PATIENT INFORMATION LEAFLET FOR

ATAZANAVIR/ RITONAVIR 300/100 MG

SCHEDULING STATUS

S4

TARITO 300/100 mg Film coated Tablets.

Each film-coated tablet contains atazanavir sulphate equivalent to atazanavir 300 mg and ritonavir 100 mg.

Contains sugar: lactose monohydrate 104,91 mg.

Read all of this leaflet carefully before you start taking TARITO

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor, pharmacist, nurse, or other health care provider.
- TARITO 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 TARITO is and what it is used for
2. What you need to know before you take TARITO
3. How to take TARITO
4. Possible side effects
5. How to store TARITO
6. Contents of the pack and other information

1. What TARITO is and what it is used for

TARITO is a combination antiretroviral medicine, and it is used in combination with other anti-retroviral medicines for the treatment of HIV infection for patients weighing 40 kg or more.

2. What you need to know before you take TARITO

Do not take TARITO:

- If you are hypersensitive (allergic) to atazanavir, ritonavir, or any of its other ingredients.
- If you have been diagnosed with moderate or severe liver disease.
- If you have been diagnosed with severe kidney damage and are being treated with haemodialysis
- If you have been diagnosed with a heart condition or experience an abnormal heartbeat.
- If you are on anti-tuberculosis (TB) medicines containing rifampicin.
- If you are pregnant or you are a mother breastfeeding a baby.
- If you are taking any of the following medicines as TARITO may impact on their concentrations and cause serious effects:
    - Alfuzosin hydrochloride
    - Pethidine, piroxicam, propoxyphene
    - Ranolazine
    - Ventoclax
    - Amiodarone, bepridil, flecainide, propafenone, quinidine, encainide, digoxin
    - Fusidic acid
    - Voriconazole
    - Colchicine
    - Astemizole, terfenadine
    - Rifampicin, rifabutin

- Blonanserin, lurasidone, clozapine, pimozide, quetiapine
- Bipridil
- Dihydroergotamine, ergonovine, ergotamine, methylergonovine
- Cisapride
- St John's Wort (*Hypericum perforatum*)
- Lovastatin, simvastatin
- Salmeterol
- Lomitapide
- Pimozide
- Sildenafil, Avanafil, vardenafil
- Indinavir
- Midazolam, triazolam, clorazepate, diazepam, estazolam, flurazepam
- Irinotecan.

Warnings and precautions

Special care should be taken with TARITO

Tell your doctor:

- If you are using medicines such as antacids which neutralise gastric acidity as the absorption of atazanavir may be reduced by these medicines.
- If you have allergic reactions such as tightness of the chest and swelling.
- If you develop a mild to moderate rash; this usually happens within the first three weeks of starting treatment with TARITO. Should a severe rash develop, do not stop taking TARITO before seeking advice from your doctor.
- If you develop changes in body fat as such changes have been seen in some patients taking TARITO. These changes may include increased amount of fat in the upper back

and neck (“buffalo hump”), breast, and around the main part of your body (trunk). Loss of fat from the legs, arms and face may also happen.

- If you have been diagnosed with liver disease, including hepatitis B or C.
- If you have been diagnosed with haemophilia (a condition in which blood doesn't clot normally, resulting in unexplained bleeding and bruising). type A and/or B, as you may experience increased bleeding.
- If you have a kidney disease and are undergoing haemodialysis (a procedure in which a machine is used to filter and clean your blood).
- If you experience signs and symptoms of kidney stones such as pain in the back, belly or side; pain or burning during urination; blood in the urine and cloudy or smelly urine.
- If you experience symptoms like nausea, vomiting, and/or pain in the stomach as your doctor may have to do laboratory tests to rule out pancreatitis (inflammation of the pancreas).
- If you have diabetes mellitus or high blood sugar levels, as your doctor may need to adjust your dose of insulin or oral treatment for diabetes.
- If you experience constant diarrhoea or vomiting, as it may affect the absorption of the medicine and influence kidney function.
- If you have been diagnosed with heart disease or are taking medicines such as verapamil
- If you experience signs and symptoms of gallstones, such as pain in the pack or stomach.
- If you have been diagnosed with chronic kidney disease. Your doctor will constantly monitor your kidney function throughout the duration of your treatment with TARITO.
- If you experience joint aches and pain, joint stiffness, or difficulty in movement.
- If you show any symptoms of infection while you are taking TARITO. People with advanced HIV infection (AIDS) have weak immune systems and are more likely to develop serious infections (opportunistic infections). When these people start with the treatment,

