PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

AVIRTAZ 150 mg (capsules)

AVIRTAZ 300 mg (capsules)

Atazanavir

AVIRTAZ 150 mg capsules contains atazanavir (as sulphate) equivalent to atazanavir 150 mg.

Contains sugar (lactose monohydrate) 84,15 mg.

AVIRTAZ 300 mg capsules contains atazanavir (as sulphate) equivalent to atazanavir 300 mg.

Contains sugar (lactose monohydrate) 168,30 mg.

Read all of this leaflet carefully before you start taking AVIRTAZ

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor, pharmacist, nurse, or other healthcare provider.
- **AVIRTAZ** 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 AVIRTAZ IS AND WHAT IT IS USED FOR

AVIRTAZ is a medicine used in combination with other anti-HIV (antiretroviral) medicines to treat adults and patients more than 12 years of age and bodyweight of 40 kg or more, who are infected with the human immunodeficiency virus (HIV). HIV is the virus that causes acquired immune deficiency syndrome (AIDS). **AVIRTAZ** is a type of anti-HIV medicine called a protease inhibitor. **AVIRTAZ** helps to block HIV protease, an enzyme that is needed for the HIV virus to multiply.

AVIRTAZ is to be co-administered with a low dose of ritonavir.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE AVIRTAZ

Do not take **AVIRTAZ:**

- If you are hypersensitive (allergic) to atazanavir or any of the other ingredients of **AVIRTAZ** (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 **AVIRTAZ**.
- If you are taking certain medicines (see “**Taking other Medicines with AVIRTAZ**”). Serious life-threatening side effects or death may happen. Before you take **AVIRTAZ**, tell your healthcare provider about all medicines you are taking or planning to take.

These include other prescription and on-prescription medicines, vitamins, and herbal supplements.

- **If you are breastfeeding your baby.**

Warnings and precautions

Talk to your doctor, nurse, or pharmacist before taking **AVIRTAZ.**

Take special care with **AVIRTAZ**:

Some people will need special care before or while taking **AVIRTAZ**. Make sure your doctor knows:

- If you have liver problems or are infected with the hepatitis B or C virus.
- If you have diabetes.
- If you have haemophilia. Some patients with haemophilia have increased bleeding problems with protease inhibitors like **AVIRTAZ**.
- If you require haemodialysis.
- If you are taking oral contraceptives (“the PILL”) to prevent pregnancy.
- If you are taking omeprazole or other proton pump inhibitors; or famotidine or other H_2-receptor antagonists (used to treat diseases related to acid in the stomach).
- 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 increase 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.

An increase in weight and in levels of blood lipids and glucose may occur during antiretroviral therapy. Such changes may in part be linked to the disease control and life style, and in the case of blood lipids sometimes to the HIV medicines themselves. Your doctor will test for these changes.

Kidney stones (also called nephrolithiasis) have been reported in patients taking **AVIRTAZ**. 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 infections, 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.

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). Signs of osteonecrosis are joint stiffness, aches and pains (especially for the hip, knee and shoulder) and difficulty in movement. If you notice any of these symptoms, please inform your doctor.
Current antiretroviral therapy, including **AVIRTAZ**, does not prevent the risk of transmission of HIV infection (AIDS) to others through sexual contact or blood contamination. Appropriate precautions should continue to be employed.

Hyperbilirubinaemia (an increase in the level of bilirubin in the blood) has occurred in patients receiving **AVIRTAZ**. These 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 (SJS), erythema multiforme, and toxic skin eruptions including drug rash with eosinophilia and systemic symptoms (DRESS) syndrome) has been reported in patients taking **AVIRTAZ**. If you develop a rash, inform your doctor immediately.

Heart problems - If you notice a change in the way your heart beats (heart rhythm changes), please inform your doctor.

Cholelithiasis, also known as gallstones, has been reported in patients taking **AVIRTAZ**. If you develop intense pain (at the upper right side of your stomach), nausea and vomiting, inform your doctor immediately.

Chronic kidney disease in HIV-infected patients treated with atazanavir, with or without ritonavir, has been reported. Your doctor will monitor your kidney function throughout the treatment duration.

Other medicines and AVIRTAZ

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

- **Do not take AVIRTAZ if you take the following medicines. Serious life-threatening side effects or death may happen.** Ergot containing medicines (such as dihydroergotamine, ergonovine, ergotamine, methylergonovine), triazolam, midazolam, quetiapine, lurasidone, astemizole, terfenadine, pimozide, cisapride, quinidine, bepridil.
- **Do not take the following medicines with AVIRTAZ because of possible serious side effects**. Irinotecan, indinavir, grazoprevir-containing medicines (including elbasvir/grazoprevir fixed-dose combination), glecaprevir/pibrentasvir fixed-dose combination, voxilaprevir- containing medicines, nevirapine, inhaled salmeterol, lovastatin, simvastatin, alfuzosin, sildenafil.
- **Do not take the following medicines with AVIRTAZ because they may lower the amount of AVIRTAZ in your blood**. Rifampicin, St. John's Wort (*Hypericum perforatum*), nevirapine.
- **Do not take the following medicine if you are taking AVIRTAZ and ritonavir:** Voriconazole, quinidine, lomitapide, oral anticoagulants/blood thinners (apixaban, rivaroxaban, dabigatran).
- **Do not take the following medicine if you are taking AVIRTAZ:** Antiplatelets (ticagrelor, clopidogrel).

