

APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

ZANRIT 300/100 mg film coated tablets

Atazanavir sulphate as atazanavir 300 mg and ritonavir 100 mg

ZANRIT contains sugar (lactose 167,292 mg)

Read all of this leaflet carefully before you start taking ZANRIT

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your medical practitioner, pharmacist, nurse or other healthcare provider.
- ZANRIT has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What ZANRIT is and what it is used for
2. What you need to know before you use ZANRIT
3. How to use ZANRIT
4. Possible side effects
5. How to store ZANRIT

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6. Contents of the pack and other information

1. What ZANRIT is and what it is used for

ZANRIT is a combination antiviral (or antiretroviral) medicine, used in combination with other antiretroviral medicines for the treatment of HIV infection.

It is one of a group called protease inhibitors. These medicines control Human Immunodeficiency Virus (HIV) infection by blocking HIV protease, an enzyme that the HIV virus 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 ZANRIT reduces the risk of developing illnesses linked to HIV infection.

HIV is the virus that causes acquired immune deficiency syndrome (AIDS).

2. What you need to know before you take ZANRIT

Do not take ZANRIT

- if you are hypersensitive (allergic) to atazanavir, ritonavir or to any of the ingredients of ZANRIT (see What ZANRIT contains)
- if you have moderate to severe liver disease
- if you are pregnant or breastfeeding your baby
- if you are currently taking any of the following medicines:
 - digoxin (a heart medicine)

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- amiodarone, bepridil, dronedarone, encainide, flecainide, propafenone, quinidine (used to correct irregular heartbeats)
- astemizole (used to treat allergy symptoms)
- alfuzosin (for enlarged prostate gland)
- voriconazole (used to treat fungal infections)*
- rifampicin (an antibiotic used to treat/prevent certain infections such as tuberculosis)
- bionanserin (used to treat schizophrenia – a chronic brain disorder that affects a person's ability to think, act and behave appropriately)
- pimozide (used to treat Tourette's syndrome - a nervous system disorder involving repetitive movements or unwanted sounds)
- ergotamine, dihydroergotamine, ergonovine, methylergonovine (used to treat headaches)
- cisapride (used to treat gastric reflux, or heartburn)
- medicines containing St. John's wort (*Hypericum perforatum*, an herbal preparation)
- simvastatin and lovastatin (used to lower blood cholesterol)
- oral midazolam and triazolam (used to treat anxiety and sleeplessness)
- 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 medical practitioner's supervision
- irinotecan (used to treat colon or rectal cancer)

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- indinavir (used in the treatment of HIV infection)
- omeprazole (used to treat acid in the stomach).

Warnings and precautions

Take special care with ZANRIT:

- ZANRIT 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 medical practitioner the precautions needed to avoid infecting other people
- tell your medical practitioner if you notice changes in body fat. Redistribution, accumulation, or loss of body fat may occur in patients receiving antiretroviral therapy. This may include an increased amount of fat in the upper back and neck (“buffalo hump”), breast and around the trunk. Loss of fat from the legs, arms, and face may also occur. The cause and long-term health effects of these conditions are not known at this time
- whilst there is no strong evidence indicating that weight gain is an effect of treatment with ZANRIT, you should inform your medical practitioner if you gain weight. Some patients have large increases in triglycerides and cholesterol (fats in the blood) as well as blood glucose levels during therapy, therefore your medical practitioner may wish to do blood tests before and during treatment and you should be treated accordingly. Weight gain, higher blood lipid and glucose levels may be linked to lifestyle rather than therapy

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- if you develop diarrhoea and vomiting whilst taking ZANRIT, inform your medical practitioner as this may affect the way your medicine works and may also affect your kidney function
- an autoimmune disorder (a condition that occurs when the immune system attacks healthy body tissue) – called IRIS (Immune reconstitution inflammatory syndrome) may also occur after you start taking medicines for the treatment of your HIV infection. This autoimmune disorder may occur within 3 months after the start of treatment. Examples of IRIS reaction to opportunistic diseases are tuberculosis (bacterial infection), an eye disorder called cytomegalovirus retinitis (an infection that attack the retina of the eye), a disease called cryptococcal meningitis inflammation (swelling of the protective membranes covering the brain and spinal cord caused by a fungus), infection of the lung caused by *Mycobacterium avium*, a common virus called cytomegalovirus or a fungal infection of the lungs. You will be treated by your medical practitioner, and generally symptoms will subside in a few weeks. Your medical practitioner may prescribe you medication called glucocorticoids (used to treat infections)
- 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

