

**Patient Information
Efavirenz Capsules USP
(eh-FAV-ir-enz)**

Important: Ask your doctor or pharmacist about medicines that should not be taken with efavirenz capsules. For more information, see the section “What should I tell my doctor before taking efavirenz capsules?”

Read this Patient Information before you start taking efavirenz capsules and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or treatment.

What are efavirenz capsules?

Efavirenz capsules are a prescription HIV-1 (Human Immunodeficiency Virus type 1) medicine used with other antiretroviral medicines to treat HIV-1 infection in adults and in children who are at least 3 months old and who weigh at least 7 pounds 12 ounces (3.5 kg). HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

It is not known if efavirenz capsules are safe and effective in children younger than 3 months of age or who weigh less than 7 pounds 12 ounces (3.5 kg).

When used with other antiretroviral medicines to treat HIV-1 infection, efavirenz capsules may help:

- reduce the amount of HIV-1 in your blood. This is called viral load.
- increase the number of CD4+ (T) cells in your blood that help fight off other infections.

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

Efavirenz capsules do not cure HIV-1 infection or AIDS. You should keep taking HIV-1 medicines to control HIV-1 infection and decrease HIV-related illnesses.

Avoid doing things that can spread HIV-1 infection to others:

- Do not share or reuse needles or other injection equipment.
- Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.
- Do not have any kind of sex without protection. Always practice safer sex by using a latex or polyurethane condom to lower the chance of sexual contact with any body fluids such as semen, vaginal secretions, or blood.

Ask your doctor if you have any questions about how to prevent passing HIV to other people.

Who should not take efavirenz capsules?

Do not take efavirenz capsules if you are allergic to efavirenz or any of the ingredients in efavirenz capsules. See the end of this leaflet for a complete list of ingredients in efavirenz capsules.

Do not take efavirenz capsules if you are currently taking elbasvir and grazoprevir (ZEPATIER®).

What should I tell my doctor before taking efavirenz capsules?

Before taking efavirenz capsules, tell your doctor if you have any medical conditions and in particular, if you:

- have a heart condition
- have ever had a mental health problem
- have ever used street drugs or large amounts of alcohol
- have liver problems, including hepatitis B or C virus infection
- have a history of seizures
- are pregnant or plan to become pregnant. Efavirenz capsules may harm your unborn baby. If you are able to become pregnant your healthcare provider should do a pregnancy test before you start efavirenz capsules. You should not become pregnant while taking efavirenz capsules and for 12 weeks after stopping treatment with efavirenz capsules.

Females who are able to become pregnant should use 2 effective forms of birth control during treatment and for 12 weeks after stopping treatment with efavirenz capsules. A barrier form of birth control should always be used along with another type of birth control.

- Barrier forms of birth control may include latex or polyurethane condom, contraceptive sponge, diaphragm with spermicide, and cervical cap.
- **Hormonal forms of birth control, such as birth control pills, injections, vaginal rings, or implants may not work during treatment with efavirenz capsules.**
- Talk to your doctor about forms of birth control that may be used during treatment with efavirenz capsules.
- **Pregnancy Registry.** There is a pregnancy registry for women who take antiretroviral medicines during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk to your doctor about how you can take part in this registry.
- **Do not breastfeed if you take efavirenz capsules.**
- You should not breastfeed if you have HIV because of the risk of passing HIV to your baby.

Tell your doctor and pharmacist about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Efavirenz capsules may affect the way other medicines work, and other medicines may affect how efavirenz capsules work, and may cause serious side effects. If you take certain medicines with efavirenz capsules, the amount of efavirenz in your body may be too low and it may not work to help control your HIV infection. The HIV virus in your body may become resistant to efavirenz or other HIV medicines that are like it.

You should not take efavirenz capsules if you take ATRIPLA (efavirenz, emtricitabine, tenofovir disoproxil fumarate) unless your doctor tells you to.

Tell your doctor and pharmacist about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines interact with efavirenz capsules.

Keep a list of your medicines to show your doctor and pharmacist.

- You can ask your doctor or pharmacist for a list of medicines that interact with efavirenz capsules.
- **Do not start taking a new medicine without telling your doctor.** Your doctor can tell you if it is safe to take efavirenz capsules with other medicines.

How should I take efavirenz capsules?

- Take efavirenz capsules exactly as your doctor tells you to.
- Do not change your dose or stop taking efavirenz capsules unless your doctor tells you to.
- Stay under the care of your doctor during treatment with efavirenz capsules.
- Efavirenz capsules must be used with other antiretroviral medicines.

