

Guide for the Caregiver Administering RALTEGRAVIR Granules as Suspension to a Baby











The Faith-Based Action for Scaling Up Testing and Treatment for Epidemic Response project, or FASTER, aims to mobilize government, civil society and faith-based organizations to achieve targets for finding, linking and retaining children and adolescents in HIV care. Through the U.S. President's Emergency Plan for AIDS Relief, or PEPFAR, the Centers for Disease Control and Prevention is funding Catholic Relief Services with the Elizabeth Glaser Pediatric AIDS Foundation to catalyze the HIV response for children and youth in Zimbabwe.

Guide for the Caregiver

Administering RALTEGRAVIR Granules as Suspension to a Baby

This tool will guide you on how to administer the medicine called RALTEGRAVIR.

You will need to give this medicine to the baby along with two other medicines given as syrup or dispersible tablets. So, in total, you will be giving three medicines to the baby every day.

Here you will learn how to prepare and give RALTEGRAVIR medicine to your baby.

Things to know before preparing RALTEGRAVIR

- For babies, RALTEGRAVIR comes in the form of small packages with granules that are mixed with water to make a suspension.
- You must always give your baby RALTEGRAVIR in combination with <u>two other</u>
 medications given as a syrup or in dispersible tablets as prescribed by your nurse or
 doctor.
- There might be additional HIV-related medicine(s) to be given to the baby, such as cotrimoxazole and others. Make sure you know what these are and how much to give to the baby.
- The dose (amount given) of RALTEGRAVIR and other medicines is prescribed by the nurse or doctor and depends on the age and weight of the baby.
- If your baby started on treatment at birth, they will take RALTEGRAVIR once daily.
 When your baby turns 8 days old, the amount of RALTEGRAVIR will double and you will need to start giving it to the baby twice daily instead of once daily.
- If your baby is started on RALTEGRAVIR after one week of age, the medicine will be given twice daily from the beginning and the amount of RALTEGRAVIR and the other two medicines will be increased as the baby grows and gains weight.
- You can give RALTEGRAVIR to your baby before or after feeding. You might notice that
 your baby tolerates medicine better with feeds or without, so you will have to choose
 what option works the best for you and your baby.
- You need to have access to clean drinking water for preparing RALTEGRAVIR suspension from granules. You must use only safe boiled/bottled water for medicine preparation.
- Make sure you receive a combination of two other medicines given to you as a syrup or as dispersible tablets.
- Make sure you were provided a small cup and oral dosing syringes to give the medicines to the baby.
- Make sure you know how to contact your health care provider if you have any challenges with administering the medicine to the baby.
- Make sure all of the other caregivers for your baby at home, who might be involved in giving medication to the baby also know how to do it, so if you are comfortable teaching them. Ask for help from clinic staff to have them trained at the health care facility or at home.

How to handle RALTEGRAVIR granules

- RALTEGRAVIR granules come as a kit that includes mixing cups, oral dosing syringes, and 60 foil packets of granules.
- RALTEGRAVIR granules should always be stored unopened, in the original container kit, in a cool dry place away from direct sunlight.
- Each foil packet of RALTEGRAVIR granules inside the medicine kit is to be used only once. Each packet contains 100 mg of RALTEGRAVIR.
- For each dose of RALTEGRAVIR, you will need to mix all of the granules of one foil package in 10 mL of clean drinking water.
- Do not use expressed breastmilk or other liquids to mix RALTEGRAVIR because the drug does not dissolve well in the breastmilk or other liquids.
- You will not use all of the medicine solution you have prepared from the foil package. The nurse or doctor will show you how to measure the correct amount for your baby. After you have measured and given the baby the right amount of RALTEGRAVIR, then you must throw away the remaining mixture of the medicine in the garbage or sink, or on the ground. Do not store the remaining solution for the next dosing!

Make sure you understand and feel comfortable preparing and giving RALTEGRAVIR and other medicines to the baby!

Try to practice with healthcare worker or treatment supporter when you can! You can use sugar packs to practice!

Do not be shy to ask questions! We are here to help!

