Package leaflet: Information for the patient

Atazanavir Sandoz 100 mg, harde capsules
Atazanavir Sandoz 150 mg, harde capsules
Atazanavir Sandoz 200 mg, harde capsules
Atazanavir Sandoz 300 mg, harde capsules
atazanavir

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- 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 [Nationally completed name] is and what it is used for

[Nationally completed name] is an antiviral (or antiretroviral) medicine. It is one of a group called *protease inhibitors*. These medicines control 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 [Nationally completed name] reduces the risk of developing illnesses linked to HIV infection.

[Nationally completed name] capsules may be used by adults and children 6 years of age and older. Your doctor has prescribed [Nationally completed name] for you because you are infected by the HIV that causes Acquired Immunodeficiency Syndrome (AIDS). It is normally used in combination with other anti-HIV medicines. Your doctor will discuss with you which combination of these medicines with [Nationally completed name] is best for you.

2. What you need to know before you take [Nationally completed name]

Do not take [Nationally completed name]
- **if you are allergic** to atazanavir 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 **[Nationally completed name]**
- **if you are taking any of these medicines:** see also *Other medicines and [Nationally completed name]*
  - rifampicin (an antibiotic used to treat tuberculosis)

- astemizole or terfenadine (commonly used to treat allergy symptoms, these medicines may be available without prescription); cisapride (used to treat gastric reflux, sometimes called heartburn); pimozide (used to treat schizophrenia); quinidine or bepridil (used to correct heart rhythm); ergotamine, dihydroergotamine, ergonovine, methylergonovine (used to treat headaches); and alfuzosin (used to treat enlarged prostatic gland)
- quetiapine (used to treat schizophrenia, bipolar disorder and major depressive disorder); lurasidone (used to treat schizophrenia)
- medicines containing St. John's wort *(Hypericum perforatum*, a herbal preparation)
- triazolam and oral (taken by mouth) midazolam (used to help you sleep and/or to relieve anxiety)
- lomitapide, simvastatin, and lovastatin (used to lower blood cholesterol)
- grazoprevir-containing products, including elbasvir/grazoprevir fixed-dose combination and glecaprevir/pibrentasvir fixed-dose combination (used to treat chronic hepatitis C infection)
- apalutamide (used to treat prostate cancer), encorafenib (used to treat cancer) and ivosidenib (used to treat cancer)
- carbamazepine, phenobarbital, and phenytoin (used to treat seizures).

Do not take sildenafil with [Nationally completed name] when sildenafil is used for the treatment of pulmonary arterial hypertension. Sildenafil is also used for the treatment of erectile dysfunction. Tell your doctor if you are using sildenafil for the treatment of erectile dysfunction.

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

Warnings and precautions

[Nationally completed name] is not a cure for HIV infection. You may continue to develop infections or other illnesses linked to HIV infection.

Some people will need special care before or while taking [Nationally completed name]. Talk to your doctor or pharmacist before taking [Nationally completed name] 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 haemophilia
- if you require haemodialysis

[Nationally completed name] may affect how well your kidneys work.

Kidney stones have been reported in patients taking atazanavir. If you develop signs or symptoms of kidney stones (pain in your side, blood in your urine, pain when you urinate), please inform your doctor immediately.

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 atazanavir. The signs may be a mild yellowing of the skin or eyes. If you notice any of these symptoms please inform your doctor.

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

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

Children
Do not give this medicine to children younger than 3 months of age and weighing less than 5 kg. The use of atazanavir in children less than 3 months of age and weighing less than 5 kg has not been studied due to the risk of serious complications.

Other medicines and [Nationally completed name]
You must not take [Nationally completed name] with certain medicines. These are listed under Do not take [Nationally completed name], at the start of Section 2.

There are other medicines that may not mix with [Nationally completed name]. Tell your doctor if you are taking, have recently taken, or might take any other medicines. It is especially important to mention these:
- other medicines to treat HIV infection (e.g., indinavir, nevirapine and efavirenz)
- sofosbuvir/velpatasvir/voxilaprevir (used to treat hepatitis C)
- sildenafil, vardenafil, or tadalafil (used by men to treat impotence (erectile dysfunction))
- if you are taking an oral contraceptive (**"the Pill"**) with [Nationally completed name] 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 [Nationally completed name] or 2 hours after taking [Nationally completed name], H_2-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, and fluvastatin (used to lower blood cholesterol)
- salmeterol (used to treat asthma)
- cyclosporin, tacrolimus, and sirolimus (medicines to decrease the effects of body's immune system)

- certain antibiotics (rifabutin, clarithromycin)
- ketoconazole, itraconazole, and voriconazole (antifungals)
- apixaban, dabigatran, edoxaban, rivaroxaban, warfarin, clopidogrel, prasugrel, and ticagrelor (used to reduce blood clots)
- lamotrigine (antiepileptics)
- irinotecan (used to treat cancer)
- elagolix (gonadotropin-releasing hormone receptor antagonists, used to treat severe pain from endometriosis)
- fostamatinib (used to treat chronic immune thrombocytopenia)
- sedative agents (e.g., midazolam administered by injection)
- buprenorphine (used to treat opioid addiction and pain)
- corticosteroids (all routes of administration; including dexamethasone).

