

PACKAGE INSERT

SURAVIR®

Atazanavir

30 capsules

AVAILABLE ONLY BY PRESCRIPTION

Important: Ask your doctor about medications that should not be taken together with SURAVIR®. For more information, read the sections "Who should not take SURAVIR®?" And "What should I tell my doctor before taking SURAVIR®?"

What is SURAVIR®?

SURAVIR® is a prescribed medication used with other antiretroviral drugs to treat HIV-1 (Human Immunodeficiency Virus Type 1) infection in adults and children 6 years of age and older. HIV-1 is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

SURAVIR® capsules should not be used in children under 6 years of age. When used with other antiretroviral drugs to treat HIV-1 infection, SURAVIR® can help:

- To reduce the amount of HIV-1 in your blood. This is called "viral load".
- To increase the amount of (T) CD4 + cells in your blood, which help fight other infections.

Reducing the amount of HIV-1 and increasing the amount of (T) CD4 + cells in your blood can help improve your immune system. This can reduce the risk of death or infections that can occur when your immune system is weak (opportunistic infections).

SURAVIR® does not cure HIV-1 infection or AIDS. You should continue to take anti-HIV-1 medications to control HIV infection and reduce HIV-related illnesses.

Who should not take SURAVIR®?

Do not take SURAVIR® if:

- You are allergic to atazanavir or any of the ingredients in SURAVIR®. See the complete list of SURAVIR® ingredients at the end of this package leaflet.
- You are taking any of the following medications. Taking SURAVIR® together with these medications can affect the way SURAVIR® works. SURAVIR® can cause serious and life-threatening side effects, or death, when used with these medications:

- Alfuzosin
- Cisapride
- Elbasvir/ Grazoprevir
- Glecaprevir/ Pibrentasvir
- Indinavir
- Irinotecan

- Lurasidone, if you take both SURAVIR® and Ritonavir
- Lovastatin
- Midazolam, when taken orally for sedation
- Nevirapine
- Pimozide
- Rifampicin
- Sildenafil, when used for the treatment of pulmonary arterial hypertension
- Simvastatin
- St. John's Wort (*Hypericum perforatum*)
- Triazolam

Serious problems can occur if you or your child takes any of the above medications with SURAVIR®.

What should I tell my doctor before taking SURAVIR®?

Before taking SURAVIR®, tell your doctor if:

- You have heart problems.
- You have liver problems, including infection with the hepatitis B or C virus.
- You are receiving dialysis.
- You have diabetes.
- You have hemophilia.
- You have any other medical condition.
- You are pregnant or plan to become pregnant. Ask your doctor about taking SURAVIR® during your pregnancy or if you are planning to become pregnant while taking the medication.

-The hormonal contraceptive methods, such as injections, vaginal rings or implants, contraceptive patches, and some oral contraceptive pills, may not work during treatment with SURAVIR®. Consult your doctor about the contraceptive methods that can be used during treatment.

-After your baby is born, tell your doctor if the skin or the white of the baby's eye turn yellow.

- You are breastfeeding or plan to breastfeed your baby. **Do not breastfeed your child if you are taking SURAVIR®.** You should not breastfeed your baby if you have HIV-1. SURAVIR® can pass into breast milk. Consult your doctor about the best way to feed your child.

Tell your doctor about every medication you take, including over-the-counter and prescribed medications, vitamins and herbal supplements.

Some medications interact with SURAVIR®. Keep a list of your medications to show your doctor. You can ask your doctor for a list of medications that interact with SURAVIR®. Do

not start taking any new medicine without talking with your doctor at first. The doctor can tell you if it is safe to take SURAVIR® with other medication.

How should I take SURAVIR®?

- Take SURAVIR® exactly as your doctor tells you.
- Do not change the dose or stop taking SURAVIR®, unless your doctor tells you to.
- Remain under medical care during treatment with SURAVIR®.
- SURAVIR® must be used with other antiretroviral drugs.
- Take SURAVIR® capsules with food.
- Swallow the whole capsule. Do not open it.
- If you miss a dose of SURAVIR®, take the missed dose as soon as you remember. Then take the next one at your usual time. Do not take 2 doses together. If you take too much SURAVIR®, call your doctor or go immediately to the emergency service or the nearest hospital.

In the event of an overdose, go to the nearest Hospital or contact the Toxicology Centers:

Pediatric Hospital Ricardo Gutiérrez: (011) 49626666/2247

Hospital A. Posadas: (011) 46546648/46587777.

When your SURAVIR® supply starts to decrease, get more from your doctor or pharmacy. It is important that you do not run out of SURAVIR®. The amount of HIV-1 in your blood may increase if you stop taking the medication, even for a short period. The virus can become resistant to SURAVIR® and more difficult to treat.

What are the possible side effects of SURAVIR®?

SURAVIR® can cause serious side effects, which include:

- **A change in the way your heart beats (change in heart rate).** Tell your doctor right away if you become dizzy. These could be symptoms of a heart problem.
- **Skin rash.** Skin rash is common with SURAVIR®, but it can, sometimes, be severe. It usually disappears within 2 weeks, without any change in treatment. Severe eruption can develop in association with other symptoms, which could be serious. If you develop a severe rash or rash with any of the following symptoms, stop taking SURAVIR® and call your doctor immediately:
 - General feeling of malaise or flu-like symptoms
 - Fever
 - Muscular or joint pain
 - Red or inflamed eyes (conjunctivitis)
 - Blisters

