APPROVED PATIENT INFORMATION LEAFLET

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ZOROVIR 150 (capsule)

ZOROVIR 200 (capsule)

ZOROVIR 300 (capsule)

Atazanavir sulfate

Read all of this leaflet carefully before you start taking ZOROVIR.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **ZOROVIR** 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.

1. WHAT ZOROVIR CONTAINS

The active ingredient is atazanavir sulfate.

ZOROVIR 150:

Each hard gelatin capsule contains atazanavir sulfate equivalent to atazanavir 150 mg. Contains sugar (lactose monohydrate).

ZOROVIR 200:

Each hard gelatin capsule contains atazanavir sulfate equivalent to atazanavir 200 mg. Contains sugar (lactose monohydrate).

ZOROVIR 300:

Each hard gelatin capsule contains atazanavir sulfate equivalent to atazanavir 300 mg. Contains sugar (lactose monohydrate).

The other ingredients of **ZOROVIR CAPSULES** are crospovidone, lactose monohydrate and magnesium stearate.

ZOROVIR 150: The capsule shell contains FD&C blue 2 (C.I. No: 73015), gelatin and

titanium dioxide (C.I. No: 77891).

ZOROVIR 150: The black ink contains potassium hydroxide, propylene glycol, shellac, strong ammonia solution and titanium dioxide (C.I. No: 77891).

ZOROVIR 200: The capsule shell contains FD&C blue 2 (C.I. No: 73015), gelatin and titanium dioxide (C.I. No: 77891).

ZOROVIR 200: The black ink contains potassium hydroxide, propylene glycol, shellac, strong ammonia solution and titanium dioxide (C.I. No: 77891).

ZOROVIR 300: The capsule shell contains FD&C blue 2 (C.I. No: 73015), gelatin, iron oxide black (C.I. No: 77499), iron oxide red (C.I. No: 77491), iron oxide yellow (C.I. No: 77492) and titanium dioxide (C.I. No: 77891).

ZOROVIR 300: The black ink contains potassium hydroxide, propylene glycol, shellac, strong ammonia solution and titanium dioxide (C.I. No: 77891).

2. WHAT ZOROVIR IS USED FOR

ZOROVIR is indicated in combination with other antiretroviral medicines for the treatment of HIV-1 infection.

3. BEFORE YOU TAKE ZOROVIR

Do not take ZOROVIR:

- If you are allergic to atazanavir or any of the ingredients of **ZOROVIR**.
- If you have severe liver problems.
- If you are pregnant or breastfeeding.
- If you are taking any of the following medicines:

  - alfuzosin, a medicine used to treat a condition known as Benign Prostatic Hyperplasia,

  - triazolam and orally administered midazolam which is used to treat anxiety and sleeplessness

  - ergot derivatives which are usually medicines used to treat headaches and migraines,

- rifampicin which is used to treat tuberculosis (TB),
- irinotecan which is used in the treatment of cancer,
- cholesterol-lowering medicines such as lovastatin and simvastatin,
- indinavir which is also used to treat HIV,
- cisapride which is used in the treatment of Gastro-oesophageal reflux disease,
- the antipsychotic medicines pimozide,
- St. John's wort which is a herbal medicine used to treat anxiety and depression and
- sildenafil which is used to treat erectile dysfunction.

Take special care with ZOROVIR:

- If you have kidney problems, then **ZOROVIR** with ritonavir is not recommended if you are undergoing haemodialysis.
- If you are suffering from a slow heartbeat, congenital long QT, electrolyte imbalances, caution is advised.
- If you are suffering from haemophilia, then **ZOROVIR** may increase bleeding.
- If you are taking **ZOROVIR**/ritonavir with other contraceptives.
- If you experience a redistribution of fat on your body e.g. a hump at the back of your neck, loss of fat from your cheeks, increase in size of your breasts.
- If you develop a severe rash which forms blisters, sloughing of your outer skin, and have mucosal involvement e.g. mouth, eyes, nose, or fever.
- You may develop other serious infections such as tuberculosis, cytomegalovirus retinitis or cryptococcal meningitis while taking **ZOROVIR**. With the appropriate treatment, these conditions resolve within a few weeks.
- If you experience joint pain, stiffness, difficulty moving you may be suffering from osteonecrosis which is a condition where the bone tissue dies.
- You can still transmit HIV through sexual contact or blood contamination while you are on **ZOROVIR** treatment.
- There is a potential of developing diabetes mellitus or elevated glucose levels or

even worsening of your existing diabetes when taking **ZOROVIR**.

