fluticasone propionate, prednisolone, triamcinolone) as atazanavir 300 mg and ritonavir 100 mg may raise the blood levels of these medicines which may lead to Cushing's syndrome (development of a rounded face) and reduce production of the hormone cortisol. Your doctor may wish to reduce the steroid dose or monitor your side effects more closely.
- Certain antibiotics (rifabutin, clarithromycin)
- Ketoconazole, itraconazole, and voriconazole (antifungals)
- Warfarin (anticoagulant, used to reduce the blood clots)
- Carbamazepine, phenytoin, phenobarbital, lamotrigine (antiepileptics)
- Colchicine (for gout) as this product may raise the blood levels of this medicine. You must not take this product with colchicine if you have kidney and/or liver problems
- Irinotecan (used to treat cancer)
- Sedative agents (e.g. midazolam administered by injection)
- Buprenorphine (used to treat opioid addiction and pain).

It is important to tell your doctor if you are taking fluticasone or budesonide (given by nose or inhaled to treat allergic symptoms or asthma).

There are medicines that may not mix with Atazor R because their effects could increase or decrease when taken together. In some cases your doctor may need to perform certain tests, change the dose or monitor you regularly. This is why you should tell your doctor if you are taking any medicines, including those you have bought yourself or herbal products, but it is especially important to mention these:

- Amphetamine or amphetamine derivatives
- Antibiotics (e.g. erythromycin, clarithromycin);
- Anticancer treatments (e.g. abemaciclib; afatinib, apalutamide, ceritinib, encorafenib, dasatinib, ibrutinib, nilotinib, venetoclax, vincristine, vinblastine)
- Anticoagulants (e.g. rivaroxaban, vorapaxar, warfarin);
- Antidepressants (e.g. amitriptyline, desipramine, fluoxetine, imipramine, nefazodone, nortriptyline, paroxetine, sertraline, trazodone);
- Antifungals (e.g. ketoconazole, itraconazole);
- Antihistamines (e.g. loratidine, fexofenadine);
- Antiretroviral medicines including HIV-protease inhibitors (amprenavir, atazanavir, darunavir, fosamprenavir, indinavir, nelfinavir, saquinavir, tipranavir) non-nucleoside reverse transcriptase inhibitors (NNRTI) (delavirdine, efavirenz, nevirapine), and others (didanosine, maraviroc, raltegravir, zidovudine);
- Anti-tuberculosis medicine (bedaquiline and delamanid)
- Antiviral medicine used to treat chronic hepatitis C virus (HCV) infection in adults (glecaprevir/pibrentasvir and simeprevir);

- Anxiety medicine, buspirone
- Asthma medicine, theophylline, salmeterol;
- Atovaquone, medicine used to treat a certain type of pneumonia and malaria
- Buprenorphine, a medicine used for the treatment of chronic pain;
- Bupropion, medicine used to help you stop smoking
- Epilepsy medicines (e.g. carbamazepine, divalproex, lamotrigine, phenytoin);
- heart medicines (e.g. disopyramide, mexiletine and calcium channel antagonists such as amlodipine, diltiazem and nifedipine);
- Immune system (e.g. cyclosporine, tacrolimus, everolimus);
- Levothyroxine (used to treat thyroid problems)
- Morphine and morphine-like medicines used to treat severe pain (e.g. methadone, fentanyl);
- Sleeping pills (e.g. alprazolam, zolpidem) and also midazolam administered by injection;
- Tranquillisers (e.g. haloperidol, risperidone, thioridazine)
- Colchicine, a treatment for gout.

Atazor R tablets with food and drink

It is important that you take Atazor R tablets with food (a meal or a substantial snack) as this helps the body absorb the medicine.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think that you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Patients should not breast-feed while taking Atazor R tablets. It is recommended that women infected with HIV do not breast-feed because the virus might be transmitted through the breast milk. It is recommended that women infected with HIV do not breast-feed because the virus might be transmitted through the breast milk.

Driving and using machines

If you feel dizzy or lightheaded, do not drive or use machines and contact your doctor immediately.

Atazor R Tablets contains lactose.

If you have been told by your doctor that you have an intolerance to some sugars (e.g. lactose), contact your doctor before taking this medicinal product.

3. How to take Atazor R Tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. This way, you can be sure your medicine is fully effective and you reduce the risk of the virus developing resistance to the treatment.

The recommended adult dose is one tablet taken once daily with food in combination with other anti-HIV medicines. Your doctor may adjust the dose of this medicine according to your anti-HIV therapy.