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pains (especially of the hip, knee and shoulder) and difficulty in movement. If you notice any of these symptoms please inform your medical practitioner

- 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 medical practitioner immediately
- you may develop the following symptoms due to the active ingredient ritonavir: hives, skin eruptions, difficulty breathing, painless swelling under the skin. In rare cases you may develop a serious allergic reaction or a rare, serious disorder of the skin and mucous membranes called Stevens-Johnson syndrome. You may develop the following symptoms due to the active ingredient atazanavir: mild to moderate flat or raised red bumps/eruptions on the skin within the first 3 weeks of therapy. In most cases the rash will resolve within 2 weeks. In some cases you may develop: the rare, serious disorder of the skin and mucous membranes called Stevens-Johnson syndrome, a skin disorder characterised by bull's-eye-shaped lesions or toxic skin eruptions which include Drug Rash, Eosinophilia, and Systemic Symptoms (DRESS) syndrome (symptoms included skin rash, fever, enlargement of lymph nodes)

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- if you have liver problems or are infected with Hepatitis B or Hepatitis C (an infection of the liver), talk to your medical practitioner before taking ZANRIT. You may develop jaundice (yellowing of the skin and eyes)
- some patients taking ZANRIT may develop serious problems with their pancreas (pancreatitis), which, if not treated, could result in death. Tell your medical practitioner as soon as possible if you experience nausea, vomiting, or severe abdominal pain. These may be signs of may be signs of inflammation of the pancreas
- diabetes and high blood sugar (hyperglycaemia) may occur if you are taking protease inhibitors such as ZANRIT, or if you already have diabetes before starting therapy, it may become worse. If you are taking ZANRIT your diabetes medication may need changing
- if you are taking medicines called corticosteroids (medicines used to treat inflammation and allergies including fluticasone) in your nose or inhaled, you may develop a disease called Cushing's syndrome (when your body has too much of the cortisol hormone in your body)
- if you are taking medicine for the inability to get and keep an erection firm enough for sex or high blood pressure, called sildenafil, tadalafil or vardenafil, please tell your medical practitioner. You may develop low blood pressure or a prolonged erection when used in combination with ZANRIT
- if you are taking the herbal product called St. John's Wort, please inform your medical practitioner as it may lower the effect of ZANRIT

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- if you are taking a class of medicines to treat high cholesterol, called statins (such as simvastatin, lovastatin, atorvastatin and rosuvastatin) as your medical practitioner may want to change these medicines
- hyperbilirubinemia (an increase in the level of bilirubin in the blood) has occurred in patients receiving ZANRIT. The signs may be a mild yellowing of the skin or eyes. If you notice any of these symptoms please inform your medical practitioner
- your medical practitioner will perform blood and urine tests before and during your treatment with ZANRIT to monitor your liver function and blood lipids (fats)
- if you have haemophilia (a disease that affects the ability of your blood to clot properly and causes increased bleeding) and are taking ZANRIT you may have increased bleeding. ZANRIT. Be sure to tell your medical practitioner if you have haemophilia types A or B
- if you have a heart condition, please inform your medical practitioner before starting treatment with ZANRIT. If you notice a change in the way your heart beats (heart rhythm changes) while taking ZANRIT, please inform your medical practitioner
- you may develop gallstones during your treatment with ZANRIT, which may result in hospitalisation and management. Your medical practitioner may temporarily stop or discontinue your treatment
- kidney stones have been reported in patients taking ZANRIT. If you develop signs or symptoms of kidney stones (pain in your side, blood in your urine, pain when you urinate), please inform your medical practitioner immediately

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- if you have any type of kidney disease, please inform your medical practitioner.