they may find that old hidden infections (such as tuberculosis) flare up, causing signs and symptoms of inflammation (such as localised swelling, area appears red and hot, painful). These symptoms are probably caused by the body's immune system becoming stronger, so that the body starts to fight these infections.

- If you develop yellowing of the skin and/or yellowing of the eyes.
- If you increased cholesterol, sugar, or lactate in the blood, or are resistant to insulin. Your healthcare professional will perform regular blood tests to confirm normal blood levels of these.
- If you have experienced changes in the levels of fat in your blood fat, liver, and other body enzymes, as well as uric acid. Your doctor will perform laboratory testing before initiating TARITO therapy and at periodic intervals or if any clinical signs or symptoms occur during treatment.
- If you are taking any of the following medicines:
    - Corticosteroids such as prednisone.
    - Salmeterol.
    - Hormonal contraceptives.
    - Medicines such as sildenafil, tadalafil or vardenafil, especially if you have been diagnosed with high blood pressure that affects the arteries in the lungs and heart.
    - Medicines to treat cholesterol such as atorvastatin.
    - Herbal medicines such as St John's wort (hypericum perforatum).
    - Digoxin.
    - Trazodone.
    - Rivaroxaban.
    - Bedaquiline.
    - Other ARV medicines such as nevirapine or efavirenz.

TARITO should only be taken by children with a body weight of 40 kg or more.

Tell your doctor if your child was diagnosed with a heart condition and is taking medicine to treat the heart condition.

The safety and efficacy of TARITO has not been established in the elderly.

TARITO does not reduce the risk of passing HIV to others through sexual contact or blood contamination. Therefore, it is important to continue to take appropriate precautions to prevent passing HIV to others.

Even if you are receiving treatment for HIV, you are still at risk of contracting other infections and other complications of the HIV infection. Therefore, you should remain under close observation by your doctor.

Important information about some of the ingredients of TARITO

TARITO contains lactose, if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Other medicines and TARITO

Always tell your healthcare professional if you are taking any other medicines.

(This includes complementary or traditional medicines).

Caution is recommended when taking TARITO with medicines such as atenolol, diltiazem, and verapamil.

Serious side effects may occur when TARITO is taken with medicines containing disopyramide, mexiletine, nefazodone or fluoxetine.

Caution must be exercised when using TARITO with antifungal medicines containing itraconazole and ketoconazole.

TARITO may increase the effect of the following medicines when taken together:

- Tenofovir
- Nevirapine
- Saquinavir
- Other ARV medicines similar to TARITO
- Amiodarone
- Lidocaine
- Warfarin
- Vincristine
- Vinblastine
- Anti-depressant medicines belonging to a class called tricyclic anti-depressants such as amitriptyline
- Trazodone
- Buspirone
- Rifabutin
- Diltiazem
- Sildenafil, tadalafil and vardenafil
- Atorvastatin
- Ciclosporin, tacrolimus and sirolimus
- Inhaled fluticasone
- Clarithromycin
- Buprenorphine and norbuprenorphine
- Oral contraceptives

TARITO may decrease the effect of the following medicines when taken together:

- Didanosine
- Bupropion
- Methadone

The following medicines may reduce the effect of TARITO when taken together:

- Efavirenz
- Nevirapine
- Antacids
- Omeprazole
- Medicines such as cimetidine
- Tobacco

Taking TARITO with the following medicines may result in serious side effects. They therefore should **NOT** be taken together.