- Sores in the mouth
- Inflammation of the face
- Painful, hot or reddened bulge under the skin
- **The yellowish color of the skin or the white part of the eyes** is common with SURAVIR® and it is generally not harmful in adults and children over 6 years of age, but it could also be a symptom of a serious problem. These effects may be due to increases in bilirubin levels in the blood (bilirubin is produced by the liver). Although these effects may not be harmful to your liver, skin or eyes, tell your doctor immediately if your skin or the white part of your eyes turn yellow.
- **Liver problems.** If you have liver problems, including hepatitis B or C infection, they can get worse when you take SURAVIR®. Your doctor will perform blood tests to check your liver before you can start SURAVIR® and during treatment. Tell your doctor immediately if you suffer from any of the following symptoms:
 - Dark urine, tea-colored
 - Yellowish color of the skin or in the white of the eye
 - Light colored feaces
 - Nausea
 - Itch
 - Pain in the stomach area
- **Chronic kidney disease.** SURAVIR® can affect how the kidneys work. Your doctor will perform blood and urine tests to check your kidneys before and during treatment.
 - Kidney stones have occurred in some people taking SURAVIR®. Tell your doctor immediately if you have symptoms of gallbladder problems, which may include:
 - Fever
 - Pain in the upper right or middle of the stomach
 - Nausea and vomiting
 - Yellowish color of the skin or in white of the eye
- **Kidney stones** have occurred in some people taking SURAVIR®. Tell your doctor right away if you have symptoms of kidney stones, which can include pain in your lower back or stomach, blood in your urine, or painful urination.
- **Gallbladder problems** have occurred in some people taking SURAVIR®. Tell your doctor immediately if you have symptoms of gallbladder problems, which may include:
 - Fever
 - Pain in the upper right or middle of the stomach
 - Nausea and vomiting
 - Yellowing of the skin or the white part of the eyes

- **Diabetes and high blood sugar (hyperglycemia)** have occurred, or the clinical picture has gotten worse in some people taking protease inhibitor medications like SURAVIR®. Some people have had to start taking medication to treat diabetes or have had to change their medication for diabetes.
- **Changes in your immune system (immune reconstitution syndrome)** can occur when you start taking anti-HIV-1 medications. Your immune system can become stronger and begin to fight infections that have been hidden in your body for a long time. Tell your doctor if you start having new symptoms after starting SURAVIR®.
- **Changes in body fat** can occur in people taking anti-HIV drugs. 1. These changes may include an increase in the amount of fat in the upper back and neck ("buffalo hump"), breast, and around the trunk. You may also notice a loss of fat in your legs, arms and face. The exact cause and long-term health effects of these conditions are unknown.
- There has been an **increase in bleeding problems in people with hemophilia** when taking protease inhibitors such as SURAVIR®.

The most common side effects of SURAVIR® include:

- Nausea
- Headache
- Pain in the stomach area
- Vomiting
- Difficulty to sleep
- Numbness, tingling or burning in hands or feet
- Dizziness
- Muscle pain
- Diarrhea
- Depression
- Fever

Tell your doctor if you have any side effects that bother you or that do not go away. These are not all possible side effects of SURAVIR®. For more information, consult your doctor.

Call your doctor for professional advice about side effects.

In case of any inconvenience with the product, the patient can fill out the form that is on the ANMAT website: <http://www.anmat.gov.ar/farmacovigilancia/Notificar.asp> or call ANMAT. 0800-333-1234.

How should I save SURAVIR®?

SURAVIR® capsules:

- Store SURAVIR® capsules at room temperature, between 15 ° C and 30 ° C.
- Keep the capsules in a tightly closed container.

Keep SURAVIR® and all medicines out of the reach of children.

General information on the safe and effective use of SURAVIR®

Medications are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. Do not use SURAVIR® for a condition for which it was not prescribed. Do not give SURAVIR® to another person, even if you have the same symptoms as you, because it can cause harm. If you want more information, consult your doctor. You can ask your doctor for information about SURAVIR® aimed at health professionals.

What are the ingredients of SURAVIR®?

Active ingredient: atazanavir sulfate

Excipients:

SURAVIR® capsules: crospovidone, lactose monohydrate and magnesium stearate. The capsule shell contains gelatin, FD & C Blue No. 2, titanium dioxide, black iron oxide, red iron oxide and yellow iron oxide. The capsules are printed with ink containing shellac, titanium dioxide, FD & C Blue No. 2, isopropyl alcohol, ammonium hydroxide, propylene glycol, n-butyl alcohol, simethicone and dehydrated alcohol.

Medicinal specialty authorized by the Ministry of Health. Certificate N °: 58748

Primary processor and conditioner: AstraZeneca Pharmaceuticals LP, 4601 Highway 62 East, Mt. Vernon, Indiana 47620 USA.

Importer and secondary conditioner: Del Fin del Mundo Laboratory, Rio Grande 9, Ushuaia, Province of Tierra del Fuego, Antártida e Islas del Atlántico Sur, Argentina. Telephone: 02901 421166. Technical Director: Mauricio Ezequiel Aput - Pharmacist.

Alternative secondary conditioner: Transfarmaco S.A.- Marcos Sastre 1002/1034/1088, EI Talar, Province of Buenos Aires, Argentina.

THIS MEDICINE MUST BE USED EXCLUSIVELY UNDER PRESCRIPTION AND MEDICAL SURVEILLANCE AND CAN NOT BE REPEATED WITHOUT A NEW MEDICAL RECIPE.

KEEP THIS AND ALL MEDICINES IN ORIGINAL CONTAINER AND OUT OF REACH OF CHILDREN.

THIS MEDICATION HAS BEEN PRESCRIBED FOR YOUR CURRENT MEDICAL PROBLEM. DO NOT RECOMMEND TO OTHER PEOPLE.

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CONSULT YOUR PHYSICIAN