Your medical practitioner may monitor your kidney function regularly, as you may develop kidney disease

- safety and efficacy of ZANRIT in the elderly have not been established.

Children

- Children receiving ZANRIT may require their hearts to be monitored by their medical practitioner.

Other medicines and ZANRIT

Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

There are some medicines you cannot take at all with ZANRIT, as listed under section 2, **Do not take ZANRIT**.

The following medicines must be used with caution with ZANRIT. These combinations may increase or decrease the effects of either medicine when taken together:

- alprazolam (a sleeping medicine)
- antiretroviral medicines including HIV-protease inhibitors (amprenavir, indinavir, nelfinavir, saquinavir) non-nucleoside reverse transcriptase inhibitors (NNRTI) (delavirdine, efavirenz, nevirapine), and others (didanosine, tenofovir zidovudine)
- anti-depressant medicines (for example, amitriptyline, bupropion, clomipramine, desipramine, fluoxetine, imipramine, nefazodone, nortriptyline, paroxetine,

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sertraline, trazodone, maprotiline, trimipramine, doxepin, venlafaxine,
fluvoxamine)

- busipirone (medicine used to treat anxiety)
- clarithromycin and erythromycin (antibiotics)
- inhalation or nasal steroid medicines (for example, fluticasone propionate, budesonide)
- antifungals (for example, ketoconazole, itraconazole, fluconazole)
- morphine and morphine-like medicines used to treat severe pain (for example, methadone, alfentanil, fentanyl, hydrocodone, oxycodone, propoxyphene, tramadol, levamethadyl, hydromorphone, pethidine)
- hormonal contraceptives containing ethinyl oestradiol (in an oral or patch dosage form) and norethindrone (oral)
- rifabutin, ethionamide (used to treat tuberculosis)
- sulfamethoxazole/trimethoprim (an antibiotic)
- tadalafil, vardenafil (for impotence - erectile dysfunction)
- theophylline (used to treat asthma)
- tobacco (contained in cigarettes)
- non steroidal anti-inflammatory medicines (for example, diclofenac, flurbiprofen, ibuprofen, nabumetone, sulindac, ketoprofen, ketorolac, naproxen)
- lidocaine, disopyramide, mexiletine and tocainide (used to treat abnormal heart rhythm)
- fusidic acid (antibiotic)

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- carbamazepine, clonazepam, phenobarbitone, phenytoin, valproate, ethosuximide (anti-epileptics)
- anti-diarrhoea medicines such as diphenoxylate and loperamide
- medicines used to treat nausea (for example, dronabinol, ondansetron, prochlorperazine, promethazine and metoclopramide)
- medicines to treat allergies such as stuffy/runny nose, itching, sneezing, relieve allergy eye symptoms, rash (fexofenadine, loratadine, triamcinolone)
- medicines used to treat infections caused by parasites (for example, quinine, proguanil, albendazole, chloroquine, metronidazole, primaquine, pyrimethamine, trimetrexate and atovaquone)
- medicines used to treat high blood pressure (for example, losartan, doxazosin, prazosin, terazosin)
- proton pump inhibitors like lansoprazole (used in the treatment of heartburn and acid reflux) medicines to lower blood pressure, to slow heart rate, or to correct heart rhythm (diltiazem, felodipine, nifedipine, nicardipine, verapamil, amlodipine, isradipine, nimodipine, nisoldipine, nitrendipine, metoprolol, penbutolol, pindolol, timolol, propranolol, betazolol)
- medicines used to treat cancer (such as tamoxifen, etoposide, paclitaxel, vinblastine, vincristine, cyclophosphamide, ifosfamide, daunorubicin, doxorubicin)
- bromocriptine (used to stop breast milk production, fertility and menstrual problems)
- methysergide (used to treat migraines)
- pentoxifylline (used to treat blood circulation disorders)