- Alfuzosin hydrochloride
- Pethidine, piroxicam, propoxyphene
- Ranolazine
- Ventoclax
- Amiodarone, bepridil, flecainide, propafenone, quinidine, encainide, digoxin
- Fusidic acid
- Voriconazole
- Colchicine
- Astemizole, terfenadine
- Rifampicin, rifabutin

- Blonanserin
- Lurasidone, clozapine, pimozide, quetiapine
- Bepridil
- Dihydroergotamine, ergonovine, ergotamine and methylergonovine
- Cisapride
- St John's Wort (*Hypericum perforatum*)
- Lovastatin, simvastatin
- Salmeterol
- Lomitapide
- Pimozide
- Sildenafil, avanafil, vardenafil
- Indinavir
- Midazolam, triazolam
- Irinotecan.

TARITO with food and drink and alcohol

TARITO should be taken with food.

Pregnancy and 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 professional for advice before taking TARITO.

Do not take TARITO if you are pregnant or breastfeeding your baby.

Effects on pregnant women

Taking TARITO during pregnancy may result in a build-up of lactate in your blood which may cause serious and possibly fatal effects.

Taking TARITO during pregnancy may also result in an increase in bilirubin in your blood.

Effects on infants

All infants exposed to TARITO during pregnancy should be monitored by a doctor for the first few days as they may have increased levels of bilirubin in their blood which may lead to brain damage.

Women taking contraceptive medicines

TARITO may reduce the effect of your hormonal contraceptive medicine. You should therefore consider other non-hormonal methods of contraception or make use of a condom.

Driving and using machines

TARITO may make you feel dizzy or sleepy, which may interfere with your ability to drive or operate machines.

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

3. How to take TARITO

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

Always take TARITO exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose is one TARITO tablet, taken once daily with food, at the same time each day.

TARITO should not be administered to paediatric patients weighing less than 40 kg.

Your doctor will tell you how long your treatment with TARITO will last. Do not stop treatment because this may cause resistance to the medicine. If you have the impression that the effect of TARITO is too strong or too weak, tell your doctor or pharmacist.

The tablets must be swallowed whole with a glass of water.

Do not crush or chew them.

Follow these instructions closely unless your doctor has advised you otherwise.

If you take more TARITO 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 TARITO

Do not take a double dose to make up for forgotten individual doses.

If you stop taking TARITO

Do not stop taking TARITO unless you have been instructed to do so by your doctor.

4. Possible side effects

TARITO can have side effects.

Not all side effects reported for TARITO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TARITO, please consult your doctor, pharmacist, or other healthcare professional for advice.

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

- Swelling of the hands, feet, face, lips, or throat which may cause difficulty swallowing or breathing.
- Severe itchy, lumpy rash (hives) or nettle rash (urticaria).
- If you experience a very fast or unusual heartbeat, chest pain or any heart related symptoms.
- Bleeding.
- Yellowing of the eyes or skin (Jaundice)
- Asthma (difficulty breathing, chest pain, cough, and wheezing)
- Fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to TARITO. 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:

- Seizures or convulsions
- Palpitations (irregular or fast heartbeat)
- Anxiety
- Difficulty breathing
- Diarrhoea or abnormal stools
- Vision problems
- Hearing impairment
- Enlarged liver
- Pneumonia (an infection of the lungs)

- A general feeling of weakness.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Inflamed throat (Pharyngitis)
- Decreased white blood cells, neutrophils and haemoglobin (determined through blood tests)
- Increased eosinophils- a type of white blood cell (determined through blood tests)
- Vitamin deficiencies
- Weakness and wasting of the body
- Fluid retention
- Redistribution of body fat
- Confusion
- Nervousness
- Decreased sex drive (libido)
- Abnormal thinking
- Changes in behaviour
- Sleepiness
- Headache
- Tingling sensation
- Taste loss
- Eye pain
- Sensitivity to light