- Take efavirenz capsules 1 time each day.
- Efavirenz comes as capsules.
- Swallow efavirenz capsules whole with liquid.

How and when to take efavirenz capsules.

- You should take efavirenz capsules on an empty stomach at bedtime. Taking efavirenz capsules with food increases the amount of medicine in your body. Some side effects may bother you less if you take efavirenz capsules on an empty stomach and at bedtime.
- Your child’s doctor will prescribe the right dose of efavirenz capsules based on your child’s weight.
- If you have difficulty swallowing capsules, tell your doctor. Your doctor may recommend opening the efavirenz capsule and mixing the contents with food or infant formula. **See the detailed “Instructions for Use” at the end of this Patient Information to learn the right way to take efavirenz capsules using the capsule sprinkle method.**
- Adults and children who take efavirenz capsules using the capsule sprinkle method should not eat for 2 hours after taking a dose of efavirenz capsules.
- Babies should not be given infant formula for 2 hours after taking a dose of efavirenz capsules using the capsule sprinkle method.
- Do not miss a dose of efavirenz capsules. If you forget to take efavirenz capsules, take the missed dose right away, unless it is almost time for your next dose. Do not take 2 doses at one time. Just take your next dose at your regularly scheduled time. If you need help in planning the best times to take your medicine, ask your doctor or pharmacist.
- If you take too much efavirenz, call your doctor or go to the nearest hospital emergency room right away.
- When your efavirenz capsules supply starts to run low, get more from your doctor or pharmacy. It is important not to run out of efavirenz capsules. The amount of HIV-1 in your blood may increase if the medicine is stopped for even a short time. The virus may become resistant to efavirenz and harder to treat.

What are the possible side effects of efavirenz capsules?

Efavirenz capsules may cause serious side effects, including:

- **Serious mental health problems** can happen in people who take efavirenz capsules. Tell your doctor right away if you have any of the following symptoms:
 - feel sad or hopeless
 - feel anxious or restless
 - have thoughts of hurting yourself (suicide) or have tried to hurt yourself or others
 - are not able to tell the difference between what is true or real and what is false or unreal
 - do not trust other people
 - hear or see things that are not real
 - are not able to move or speak normally
- **Nervous system symptoms** are common in people who take efavirenz capsules and can be severe. These symptoms usually begin during the first or second day of treatment with efavirenz capsules and usually go away after 2 to 4 weeks of treatment. Some symptoms may occur months to years after beginning efavirenz capsules therapy. These symptoms may become worse if you drink alcohol, take a medicine for mental health problems, or use certain street drugs during treatment with efavirenz capsules. Symptoms may include:
 - dizziness
 - trouble sleeping
 - trouble concentrating
 - drowsiness
 - unusual dreams
 - lack of coordination or difficulty with balance

If you have dizziness, trouble concentrating or drowsiness, do not drive a car, use machinery, or do anything that needs you to be alert. Some nervous system symptoms (e.g., confusion, slow thoughts and physical movement, and delusions [false beliefs] or hallucinations [seeing or hearing things that others do not see or hear]) may occur months to years after beginning efavirenz capsules therapy. Promptly contact your health care provider should any of these symptoms occur.

Skin rash is common with efavirenz capsules but can sometimes be severe. Skin rash usually goes away without any change in treatment. If you develop a rash with any of the following symptoms, tell your doctor right away:

- skin rash, with or without itching
- fever
- swelling of your face
- blisters or skin lesions
- peeling skin
- mouth sores
- red or inflamed eyes, like “pink eye” (conjunctivitis)

Liver problems, including liver failure and death can happen in people who take efavirenz capsules. Liver problems can happen in people without a history of liver problems. Your doctor will do blood tests to check your liver before you start efavirenz capsules and during treatment. Tell your doctor right away if you get any of the following symptoms:

- your skin or the white part of your eyes turns yellow (jaundice)
- your urine turns dark
- your bowel movements (stools) turn light in color
- you don’t feel like eating food for several days or longer
- you feel sick to your stomach (nausea)
- you have lower stomach area (abdominal) pain

Seizures can happen in people who take efavirenz capsules. Seizures are more likely to happen if you have had seizures in the past. Tell your doctor if you have had a seizure or if you take a medicine to help prevent seizures.

Changes in your immune system (Immune Reconstitution Syndrome) can happen when you start taking HIV-1 medicines. Your immune system may get 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 your HIV-1 medicine.