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- medicines used to treat blood glucose levels (for example, glimepiride, glipizide, glyburide, tolbutamide)
- medicines used to treat cholesterol (gemfibrozil, clofibrate)
- ciclosporin, tacrolimus, sirolimus (medicines to decrease the effects of body's immune system)
- chlorpromazine, haloperidol, perphenazine, risperidone, thioridazine, clozapine (antipsychotics)
- buspirone, clorazepate, diazepam, estazolam, flurazepam, zolpidem, lorazepam, oxazepam, propofol, temazepam (anxiety medicines)
- dexamethasone, prednisone (steroids) (steroid medicines are used to treat rheumatic problems, a number of skin diseases, severe allergies and etc.)
- amphetamines
- any medicines used to treat diseases related to the acid in the stomach (e.g. antacids) to be taken 1 hour before, or 2 hours after taking ZANRIT
- warfarin, rivaroxaban, and vorapaxar (anticoagulants, used to reduce the blood clots)
- H2-blockers (used to treat stomach ulcers) like famotidine

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ZANRIT with food and drink

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

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, please consult your medical practitioner, pharmacist or other healthcare professional for advice before using ZANRIT.

Do not use ZANRIT if you are pregnant or breastfeeding your baby.

The active substances of ZANRIT, are both excreted in human milk. You should not breast-feed while taking ZANRIT.

You should be aware that if your baby does not already have HIV, there is a chance that HIV can be transmitted through breastfeeding.

Driving and using machines

Nervous system side effects such as dizziness, sleepiness, feeling disorientated, blurred vision and fainting are known undesirable effects which may interfere with your ability to perform potentially hazardous tasks like driving a car or operating heavy machinery.

It is not always possible to predict to what extent ZANRIT may interfere with your daily activities of a patient. Ensure that you do not engage in the above activities until you are aware of the measure to which ZANRIT affects you.

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ZANRIT contains lactose

ZANRIT contains lactose. If you have been told by your medical practitioner that you have an intolerance to some sugars, contact your medical practitioner before taking this medicine.

3. How to take ZANRIT

Do not share medicines prescribed for you with any other person. Always use ZANRIT exactly as your medical practitioner has instructed. You should check with your medical practitioner or pharmacist if you are unsure.

Adults

The recommended adult dose of ZANRIT one tablet, once daily and with food. The tablet should be swallowed whole.

Patients with severe kidney or liver disease

ZANRIT is not recommended for use in patients with severe kidney disease who are managed with haemodialysis, or in patients with moderate to severe liver disease.

Your medical practitioner will tell you how long your treatment with ZANRIT will last. Do not stop treatment early without talking to your medical practitioner.

If you have the impression that the effect of ZANRIT is too strong or too weak, tell your medical practitioner or pharmacist.

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If you take more ZANRIT than you should

In the event of overdosage, consult your medical practitioner or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Symptoms of overdose may include:

- yellowing of the skin and/or eyes (jaundice) and irregular heart beat (QTc prolongation) may occur.

If you forget to take ZANRIT:

If you forget to take ZANRIT, take as soon as you remember on the same day. If you do not take a tablet that same day, take your normal dose the next day. Do not take a double dose to make up for forgotten individual doses.

If you stop taking ZANRIT

Do not stop taking ZANRIT before talking to your medical practitioner.

4. Possible side effects

ZANRIT can have side effects.

Not all side effects reported for ZANRIT are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using ZANRIT, please consult your healthcare provider for advice.

If any of the following happens, stop using ZANRIT and tell your medical practitioner immediately or go to the casualty department at your nearest hospital:

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- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to ZANRIT. You may need urgent medical attention or hospitalisation.