Some medicines may interact with ritonavir, a medicine that is taken with [Nationally completed name]. It is important to tell your doctor if you are taking an inhaled or nasal (given in the nose) corticosteroid, including fluticasone or budesonide (given to treat allergic symptoms or asthma).

[Nationally completed name] with food and drink
It is important that you take [Nationally completed name] 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 think that you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Atazanavir, the active substance of [Nationally completed name], is excreted in human milk. Patients should not breast-feed while taking [Nationally completed name].

Breast-feeding is ***not recommended*** in women living with HIV because HIV infection can be passed on to the baby in breast milk.

If you are breast-feeding, or thinking about breast-feeding, you ***should discuss it with*** your doctor ***as soon as possible***.

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

[Nationally completed name] contains sodium and lactose
This medicine contains less than 1 mmol sodium (23 mg) per hard capsule, that is to say essentially 'sodium-free'.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take [Nationally completed name]

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 of [Nationally completed name] capsules is 300 mg once daily with 100 mg ritonavir once daily and with food, in combination with other anti-HIV medicines. Your doctor may adjust the dose of [Nationally completed name] according to your anti-HIV therapy.

For children (6 to less than 18 years of age), your child's doctor will decide the right dose based on your child's weight. The dose of [Nationally completed name] capsules for children is calculated by body weight and is taken once daily with food and 100 mg ritonavir as shown below:

Body Weight (kg)	**[Nationally completed name] Dose once daily (mg)**	**Ritonavir Dose* once daily (mg)**
15 to less than 35	200	100
at least 35	300	100
*Ritonavir capsules, tablets or oral solution may be used.		

Other forms of this medicine may be available for use in children at least 3 months old and weighing at least 5 kg. Switching to capsules from other formulations is encouraged as soon as patients are able to consistently swallow capsules.

A change in dose may occur when switching between other formulations and capsules. Your doctor will decide the right dose based on your child's weight.

There are no dosing recommendations for [Nationally completed name] in paediatric patients less than 3 months of age.

Take [Nationally completed name] capsules with food (a meal or a substantial snack). Swallow the capsules whole.
Do not open the capsules.

If you take more [Nationally completed name] than you should
Yellowing of the skin and/or eyes (jaundice) and irregular heart beat (QTc prolongation) may occur if you or your child take too much [Nationally completed name].
If you accidentally take more [Nationally completed name] capsules than your doctor recommended, contact your HIV doctor at once or contact the nearest hospital for advice.

If you forget to take [Nationally completed name]
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 [Nationally completed name]
Do not stop taking [Nationally completed name] before talking to your doctor.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

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 [Nationally completed name], by the other medicines you are taking, or by the HIV infection

itself. Tell your doctor if you notice anything unusual about your health.

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.

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 [Nationally completed name] treatment. Severe rash may be developed in association with other symptoms which could be serious. Stop taking [Nationally completed name] 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 [Nationally completed name] 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 atazanavir. 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.
- [Nationally completed name] may affect how well your kidneys work.
- Kidney stones uncommonly happen in people taking atazanavir. 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 reported for patients treated with [Nationally completed name] are the following:

Common (may affect up to 1 in 10 people):
- headache
- vomiting, diarrhoea, abdominal pain (stomach pain of discomfort), nausea, dyspepsia (indigestion)
- fatigue (extreme tiredness)

Uncommon (may affect up to 1 in 100 people):
- peripheral neuropathy (numbness, weakness, tingling or pain in the arms and legs)
- hypersensitivity (allergic reaction)
- asthenia (unusual tiredness or weakness)
- weight decreased, weight gain, anorexia (loss of appetite), appetite increased
- depression, anxiety, sleep disorder
- disorientation, amnesia (loss of memory), dizziness, somnolence (sleepiness), abnormal

dream
- syncope (fainting), hypertension (high blood pressure)
- 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), flatulence (wind), 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), fever
- insomnia (difficulty sleeping)

Rare (may affect up to 1 in 1,000 people):
- gait disturbance (abnormal manner of walking)
- oedema (swelling)
- hepatosplenomegaly (enlargement of the liver and spleen)
- myopathy (aching muscles, muscle tenderness of weakness, not caused by exercise)
- kidney pain

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Nationally completed name]

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, bottle label or blister after "EXP". The expiry date refers to the last day of that month.

Do not store above 30°C.

Shelf life after first opening of the bottle:
[NL/H/4117/001-002-003, NL/H/4118/001-002]
Use within 4 months after first opening.
[NL/H/4117/004, NL/H/4118/003]
Use within 2 months after first opening.

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

6. Contents of the pack and other information

What [Nationally completed name] contains
- The active substance is atazanavir.

Each capsule contains 100 mg of atazanavir (as sulfate).
Each capsule contains 150 mg of atazanavir (as sulfate).
Each capsule contains 200 mg of atazanavir (as sulfate).
Each capsule contains 300 mg of atazanavir (as sulfate).