The following medicines may require your healthcare provider to monitor your therapy more closely (for some medicines a change in the dose or dose schedule may be needed).

- **AVIRTAZ** may increase the chance of serious side effects when taken with tadalafil, vardenafil, atorvastatin, amiodarone, lidocaine, quinidine, warfarin, tricyclic antidepressants (amitriptyline, trimipramine, imipramine), immunosuppressants

(ciclosporin, sirolimus, tacrolimus), anticancer medicines (apalutamide, encorafenib, ivosidenib), trazodone, fluticasone propionate.

- **The following medicines may require a change in dose or dose schedule of either AVIRTAZ or the other medicines:** Saquinavir, ritonavir, efavirenz, antacids or buffered medicines, didanosine, tenofovir, rifabutin, atenolol, calcium channel blockers (diltiazem, verapamil, felodipine, nifedipine, nicardipine), blood thinner (edoxaban), antiepileptics (carbamazepine, phenytoin, phenobarbital, lamotrigine), fostamatinib, clarithromycin, antacids (nizatidine, famotidine, cimetidine, ranitidine), buprenorphine.

Talk to your healthcare provider about choosing an effective method of contraception.

AVIRTAZ may affect the safety and effectiveness of hormonal contraceptives such as birth control pills or the contraceptive patch. Hormonal contraceptives do not prevent the spread of HIV to others.

Taking AVIRTAZ with food and drink

Always take **AVIRTAZ** with food (a meal or snack) as this helps the body absorb the medicine.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other healthcare provider for advice before taking this medicine.

Because of both the potential for HIV transmission and the potential for serious adverse reactions in breastfed infants you should not breastfeed your baby if you are treated with AVIRTAZ.

Driving and using machines

AVIRTAZ may influence your ability to drive and use machines. You should not drive, and use machined until you know how treatment with AVIRTAZ is affecting you.

There have been reports of adverse nervous system side effects that may influence your ability to drive or use machines such as dizziness, drowsiness or light headedness.

Important information about some of the ingredients of AVIRTAZ

AVIRTAZ contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

3. HOW TO TAKE AVIRTAZ

Do not share medicines prescribed for you with any other person.

Always take **AVIRTAZ** exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Take **AVIRTAZ** once every day as instructed by your healthcare provider.

Your healthcare provider will prescribe the amount of **AVIRTAZ** that is right for you.

- Your dose will depend on your liver function and on the other anti-HIV medicines that you are taking. **AVIRTAZ** is always used with other anti-HIV medicines. If you are taking **AVIRTAZ** with efavirenz or with tenofovir, you should also be taking ritonavir.
- **Always take AVIRTAZ with food** (a meal or snack) to help it work better.

  Swallow the capsules whole. Do not open the capsules. Try to take **AVIRTAZ** at the same time each day.
- **If you are taking antacids or didanosine chewable/ dispersible buffered tablets**, take **AVIRTAZ** 2 hours before or 1 hour after these medicines.
- **If you are taking medicines for indigestion, heartburn, or ulcers such as nizatidine, famotidine, cimetidine or ranitidine,** talk to your healthcare provider.

If you take more AVIRTAZ than you should

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

If you forget to take a dose of AVIRTAZ

If you miss a dose of **AVIRTAZ**, take it as soon as possible and then take your next scheduled dose at its regular time. If, however, it is within 6 hours of your next dose, do not take the missed dose. Wait and take the next dose at the regular time. Do not double the next dose. It is important that you do not miss any doses of **AVIRTAZ** or your other anti-HIV medicines.

If you stop taking AVIRTAZ

- Do not change your dose or stop taking **AVIRTAZ** without first talking with your healthcare provider. It is important to stay under a healthcare provider's care while taking **AVIRTAZ**.
- Do not share medicines prescribed for you with others.
- When your supply of **AVIRTAZ** starts to run low, get more from your healthcare provider or pharmacy. It is important not to run out of **AVIRTAZ**. The amount of HIV in your blood may increase if the medicine is stopped for even a short time.

4. POSSIBLE SIDE EFFECTS

AVIRTAZ can have side effects.

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

If any of the following happens, stop taking **AVIRTAZ** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- **Rash** (redness and itching) sometime occurs in patients taking **AVIRTAZ**, most often in the first few weeks after the medicine is started.
- **Severe rash:** Rash may develop in association with other symptoms which could be serious and potentially cause death (such as drug rash with eosinophilia and systemic symptoms (DRESS syndrome) and Stevens-Johnson syndrome).