- Yellow coloured eyes (scleral icterus)
- Migraine
- A drop in blood pressure
- Coldness of the extremities (hands and feet)
- Increase in cough
- Abdominal pain
- Dry mouth
- Bloating
- Passing of wind
- Mouth ulcer
- Increased blood bilirubin (determined through blood tests)
- Sweating
- Rash
- Acne
- Dry skin
- Eczema (Dry itchy skin)
- Muscle aches and weakness
- Back pain
- Stiffness and pain of the neck
- Twitching
- Discomfort when urinating
- Frequent urination
- Kidney pain
- Urination at night
- Inflammation of the kidney and urethra

- Difficulty urinating
- Heavy menstruation
- Flushing and feeling hot
- Fever
- Pain
- Abnormal liver function tests (determined through blood tests)
- Decreased thyroid hormone (determined through blood tests)
- Dilation of blood vessels
- Increased blood pressure
- Heartburn.
- Weight loss

Less frequent side effects:

- Anaemia (symptoms include feeling tired, pale skin, shortness of breath, light-headedness, dizziness or a fast heartbeat)
- Swelling of the lymph nodes
- Low number of platelets in blood (determined through blood tests)
- Diabetes mellitus
- Anorexia (eating disorder)
- Weight gain
- Sleep disorder
- Abnormal dreams
- Memory loss (amnesia)
- Communication disorder
- Impaired balance or coordination

- Ear pain
- Hearing impairment
- Increased ear wax
- Ringing sensation in ear
- Motion sickness
- Hiccup
- Nose bleeds
- Stuffy nose
- Impotence (a man's inability to get or keep an erection)
- Penis disorder
- Flu syndrome
- Abnormal walking (gait)
- Altered hormone levels.

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. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: http://www.sahpra.org.za/publications/index/8 or to Cipla Medpro (Pty) Ltd by email: drugsafetysa@cipla.com. By reporting side effects, you can help provide more information on the safety of TARITO.

5. How to store TARITO

Store all medicines out of reach of children.

Store at or below 30 °C.

Do not refrigerate.

Store in the original packaging.

Keep the container tightly closed.

Do not store in a bathroom.

Do not use TARITO after the expiry date stated on the carton.

Return all unused medicines to your pharmacist.

Do not dispose unused medicines in drains or sewage systems. (e.g. Toilets)

6. Contents of the pack and other information

What TARITO contains:

The active substances are

- Atazanavir 300 mg and Ritonavir 100 mg per tablet.

The other ingredients are:

Anhydrous dibasic calcium phosphate, Colloidal silicon dioxide, Copovidone, Crospovidone, Hypromellose, Iron oxide yellow, Isopropyl alcohol, Lactose monohydrate, Magnesium stearate, Methylene chloride, Sodium stearyl fumarate, Sorbitan monolaurate, Talc, Opadry II 85G520033 yellow film-coating, Purified water.

Contents of the film-coating (opadry):

Iron oxide yellow, Lecithin, Macrogol, Polyvinyl alcohol (partly hydrolysed), Talc, Titanium dioxide

What TARITO looks like and contents of the pack

TARITO are yellow coloured capsule shaped, biconvex, film coated tablets debossed with “SVN” on one side and plain on other side.

TARITO film-coated tablets are marketed in packs of 30’s and packed into a white HDPE bottle that is fitted with a non-child resistant cap and contains 1 g silica gel bags and Rayon Sani coil.

TARITO film-coated tablets are marketed in Alu/Alu blisters containing 10 tablets per blister and ten (10) blisters are placed into an outer carton.

Holder of certificate of registration

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Access to the corresponding professional information

The professional information is contained in the packaging of TARITO