- If you are suffering from chronic Hepatitis B or C infections you may be more prone to liver problems if you take **ZOROVIR**.
- You may experience yellowing of your skin, eyes and nails due to an elevation of bilirubin in your blood.
- If you taking medicines that reduce the pH in your stomach such as medicines that are used to treat stomach ulcers.
- You may develop kidney stones and may have to discontinue **ZOROVIR** treatment for a while.

Taking ZOROVIR with food and drink:

- It is recommended to take **ZOROVIR** with food.

Pregnancy and Breast-feeding:

Do not take **ZOROVIR** if:

- You are pregnant or planning to become pregnant.
- You are breast-feeding.

If you are pregnant or breast-feeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking **ZOROVIR**.

Driving and using machinery:

ZOROVIR may cause problems with your vision. If affected do not drive or operate machinery.

Important information about some of the ingredients of ZOROVIR

ZOROVIR contains lactose, which is a type of sugar. So Before taking **ZOROVIR**, please consult your doctor for advice if you have an intolerance to some sugars.

Taking other medicines with ZOROVIR:

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

(This includes complementary or traditional medicines.)

- Do not take **ZOROVIR** with the cholesterol-lowering medicine atorvastatin.
- Do not take **ZOROVIR** with the antiretrovirals nevirapine or efavirenz.
- Do not take **ZOROVIR** with antiretroviral medicine ritonavir and medicinal products that induce CYP3A4.
- Do not take the antifungal voriconazole and **ZOROVIR** with ritonavir.
- Do not take salmeterol, the medicine used to treat the symptoms of asthma and **ZOROVIR** together.
- Do not take medicines called proton pump inhibitors (omeprazole) which are used to treat stomach ulcers with **ZOROVIR**.
- Do not take **ZOROVIR** with hormonal or oral contraceptives.

4. HOW TO TAKE ZOROVIR

- **ZOROVIR** should be swallowed whole with a half a glass of water.
- **ZOROVIR** must be taken with food.

Always take **ZOROVIR** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **ZOROVIR** is too strong or too weak, talk to your doctor or pharmacist.

If you take more ZOROVIR 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 ZOROVIR:

If you forgot to take a dose, take it as soon as you remember unless it is nearly time for your next dose. Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE-EFFECTS

If any of the following happen, stop taking **ZOROVIR** and tell your doctor immediately or

go to the casualty department at your nearest hospital:

Difficulty in breathing, with or without swelling of the face, lips, tongue and/or throat.

Swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing.

Severe itching of the skin (with raised lumps).

Also, stop taking **ZOROVIR** and talk to your doctor immediately if you have any unusual aches or pains in your muscles which go on for longer than you might expect.

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

All of these very serious side effects occur less frequently.

The following side-effects occur frequently:

- Headache
- Ocular icterus (yellowing of the whites of the eyes caused by an accumulation of bile pigment (bilirubin) in the blood; can be a symptom of gallstones or liver infection or anaemia)
- Vomiting
- Diarrhoea
- Abdominal pain
- Nausea
- Dyspepsia (impairment of the power or function of digestion)
- Jaundice
- Rash
- Lipodystrophy syndrome (disturbance in fat metabolism)
- Fatigue (temporary loss of strength and energy resulting from hard
- physical or mental work)

The following side-effects occur less frequently:

- Hypersensitivity
- Diabetes
- Hyperglycaemia (high blood sugar)

- Decreased weight
- Weight gain
- Anorexia (loss of appetite)
- Increased appetite
- Depression
- Disorientation
- Anxiety
- Insomnia (sleeplessness)
- Sleep disorder
- Abnormal dreams
- Weakness, numbness and pain, usually in your hands and feet
- Syncope (fainting)
- Amnesia (loss of memory)
- Dizziness
- Somnolence (sleepiness)
- Dysgeusia (bad taste in the mouth)
- High blood pressure
- Dyspnoea (difficulty breathing)
- Pancreatitis (inflammation in the pancreas)
- Gastritis (inflammation of the stomach)
- Abdominal distension
- Stomatitis aphthous (inflammation of the oral mucosa)
- Flatulence (a state of excessive gas in the alimentary canal)
- Dry mouth
- Hepatitis (inflammation of the liver caused by a virus or a toxin)
- Cholilithiasis (the presence of gallstones in the gallbladder)
- Cholestasis (a condition in which little or no bile is secreted or the flow of bile into the digestive tract is obstructed)
- Hepatosplenomegaly (enlargement of the liver and the spleen)