For children, your child's doctor will decide the right dose based on your child's weight. Atazor R Tablets shall be given to children if the weight is at least 35 kg.

This medicine should be taken every day to help control your HIV, no matter how much better you feel. If a side effect is preventing you from taking the medicinal product as directed, tell your doctor straight away. During episodes of diarrhoea your doctor may decide that extra monitoring is needed.

Take Atazor R Tablets with food (a meal or a substantial snack). Atazor R Tablets are swallowed whole and not chewed, broken or crushed

If you take more Atazor R Tablets than you should

Yellowing of the skin and/or eyes (jaundice), irregular heart beat (QTc prolongation), numbness, tingling or a 'pins and needles' sensation may occur if you or your child takes too much Atazor R Tablets.

If you accidentally take more Atazor R Tablets than your doctor recommended, contact your HIV doctor at once or contact the nearest hospital for advice.

If you forget to take Atazor R Tablets

If you miss a dose, take the missed dose as soon as possible with food and then take your next scheduled dose at its regular time. If it is almost time for your next dose, do not take the missed dose. Wait and take the next dose at its regular time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Atazor R Tablets

Do not stop taking Atazor R Tablets before talking to your doctor. If you have any further questions on the use of this medicine, ask your doctor. Even if you feel better, do not stop taking this medicine without talking to your doctor. Taking this medicine as recommended should give you the best chance of delaying resistance to the medicines.

4. Possible side effects

During HIV therapy there may be an increase in weight and in levels of blood lipids and glucose. This is partly linked to restored health and life style, and in the case of blood lipids sometimes to the HIV medicines themselves. Your doctor will test for these changes.

Like all medicines, this medicine can cause side effects, although not everybody gets them. When treating HIV infection, it is not always easy to identify what side effects are caused by Atazor R tablets, by the other medicines you are taking, or by the HIV infection itself. Tell your doctor if you notice anything unusual about your health.

Tell your doctor immediately if you develop any of the following serious side effects:

- Skin rash, itching that may occasionally be severe has been reported. The rash usually disappears within 2 weeks without any change to your Atazor R tablets treatment. Severe rash may be developed in association with other symptoms which could be serious. Stop taking Atazor R tablets and talk to your doctor immediately if you develop a severe rash or a rash with flu-like illness symptoms, blisters, fever, mouth sores, muscle or joint pain, swelling in the face, inflammation of the eye which causes redness (conjunctivitis), painful, warm, or red lumps (nodules).
- Yellowing of your skin or the white part of your eyes caused by high levels of bilirubin in your blood has been commonly reported. This side effect is usually not dangerous in adults and infants older than 3 months of age; but it might be a symptom of a serious problem. If your skin or the white part of your eyes turns yellow, talk to your doctor immediately.
- Changes in the way your heart beats (heart rhythm change) may occasionally happen. Talk to your doctor immediately if you get dizzy, lightheaded or if you suddenly faint. These could be symptoms of a serious heart problem.
- Liver problems may uncommonly happen. Your doctor should do blood tests prior you start Atazor R tablets and during treatment. If you have liver problems, including hepatitis B or C infection, you may experience a worsening of your liver problems. Talk to your doctor immediately if you get dark (tea-colored) urine, itching, yellowing of your skin or the white part of your eyes, pain around the stomach, pale colored stools or nausea.
- Gallbladder problems uncommonly happen in people taking Atazor R tablets. Symptoms of gallbladder problems may include pain in the right or middle upper stomach area, nausea, vomiting, fever or yellowing your skin or the white part of your eyes.
- Atazor R may affect how well your kidneys work.
- Kidney stones uncommonly happen in people taking Atazor R tablets. Talk to your doctor immediately if you get symptoms of kidney stones which may include, pain in your low back or low stomach-area, blood in your urine or pain when you urinate.