Tell your medical practitioner immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- inflammation of the pancreas, which causes severe pain in the abdomen and back (pancreatitis)
- yellowing of the skin or whites of the eyes, or urine getting darker and stools paler, fatigue, weakness, malaise, loss of appetite, nausea or vomiting caused by liver problems (signs of hepatitis, jaundice, liver problems), liver damage
- changes in the way your heart beats (heart rhythm change) may occasionally happen or you may experience a heart attack. Talk to your medical practitioner immediately if you get dizzy, lightheaded or if you suddenly faint. These could be symptoms of a serious heart problem
- serious skin rashes including Stevens-Johnson syndrome and toxic epidermal necrolysis. These can appear as reddish target-like macules or circular patches often with central blisters on the trunk, skin peeling, ulcers of the mouth, throat, nose, genitals and eyes and can be preceded by fever and flu-like symptoms (very rare side effects, potentially life threatening)

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- mental disturbances including psychotic reactions such as hallucinations and personality disorder, abnormal thinking
- seizure (convulsions)
- urinating less than usual or not at all, fatigue, confusion, nausea, weakness due to kidney failure
- unexplained or continual muscle pain, tenderness, weakness or cramps (rhabdomyolysis).

These are all serious side effects. You may need urgent medical attention.

Tell your medical practitioner if you notice any of the following:

Frequent side effects

- headache, dizziness, a tingling sensation or numbness in the hands, feet or around the lips and mouth (pins and needles), taste disorder, dizziness, skin very sensitive to touch, sleepiness
- yellowing of the white section of the eye
- increased cough, sore throat due to inflammation
- abdominal pain, diarrhoea, indigestion, nausea, vomiting, dry mouth, belching, flatulence, mouth ulcers
- rash
- weakness, tiredness, fever, pain, flushing
- lipodystrophy (a rare syndrome that causes you to lose fat from some parts of the body, while gaining it in others, including on organs like the liver)

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- anorexia, weight loss, high blood cholesterol levels, high lipid (fat) levels in your blood (i.e. triglycerides)
- anxiety
- a tingling sensation or numbness in the hands, feet or around the lips and mouth (pins and needles), taste disorder, dizziness, skin very sensitive to touch, sleepiness
- serious infection of the liver's bile ducts (symptoms include pain in the upper right part of your belly, fever, chills, nausea and vomiting, dark urine, clay-colored stools), enlarged liver, abnormal liver blood test results which cause yellowing of the skin and eyes
- skin rash (may be red, raised, itchy or blisters), itching, sweating
- myalgia (aching muscles)
- decrease in blood cell test results
- abnormal liver function test results
- dilatation of blood vessels, which decreases blood pressure (vasodilation).

Less frequent side effects

- increase in appetite, weight loss and weight gain
- high blood glucose levels as in diabetes, vitamin deficiency, weight loss and weakness due to wasting of the body as a result of being very sick, dehydration, swelling under the tissues, swelling of the hands and feet, glucose in your urine (as tested by your medical practitioner), gout, accumulation or redistribution of body fat

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- depression, sleep disorder, abnormal dreams, disorientation, confusion, feeling agitated, sleeplessness, agitation (feeling anxious or nervously excited), extreme changes in your mood, euphoria, decreased libido, nervousness, abnormal thinking
- loss in memory, feeling tired, feeling faint, an unusual walking pattern
- abnormal vision, blurred vision, inflammation of the eyelid (red, swollen itchy eyelids), double vision eye pain, inflammation of the colored part of your eye, sensitivity to light, dry eyes, inflammation of the eye
- fast heart rate
- high blood pressure
- bleeding due to a ruptured blood vessel, low blood pressure, low blood pressure when standing up migraine, coldness in the hands and feet
- shortness of breath, asthma, nosebleed, hiccups, slowed breathing rate, pneumonia (infection of the lungs), lung disorders, stuffy nose, runny nose, sneezing, and post-nasal drip
- stomach inflammation, canker sore (small shallow sore inside the mouth or at the base of the gums, enlarged abdomen, abnormal stools, bloody diarrhoea, inflammation of the lips, colon infection, constipation, difficulty swallowing, throat inflammation, stomach flu, disorder of the intestines, bleeding in the intestines, gum inflammation, irritation or inflammation of the small intestine, oral thrush (yeast infection of the mouth), tooth abscess (boil, sore), rectal disorder (hemorrhoids, abscesses, anal itching, warts), feeling that you need to pass stools, thirst