- Cholecystitis (inflammation of the gall bladder)
- Erythema multiforme (sudden eruption of erythmatous papules, some of which evolve into target lesions consisting of a central papule surrounded by a discoloured ring)
- Toxic skin eruptions
- Rash, fever and/ or blood count abnormalities
- Urticaria (an itchy skin eruption characterized by weals with pale interiors and well-defined red margins)
- Alopecia (hair loss)
- Pruritus (itching skin)
- Flu-like symptoms, followed by a painful red or purplish rash that spreads and blisters, shedding of your skin and tongue/ facial swelling
- Rash that appears to contain fluid
- Eczema (inflammatory condition of the skin)
- Vasodilation (dilation of blood vessels)
- Muscle atrophy (wasting of muscle tissue)
- Arthralgia (pain in a joint)
- Myalgia (pain in the muscle)
- Myopathy (any disease of a muscle)
- Nephrolithiasis (formation of renal calculi)
- Haematuria (presence of blood in the urine)
- Proteinuria (presence of excessive proteins in the urine)
- Pollakiuria (urinary frequency)
- Kidney pain
- Gynaecomastia (excessive growth of the male mammary glands)
- Chest pain
- Malaise (a vague feeling of bodily discomfort)
- Pyrexia (fever)
- Asthenia (abnormal loss of strength)

- Gait disturbance (abnormal manner of walking)

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

6. STORING AND DISPOSING OF ZOROVIR

Store at or below 30 °C. Protect from moisture.

Keep the blisters in the carton until required for use.

Keep HDPE containers tightly closed.

Store all medicines out of the reach of children.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF ZOROVIR

ZOROVIR 150:

1) Blister pack:

Capsules are packed in 25 micrometer polyamide/ 45 micron aluminium foil/ 60 micron PVC film as the forming material and 25 micron aluminium foil with 7 g/m^2 heat seal lacquer as the lidding material.

Pack size: 60's - Each carton contains 6 blisters of 10 capsules each.

2) HDPE Container Pack:

Capsules are packed in white opaque round 75 ml HDPE container with 38 mm neck finish closed with 38 mm white opaque polypropylene child resistant closure with wad having induction sealing liner.

Pack size: 60's - One HDPE container contains 60 capsules.

ZOROVIR 200:

1) Blister pack:

Capsules are packed in 25 micrometer polyamide/ 45 micron aluminium foil/ 60 micron PVC film as the forming material and 25 micron aluminium foil with 7 g/m^2 heat seal

lacquer as the lidding material.

Pack size: 60's - Each carton contains 6 blisters of 10 capsules each.

2) HDPE Container Pack:

Capsules are packed in white opaque round 120 ml HDPE container with 38 mm neck finish closed with 38 mm white opaque polypropylene child resistant closure with wad having induction sealing liner.

Pack size: 60's - One HDPE container contains 60 capsules.

ZOROVIR 300:

1) Blister pack:

Capsules are packed in 25 micrometer polyamide/ 45 micron aluminium foil/ 60 micron PVC film as the forming material and 25 micron aluminium foil with 7 g/m^2 heat seal lacquer as the lidding material.

Pack size: 30's - Each carton contains 3 blisters of 10 capsules each.

2) HDPE Container Pack:

Capsules are packed in white opaque round 75 ml HDPE container with 38 mm neck finish closed with 38 mm white opaque polypropylene child resistant closure with wad having induction sealing liner.

Pack size: 30's - One HDPE container contains 30 capsules.

8. IDENTIFICATION OF ZOROVIR

ZOROVIR 150:

Blue/Powder blue size '1' hard gelatin capsule filled with off-white to pale yellow granular powder and imprinted with '150 mg' on blue cap and 'T24' on powder blue body with white edible ink.

ZOROVIR 200:

Blue/Blue size '0' hard gelatin capsule filled with off-white to pale yellow granular powder and imprinted with '200 mg' on blue cap and 'T25' on blue body with white edible ink.

ZOROVIR 300:

Red/Blue size '00' hard gelatin capsule filled with off-white to pale yellow granular powder and imprinted with '300 mg' on red cap and 'T26' on blue body with white edible

ink.

9. REGISTRATION NUMBER

To be allocated.

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Aurobindo Pharma (Pty) Ltd

Woodhill Office Park, Building 1,

53 Phillip Engelbrecht Avenue

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11. DATE OF PUBLICATION

To be determined