Other side effects

Very common: may affect more than 1 in 10 people

- upper or lower stomach ache
- Vomiting
- diarrhoea (may be severe)
- feeling sick (nausea)
- flushing, feeling hot
- headache
- dizziness

- pain in the throat
- cough
- upset stomach or indigestion
- a tingling sensation or numbness in the hands, feet or around the lips and mouth
- feeling weak/tired
- bad taste in the mouth
- damage to the nerves that can cause weakness and pain
- itching
- rash
- joint pain and back pain

Common: may affect up to 1 in 10 people

- allergic reactions including skin rashes (may be red, raised, itchy), severe swelling of the skin and other tissues
- inability to sleep (insomnia)
- anxiety
- increase in cholesterol
- increase in triglycerides
- gout
- stomach bleeding
- inflammation of the liver and yellowing of skin or whites of the eyes
- increase in urination
- reduced kidney function
- seizures (fits)
- low levels of blood platelets
- thirst (dehydration)
- abnormally heavy periods
- wind (flatulence)
- loss of appetite
- mouth ulcer
- muscle aches (pain), tenderness or weakness
- fever
- weight loss
- laboratory test results: changes in blood test results (such as blood chemistry and blood count)
- confusion
- difficulty paying attention
- fainting
- blurred vision
- swelling of the hands and feet
- high blood pressure
- low blood pressure and feeling faint when getting up
- coldness in the hands and feet
- acne

Uncommon: may affect up to 1 in 100 people

- heart attack
- kidney failure
- diabetes
- asthenia (unusual tiredness or weakness)
- weight decreased, weight gain, appetite increased
- depression, sleep disorder
- disorientation, amnesia (loss of memory), dizziness, somnolence (sleepiness), abnormal dream
- syncope (fainting)
- dyspnoea (shortness of breath)
- pancreatitis (inflammation of the pancreas), gastritis (inflammation of the stomach), stomatitis aphthous (mouth ulcers and cold sores), dysgeusia (impairment of the sense of taste), dry mouth, abdominal distension
- angioedema (severe swelling of the skin and other tissues most often the lips or the eyes)
- alopecia (unusual hair loss or thinning), pruritus (itching)
- muscle atrophy (muscle shrinkage), arthralgia (joint pain), myalgia (aching muscles)
- interstitial nephritis (kidney inflammation), haematuria (blood in the urine), proteinuria (excess protein in the urine), pollakiuria (increased frequency of urination)
- gynaecomastia (breast enlargement in men)
- chest pain, malaise (generally feeling unwell),

Rare: may affect up to 1 in 1000 people

- severe or life threatening skin reaction including blisters (Stevens Johnson syndrome, toxic epidermal necrolysis),
- serious allergic reaction (anaphylaxis)
- high levels of sugar in the blood
- gait disturbance (abnormal manner of walking)
- oedema (swelling)
- hepatosplenomegaly (enlargement of the liver and spleen)
- myopathy (aching muscles, muscle tenderness or weakness, not caused by exercise)
- kidney pain

Tell your doctor if you feel sick (nauseous), are vomiting, or have stomach pain, because these may be signs of an inflamed pancreas. Also tell your doctor if you experience joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty moving, as this may be a sign of osteonecrosis

In patients with haemophilia type A and B, there have been reports of increased bleeding while taking this treatment or another protease inhibitor. Should this happen to you, seek immediate advice from your doctor.

Abnormal liver function tests, hepatitis (inflammation of the liver), and rarely jaundice, have been reported in patients taking ritonavir. Some people had other illnesses or were taking other medicines. People with liver disease or hepatitis may have worsening of liver disease.

There have been reports of muscle pain, tenderness or weakness, particularly when taking medicines to lower cholesterol in combination with antiretroviral therapy, including protease inhibitors and nucleoside analogues. On rare occasions these muscle disorders have been serious (rhabdomyolysis). In the event of unexplained or continual muscle pain, tenderness, weakness or cramps, stop taking the medicine, contact your doctor as soon as possible or go to the nearest hospital.

Inform your doctor as soon as possible if you experience any symptoms that suggest an allergic reaction after taking this medicine such as rash, hives or breathing difficulties

5. How to store Atazor-R tablets

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and on the blister.

The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help the environment.

Do not store above 30°C. Protect from moisture

6. Contents of the pack and other information

What Atazor-R tablets contains

The active substance is Atazanavir Sulfate 300 mg and Ritonavir 100 mg.

The other ingredients are Lactose Monohydrate, Crospovidone, Microcrystalline Cellulose, Colloidal Silicon Dioxide, Magnesium Stearate, Copovidone, Sorbitan Monolaurate, Polysorbate 80, Sodium Stearyl Fumarate, Opadry Yellow 15B82855 and Purified Water.

What Atazor-R tablets looks like and contents of the pack

Creamish yellow colored, modified capsule shaped film coated tablets debossed with "EM" on one side and "149" on other side.

Pack: HDPE bottle containing 30 tablets.

Marketing Authorisation Holder and Manufacturer:

Emcure Pharmaceuticals Limited.

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