100 mg, 150 mg, 200 mg hard capsules
- The other ingredients are lactose monohydrate, crospovidone (type A) (E 1202), colloidal anhydrous silica (E 551), magnesium stearate (E 470b). The capsule shell and printing ink contain gelatin, titanium dioxide (E 171), indigotine (E 132) (contains sodium), shellac, propylene glycol (E 1520).

300 mg hard capsules
- The other ingredients are lactose monohydrate, crospovidone (type A) (E 1202), colloidal anhydrous silica (E 551), magnesium stearate (E 470b). The capsule shell and printing ink contain gelatin, titanium dioxide (E 171), indigotine (E 132) (contains sodium), red iron oxide (E 172), shellac, propylene glycol (E 1520).

What [Nationally completed name] looks like and contents of the pack
100 mg hard capsules
Opaque, blue and white capsule of size 2 printed with white ink, with “100 mg” on the cap.

150 mg hard capsules:
Opaque, blue and powder blue capsule of size 1 printed with white ink, with “150 mg” on the cap.

200 mg hard capsules:
Opaque, blue capsule of size 0 printed with white ink, with “200 mg” on the cap.

300 mg hard capsules:
Opaque red and blue capsule of size 00 printed with white ink, with “300 mg” on the cap.

[NL/H/4117/001-002-003-004]
The hard capsules are packed in Aluminium-OPA/Alu/PVC unit dose perforated blisters, Aluminium-OPA/Alu/PVC blisters or HDPE bottles closed with child-resistant polypropylene closure.

[NL/H/4118/001-002-003]
The hard capsules are packed in Aluminium-OPA/Alu/PVC unit dose perforated blisters or HDPE bottles closed with child-resistant polypropylene closure.

Pack sizes:
[NL/H/4117/001-002-003]
Unit dose blister: 60 x 1 hard capsules; 10 blister cards of 6 x 1 hard capsules each
Blister: 60 hard capsules; 10 blister cards of 6 hard capsules each
Bottle: 60 hard capsules

[NL/H/4117/004]
Unit dose blister:
30 x 1 hard capsules; 5 blister cards of 6 x 1 hard capsules each
multipack containing 60 x 1 (2 packs of 30 x 1) hard capsule
multipack containing 90 x 1 (3 packs of 30 x 1) hard capsules
multipack containing 120 x 1 (4 packs of 30 x 1) hard capsules
Blister:

30 hard capsules; 5 blister cards of 6 hard capsules each
multipack containing 60 (2 packs of 30) hard capsules
multipack containing 90 (3 packs of 30) hard capsules
multipack containing 120 (4 packs of 30) hard capsules
Bottles:
30 hard capsules
multipack containing 60 (2 packs of 30) hard capsules
multipack containing 90 (3 packs of 30) hard capsules
multipack containing 120 (4 packs of 30) hard capsules

[NL/H/4118/001-002]
Unit dose blister: 60 x 1 hard capsules; 10 blister cards of 6 x 1 hard capsules each.
Bottle: 60 hard capsules

[NL/H/4118/003]
Unit dose blister:
30 x 1 hard capsules; 5 blister cards of 6 x 1 hard capsules each
multipack containing 90 x 1 (3 packs of 30 x 1) hard capsules
Bottle:
30 hard capsules
multipack containing 90 (3 packs of 30) hard capsules

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen
Sandoz B.V., Hospitaaldreef 29, 1315 RC Almere, Nederland

Fabrikant
Remedica Ltd.
Aharnon Street, Limassol Industrial Estate
Limassol
Cyprus

Lek Pharmaceuticals dd.
Verovškova ulica 57
Ljubljana
Slovenia

In het register ingeschreven onder
RVG 121563 - Atazanavir Sandoz 100 mg, harde capsules
RVG 121564 - Atazanavir Sandoz 150 mg, harde capsules
RVG 121565 - Atazanavir Sandoz 200 mg, harde capsules
RVG 121566 - Atazanavir Sandoz 300 mg, harde capsules

Dit geneesmiddel is geregistreerd in lidstaten van de Europese Economische Ruimte en het Verenigd Koninkrijk (Noord-Ierland) onder de volgende namen:

Nederland:	Atazanavir Sandoz 100, 150, 200, 300 mg, harde capsules
Duitsland:	Atazanavir - 1 A Pharma 100, 150, 200, 300 mg Hartkapseln
Frankrijk:	ATAZANAVIR SANDOZ 150, 200, 300 mg, gélule
Ierland:	Atazanavir sulphate Rowex 100 mg, 150 mg, 200 mg, 300 mg, Capsules hard
Letland:	Atazanavir Sandoz 200, 300 mg cietās kapsulas
Polen:	Atazanavir Sandoz

Portugal:	Atazanavir Sandoz
Roemenië:	Atazanavir Sandoz 100, 150, 200, 300 mg capsule
Noord-Ierland:	Atazanavir sulphate Sandoz 100, 150, 200, 300 mg capsule, hard

Deze bijsluiter is voor het laatst goedgekeurd in december 2024