Changes in body fat can happen in people who take HIV-1 medicine. 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. The cause and long-term health effects of these conditions are not known.

The most common side effects of efavirenz capsules include:

- rash
- dizziness
- nausea
- headache
- difficulty concentrating
- abnormal dreams
- tiredness
- trouble sleeping
- vomiting

Some patients taking efavirenz capsules have experienced increased levels of lipids (cholesterol and triglycerides) in the blood. Tell your doctor if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of efavirenz capsules. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store efavirenz capsules?

- Store efavirenz capsules at room temperature between 68° to 77°F (20° to 25°C).

Keep efavirenz capsules and all medicines out of the reach of children. General information about efavirenz capsules

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use efavirenz capsules for a condition for which it was not prescribed. Do not give efavirenz capsules to other people, even if they have the same symptoms that you have. It may harm them.

If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about efavirenz capsules that is written for health professionals. For more information, call Aurobindo Pharma USA, Inc. at 1-866-850-2876.

What are the ingredients in efavirenz capsules?

Active ingredient: efavirenz

Inactive ingredients: lactose monohydrate, magnesium stearate, sodium lauryl sulfate and sodium starch glycolate (potato). The capsule shell contains gelatin, silicon dioxide and sodium lauryl sulfate. In addition 50 mg contains titanium dioxide and yellow iron oxide, 100 mg contains titanium dioxide and 200 mg contains yellow iron oxide. The capsules are printed with edible ink containing black iron oxide and shellac.

This Patient Information has been approved by the U.S. Food and Drug Administration.

Distributed by:
Aurobindo Pharma USA, Inc.
279 Princeton-Hightstown Road
East Windsor, NJ 08520

Manufactured by:
Aurobindo Pharma Limited
Hyderabad-500 032, India

Revised: 12/2021

ATRIPLA is a registered trademark of Bristol-Myers Squibb & Gilead Sciences, LLC.

ZEPATIER is a registered trademark of Merck Sharp & Dohme Corp.

**Instructions for Use
Efavirenz Capsules USP
(eh-FAV-ir-enz)**

Preparing a dose of efavirenz capsules using the capsule sprinkle method

Read this Instructions for Use before you prepare your first dose of efavirenz capsules mixed with food or infant formula using the capsule sprinkle method, each time you get a refill, and as needed. There may be new information. This information does not take the place of talking to your doctor about your medical condition or treatment. Ask your doctor or pharmacist if you have any questions about how to mix or give a dose of efavirenz capsules using the capsule sprinkle method.

Important Information:

- For more information about efavirenz capsules, see the Patient Information leaflet.
- The capsule sprinkle method for mixing the contents of efavirenz capsules with soft food or infant formula may be used for adults or children who cannot swallow capsules.
- You should take efavirenz capsules on an empty stomach at bedtime.
- You should not eat for 2 hours after taking efavirenz capsules mixed with food.
- Babies who are old enough to swallow food should be given efavirenz capsules using the capsule sprinkle method mixed with food instead of with infant formula.
- Talk with your doctor to help decide the best schedule for giving your baby efavirenz capsules mixed with infant formula using the capsule sprinkle method.

Preparing a dose of efavirenz capsules mixed with food using the capsule sprinkle method.

Before you prepare a dose of efavirenz capsules mixed with food using the capsule sprinkle method, gather the following supplies:

- paper towels
- teaspoon for measuring
- small spoon for stirring and feeding
- **small** clean container (such as a **small** cup or bowl)
- soft food such as applesauce, grape jelly, or yogurt

Step 1. Choose a clean, flat work surface. Place a clean paper towel on the work surface. Then place the other supplies on the paper towel.

Step 2. Wash and dry your hands well.

Step 3. Place 1 to 2 teaspoons of soft food such as applesauce, grape jelly, or yogurt in the small container (see Figure A). The color and thickness of the food may change when mixed with the medicine.

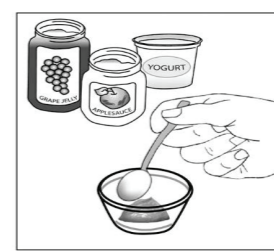


Figure A

Step 4. There are 2 parts of the efavirenz capsule. Look at the efavirenz capsule to see which part of the capsule overlaps the other part (see Figure B).

