

Instructions for Use
SUSTIVA® (sus-TEE-vah)
(efavirenz)
capsules

Preparing a dose of SUSTIVA using the capsule sprinkle method

Read this Instructions for Use before you prepare your first dose of SUSTIVA 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 SUSTIVA using the capsule sprinkle method.

Important Information:

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

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

Before you prepare a dose of SUSTIVA 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.

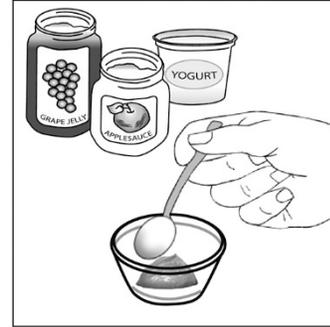


Figure A

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

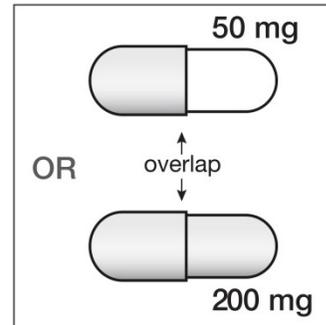


Figure B

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

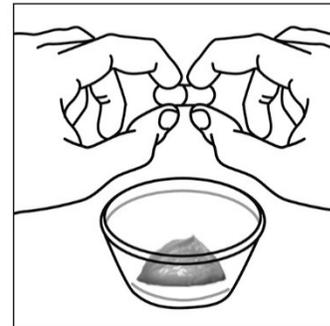


Figure C

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

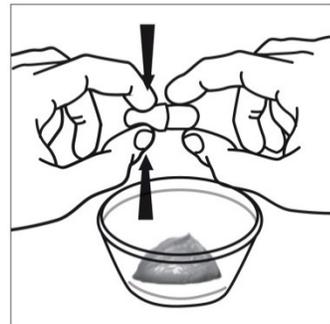


Figure D

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

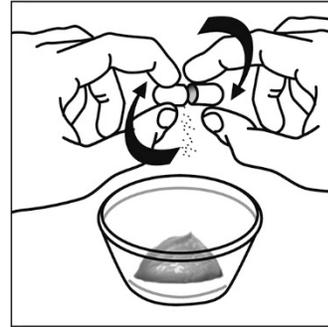


Figure E

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

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

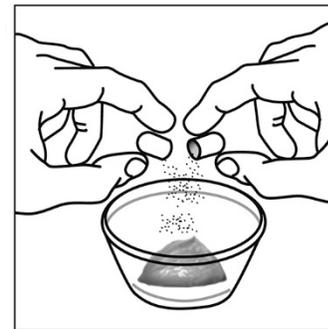


Figure F

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).

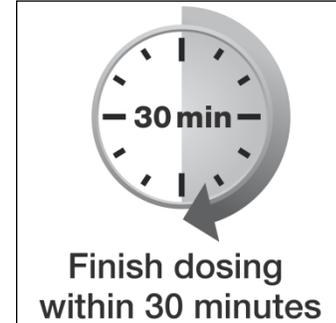


Figure G

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 SUSTIVA mixed with infant formula using the capsule sprinkle method

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

Before you prepare a dose of SUSTIVA 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.

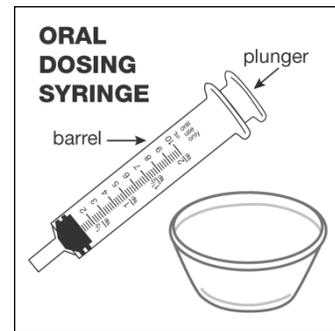


Figure I

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 SUSTIVA capsule. Look at the SUSTIVA capsule to see which part of the capsule overlaps the other part (see Figure K).