  If you develop a rash with any of the following symptoms stop using AVIRTAZ and call your healthcare provider right away:

  - shortness of breath

  - general ill feeling or “flu-like” symptoms
  - fever
  - muscle or joint aches
  - conjunctivitis (red or inflamed eyes, like “pink eye”)
  - blisters
  - mouth sores
  - swelling of your face.
- **Jaundice - yellowing of the skin or eyes (ocular icterus).** These effects may be due to increases in bilirubin levels in the blood (bilirubin is made by the liver). Although these effects may not be damaging to your liver, skin or eyes, call your healthcare provider promptly if your skin or the white part of your eyes turn yellow.

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

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

- **A change in the way your heart beats (heart rhythm change)**. If you experience dizziness or light-headedness, these could be symptoms of a heart problem.
- **Pancreatitis** (inflammation of the pancreas) - common symptoms include severe abdominal pain, nausea, vomiting, and fever).

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

Tell your doctor if you notice any of the following:

- **Weight and levels of blood lipids and glucose** may increase during antiretroviral therapy. Your doctor will test for these changes.
- **Diabetes and high blood sugar (hyperglycaemia)** sometimes happen in patients taking protease inhibitor medicines like AVIRTAZ. Some patients had diabetes before taking protease inhibitors while others did not. Some patients may need changes in their diabetes medicine.
- **If you have liver disease** including hepatitis B or C, your liver disease may worsen when you take anti-HIV medicines like AVIRTAZ.

Other frequent side effects of **AVIRTAZ** may include:

- headache,
- nausea,
- abdominal pain (stomach pains), dyspepsia (indigestion),
- vomiting,
- diarrhoea,
- asthenia (lack of energy),
- fatigue/tiredness.

Other less frequent side effects of **AVIRTAZ** may include:

- fever,
- dizziness, somnolence (drowsiness or excessive sleepiness),
- amnesia (memory loss),
- trouble sleeping, abnormal dreams, disorientation/confusion,
- numbness, tingling or burning of hands or feet,

- dry mouth, dysgeusia (altered sense of taste), stomatitis aphthous (mouth ulcers and cold sores),
- flatulence or wind, gastritis (inflammation of the stomach), distended/bloated stomach,
- hepatosplenomegaly (enlargement of the liver and spleen),
- anorexia (loss of appetite), appetite increased,
- decreased weight or weight gain,
- kidney pain, haematuria (blood in the urine), pollakiuria (abnormally frequent urination), nephrolithiasis (kidney stones), proteinuria (excess protein in the urine), interstitial nephritis (kidney inflammation), chronic kidney disease,
- anxiety, depression, sleep disorder,
- myalgia (muscle pain), myopathy (muscle weakness), muscle atrophy (muscle wasting), arthralgia (joint pain), chest pain,
- oedema (swelling),
- angioedema (severe swelling of the skin and other tissues often due to allergic reactions),
- eczema (chronic inflammatory skin condition that causes dry, itchy, and inflamed skin),
- syncope (fainting), hypertension (high blood pressure), palpitations (heart beating rapidly),
- dyspnoea (shortness of breath),
- alopecia (unusual hair loss or thinning),
- pruritus (itching), urticaria/hives,
- malaise (generally feeling unwell),
- Gait disturbance (abnormal manner of walking),
- gynaecomastia (breast enlargement in men).

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **AVIRTAZ**.

5. HOW TO STORE AVIRTAZ

Store all medicines out of reach of children.

Store at or below 30 ºC.

Store in the original container.

Keep the bottle tightly closed.

Keep the bottle in the carton until required for use.

Do not use after the expiry date stated on the label / carton / bottle. The expiry date refers to the last day of that month.

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 AVIRTAZ contains

The active substance is atazanavir (as sulphate) equivalent to atazanavir 150 mg or 300 mg.

The other ingredients are: crospovidone, lactose monohydrate and magnesium stearate.

Capsule shell: FD&C blue #2, gelatin and titanium dioxide.

Capsule shell imprints (edible ink): black iron oxide and shellac.

What AVIRTAZ looks like and contents of the pack

AVIRTAZ 150 mg

White to pale yellow powder filled in capsules with light sky blue opaque colour cap and light sky blue opaque colour body imprinted with ‘M166’ on both cap and body in black ink.

AVIRTAZ 300 mg

White to pale yellow powder filled in capsules with blue opaque colour cap and light sky blue opaque colour body imprinted with ‘M167’ on both cap and body in black ink.

AVIRTAZ 150 mg is packed in a round, wide mouth, white HDPE bottle with white opaque screw cap with induction sealing liner. Packed in an outer carton in pack sizes of 28’, 30’s & 100’s.

AVIRTAZ 300 mg is packed in a round, wide mouth, white HDPE bottle with white opaque screw cap with induction sealing liner. Packed in an outer carton in pack sizes of 28’s, 30’s & 100’s.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Viatris Healthcare (Pty) Ltd

4 Brewery Street,

Isando,

Kempton Park,

Gauteng, 1601

Tel.: +2711 451 1300

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