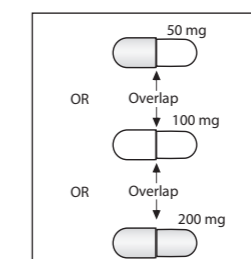



Figure B

A/s: 320 x 470 mm ■ Black

 AUROBINDO Packaging Development	Product Name	Component	Item Code	Date & Time
	Efavirenz Capsules USP	PIS	P1528928	28.12.2021 & 12.45 pm
	Country	Version No.	Reason Of Issue	Reviewed / Approved by
	USA_APL	01	Submission	
Team Leader	Jagan	Dimensions (mm)	Colours: 01	
Initiator	Sindhoor	A/s: 320 x 470 mm		
Artist	Sree Designers			
Additional Information: Supersede Code: P1523102				

Step 5. Hold the efavirenz capsule in a sideways (horizontal) position directly over the container of food. Hold each end of the efavirenz capsule between your thumbs and index (pointer) fingers (see Figure C).

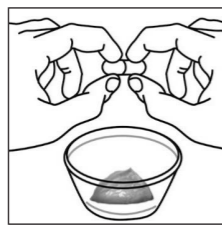


Figure C

Step 6. Use your thumb and index finger to pinch near the end of the overlapping part of the efavirenz capsule (see Figure D).

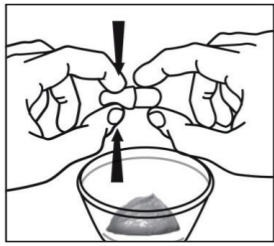


Figure D

Then, carefully twist both ends of the efavirenz capsule in opposite directions to open it (see Figure E). Be careful not to spill the capsule contents or spread it in the air.

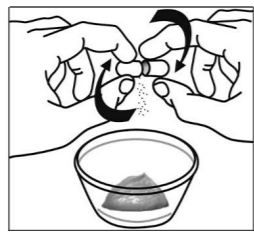


Figure E

Step 7. Sprinkle the contents of the efavirenz capsule onto the food (see Figure F).

- Check the capsule shells to make sure they are empty.
- Throw away the empty capsule shells.



Figure F

If the total prescribed dose is more than 1 capsule, follow Steps 4 through 7 for each capsule. Do not add more food.

Steps 8 through 11 should be completed **within 30 minutes** of mixing the medicine (see Figure G).

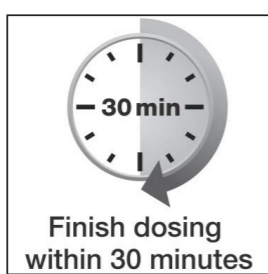


Figure G

Step 8. Use the small spoon to gently mix the capsule contents and food together (see Figure H). Sprinkles will not dissolve. Mixture will look grainy but should not be lumpy.



Figure H

Step 9. Use the small spoon to give or take the food and capsule contents mixture. Make sure that all of the mixture is swallowed.

Step 10. Add about 2 teaspoons more of the food to the empty container and gently stir with the small spoon to mix with any capsule contents that may still be in the container.

Step 11. Use the small spoon to give or take the food and capsule contents mixture. Make sure all of the mixture is swallowed.

Step 12. Wash the container and spoons. Throw away the paper towel and clean the work surface. Wash your hands.

Preparing a dose of efavirenz capsules mixed with infant formula using the capsule sprinkle method

To make sure that your baby gets all of the medicine, do not give efavirenz capsule contents to your baby in a bottle.

Before you prepare a dose of efavirenz capsules mixed with infant formula using the capsule sprinkle method, gather the following supplies:

- paper towels
- teaspoon for stirring and measuring
- **small** clean container (such as a **small** cup or bowl) (see Figure I).
- 10 mL oral dosing syringe (ask your pharmacist for this) (see Figure I).
- infant formula at room temperature.



Figure I

Step 1. Prepare the infant formula according to the directions on the infant formula package. You will use about 1 ounce of the formula to give the medicine. Any remaining formula should not be given to the child for 2 hours.

Step 2. Choose a clean, flat work surface. Place a clean paper towel on the work surface. Place the supplies you will need on the paper towel.

Step 3. Wash and dry your hands well.

Step 4. Pour 2 teaspoons of room temperature infant formula into the container (see Figure J).



Figure J

Step 5. There are 2 parts of the efavirenz capsule. Look at the efavirenz capsule to see which part of the capsule overlaps the other part (see Figure K).

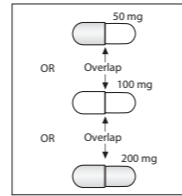


Figure K

Step 6. Hold the efavirenz capsule in a sideways (horizontal) position directly over the container with the infant formula. Hold each end of the efavirenz capsule between your thumbs and index (pointer) fingers (see Figure L).