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- liver and spleen swell beyond their normal size
- gallstones, a condition in which the flow of bile from the liver stops or slows, gallbladder inflammation
- hair loss (alopecia), angioedema (severe swelling of the skin and other tissues most often the lips or the eyes), DRESS syndrome (autoimmune disease with symptoms like fever, rash, facial swelling, enlarged lymph nodes and kidney or liver injury), flushing
- acne, skin rash caused by contact with a certain substance, dry skin, eczema (itchy inflammation of the skin), swelling of the face, folliculitis (a common skin condition in which hair follicles become inflamed), a viral skin infection which causes round, firm, painless bumps, that yield a milky fluid when squeezed), sensitivity to sunlight, psoriasis (skin disease in which skin cells build up and form scales and itchy dry patches), oily skin, hives, rash which may occur after exposure to brighter sunlight
- arthralgia (joint pain), muscle atrophy (muscle shrinkage), face pain, back pain, joint disorder, muscle cramps, muscle weakness, muscle inflammation, neck pain, stiff neck, twitching, disease affecting the muscles
- kidney disorders such as kidney stones, interstitial nephritis (kidney inflammation), kidney pain, proteinuria (excess protein in the urine)
- breast enlargement in men, inability in a man to achieve an erection or orgasm, penis disorder
- chest pain, fever, general feeling of discomfort, illness, or unease, imbalance, shuffling, chills, flu-like symptoms, pressure-like pain in the chest

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- abnormal blood test results indicating anaemia (low levels of red blood cells in your blood), bruising, low number of special white blood cells (leukocytes, neutrophils), increase in white blood cells, blood disorder where blood takes too long to form a clot
- ear pain, hearing disorder, increased ear wax, ringing or buzzing in the ears, spinning sensation and loss of balance (vertigo)
- irregular eye test results, blood tests indicating changes in hormone levels
- increased occurrence of accidental injuries, hypothermia (dangerously low body temperature).

The following side effects have been reported but the frequency for them to occur is not known:

- numbness and pain from nerve damage, usually in the hands and feet, speech disorder (inability or impaired ability produce speech), lack of muscle control or coordination, convulsions (fits), inco-ordination, stabbing, burning, and often severe pain (irritated or damaged nerve), damage of nerves, paralysis, distortion of smell, weakness, numbness and pain from nerve damage, usually in the hands and feet tremors, partial vision loss
- heavy periods
- low number of platelets in the blood.

If you notice any side effects not mentioned in this leaflet, please inform your medical practitioner or pharmacist.

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Reporting of side effects

If you get side effects, talk to your medical practitioner or, pharmacist or nurse. You can also report side effects to SAHPRA via the online service for adverse drug reaction reporting by following the links: <https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/>

<https://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of ZANRIT. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store ZANRIT

Store all medicines out of reach of children.

Do not store above 30 °C. Store in the original container.

Do not use after the expiry date stated on the carton. Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What ZANRIT contains

Each film coated tablet contains:

atazanavir sulphate equivalent to 300 mg atazanavir and ritonavir 100 mg.

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The other ingredients are

Tablet cores

Colloidal silicon dioxide, copovidone, crospovidone, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium stearyl fumarate, sorbitan monolaurate.

Film coating

Opadry 03F190003 Clear (consisting of:

HPMC 2910/Hypromellose and macrogol/PEG), methylene chloride.

What ZANRIT looks like and contents of the pack

ZANRIT is a bilayer, capsule shaped, biconvex, film coated tablet having one layer with white to pale yellow colour and other white to off-white colour, plain on both the sides. A thin line on the tablet side may be visible.

ZANRIT tablets are available round opaque white HDPE bottle containing 30 tablets and one 2g silica gel sachet and a white, round, fine ribbed, non-CR cap, sealed by induction sealing process.

Holder of Certificate of Registration

Pharma Dynamics (Pty) Ltd

1st Floor Grapevine House, Steenberg Office Park

Silverwood Close

Atazanavir Sulphate and Ritonavir Tablets
Pharma Dynamics (Pty) Ltd

*Each tablet contains 300 mg atazanavir and 100 mg
ritonavir*

Approved: 12 Sept 2023

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Westlake, Cape Town

7945, South Africa

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