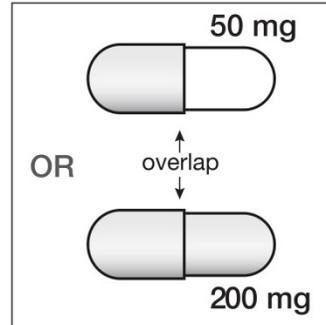


Figure K

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

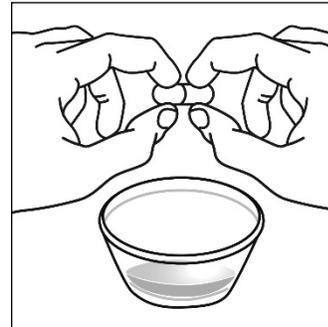


Figure L

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

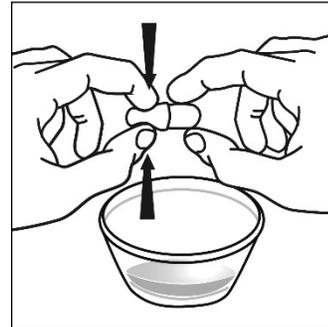


Figure M

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

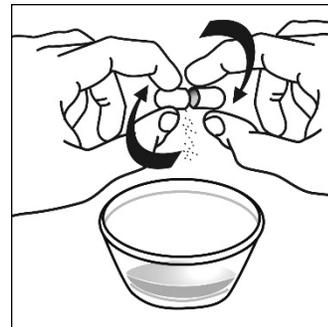


Figure N

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

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

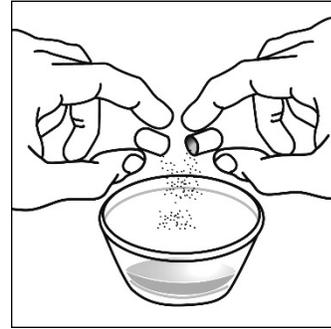


Figure O

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).

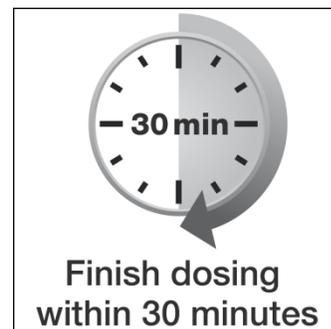


Figure P

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.

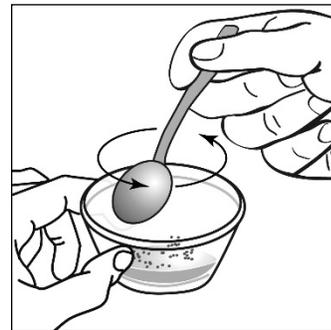


Figure Q

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).

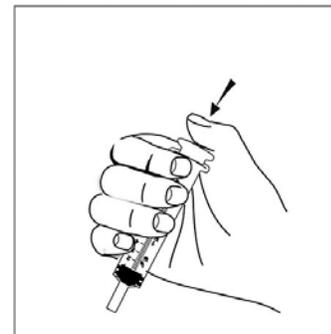


Figure R

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

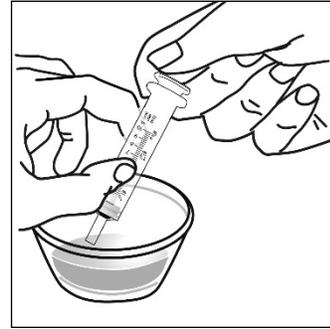


Figure S

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

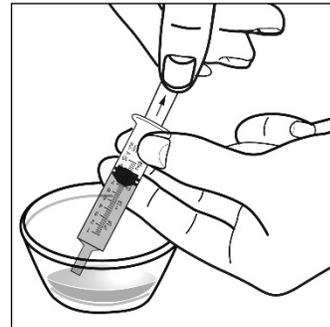


Figure T

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.

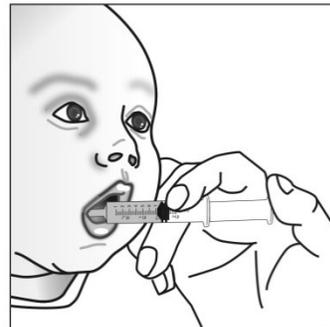


Figure U

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).

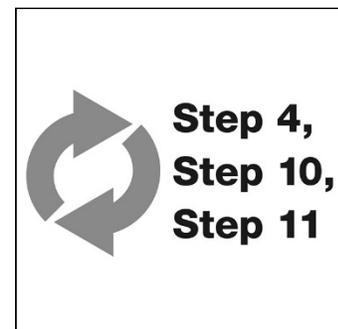


Figure V

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 SUSTIVA capsules?

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

Keep SUSTIVA 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.

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