Figure L

Step 7. Use your thumb and index finger to pinch near the end of the overlapping part of the efavirenz capsule (see Figure M).

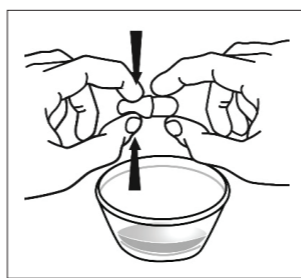


Figure M

Then, carefully twist both ends of the efavirenz capsule in opposite directions to open it (see Figure N). Be careful not to spill the capsule contents or spread it in the air.



Figure N

Step 8. Sprinkle the contents of the efavirenz capsule onto the infant formula (see Figure O).

- Check the capsule shells to make sure they are empty.
- Throw away the empty capsule shells.

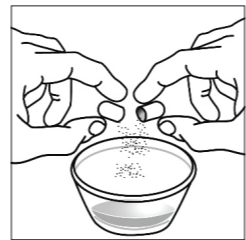


Figure O

If the total prescribed dose is more than 1 capsule, follow Steps 5 through 8 for each capsule. Do not add more infant formula.

Steps 9 through 12 should be completed **within 30 minutes** of mixing the medicine (see Figure P).



Figure P

Step 9. Hold the container with one hand. With your other hand, use the teaspoon to gently mix the capsule contents and the infant formula (see Figure Q). Sprinkles will not dissolve. Mixture will look grainy but should not be lumpy.



Figure Q

Step 10. To draw up all of the mixture into the oral dosing syringe:

- Check that the plunger is completely pushed into barrel of the syringe (see Figure R).

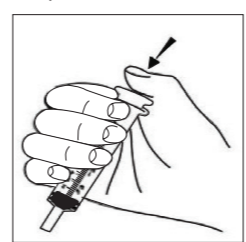


Figure R

- Place the tip of the syringe into the mixture in the container (see Figure S).

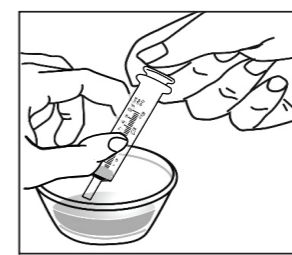


Figure S

- Slowly pull back on the plunger and draw up all of the mixture (see Figure T).

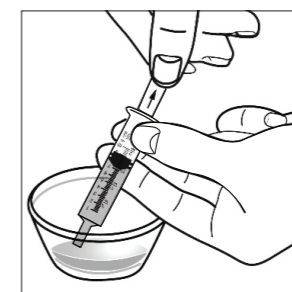


Figure T

Step 11. Place the tip of the syringe in your baby's mouth along the inner cheek (see Figure U). Slowly push on the plunger to give your baby all of the mixture.

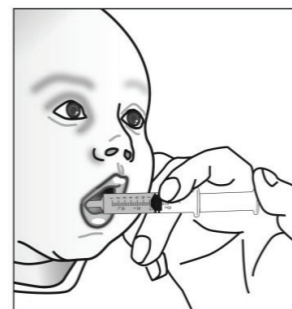


Figure U

Step 12. To make sure all of the medicine is given to your baby:

- Repeat Step 4 above.
- Stir with a teaspoon.
- Then, repeat Steps 10 and 11 above (see Figure V).

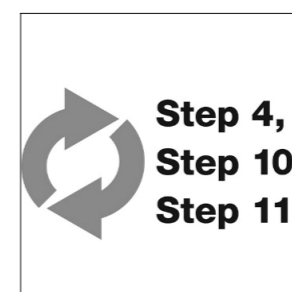


Figure V

Step 13. Remove the plunger from the oral dosing syringe. Wash the container, teaspoon, and oral dosing syringe. Allow the plunger and the syringe barrel to dry before putting them back together.

Step 14. Throw away the paper towel and clean the work surface. Wash your hands.

How should I store efavirenz capsules?

- Store efavirenz capsules at room temperature between 68° to 77°F (20° to 25°C).

Keep efavirenz capsules and all medicines out of the reach of children.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Dispense with Patient Information available at:
www.aurobindousa.com/medication-guides

Distributed by:
Aurobindo Pharma USA, Inc.
279 Princeton-Hightstown Road
East Windsor, NJ 08520

Manufactured by:
Aurobindo Pharma Limited
Hyderabad-500 032, India
Revised: 12/2021