Things To Know When Giving RALTEGRAVIR to your baby

- When giving the medicines, place the syringe inside of the mouth to the inner cheek to avoid the baby tasting it!
- If the baby vomits within 15 minutes of taking RALTEGRAVIR, repeat the dose. If the baby vomits 15 minutes after taking the repeat dose, **do not re-administer the dose for the third time.** If you are giving the baby multiple medicines at the same time and the baby is vomiting, try to space administration of each medicine by 5-10 minute breaks in between.
- If the baby is taking RALTEGRAVIR <u>once daily</u> and misses a dose, give the dose as soon as possible when you remember that you forgot. If it is more than 18 hours after the missed dose, skip the missed dose and just give the next dose at the regular time. If it is less than 18 hours after the missed dose, administer the missed dose and delay the next dose by an hour or two if feasible. If the delay is not feasible, administer the next dose after six hours. This close dosing can be done on occasional basis and should not be repeated regularly. If you miss the doses regularly, promptly discuss with your nurse or doctor.
- If the baby is taking RALTEGRAVIR twice daily and misses a dose, give the dose as soon as possible. If it is more than nine hours after the missed dose, skip the missed dose and just give the next dose at the regular time. If it is less than nine hours after the missed dose, administer the missed dose and delay the next dose by an hour or two if feasible. If the delay is not feasible, administer the next dose after six hours. This close dosing can be done on occasional basis and should not be repeated regularly. If you miss the doses regularly, discuss promptly with your nurse or doctor.

Important: Do not give two doses at the same time to make up for a missed dose. If you are unsure whether or not to administer the dose, call your nurse or doctor for guidance.

- Contact your nurse or doctor if you observe any signs of an allergic reaction (skin rash/hives, persistent vomiting/poor feeding, change in the amount or color of urine, development of jaundice (yellowing of skin and eyes)) in your baby. Do not give next dose of RALTEGRAVIR or other medicines until you have spoken with the nurse or the doctor.
- Some drug reactions can be severe, such as swelling of the face, tongue, and throat, as well as difficulties breathing and swallowing. These reactions are rare, but they can be life threatening. If your baby has any difficulties breathing, swallowing, or feeding, take your baby immediately to the nearest healthcare facility!

How to follow up with the healthcare worker

- If your baby was started on RALTEGRAVIR within first week of life, after the baby turns
 one week of age (on day 8 of life), you will need to start giving the medicine two times
 a day. And you will need to increase the amount of RALTEGRAVIR in each dose (as
 instructed by clinic or hospital staff).
- Get in touch with your nurse or doctor either by phone, SMS, or in person, if you have any challenges giving the medicines to your baby, adjusting the dose, or if you need to refresh the instructions on how to do it.
- Feel free to share with the clinic staff any issues you may have encountered with preparing or administering RALTEGRAVIR, and/or any adverse events you may have observed.
- Remember, at each clinic visit, the baby will be weighed, and based on the baby's weight, your nurse or doctor will check the dose of all medicines including RALTEGRAVIR and may increase the dose at each visit.

Steps in Preparing RALTEGRAVIR Suspension From the Granules



Hello, I am Martha! I am 21 years old and I am a young mother of a beautiful little boy, Joshua. My baby takes medicine called RALTEGRAVIR along with two other medicines. I have learned how to prepare and give the medicine to him and I am going to show you how to do it. I hope I am a good teacher!

Now I am going to explain the steps I use in preparing RALTEGRAVIR suspension from the granules so that you can also learn and give it to your baby as prescribed by the nurse or doctor along with two other medicines that already come as suspensions or dispersible tablets.

Let us do it step by step!

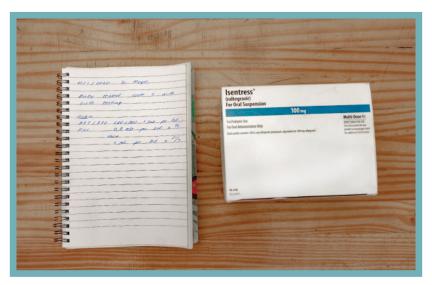
Step 1. Make sure the medicine is OK!

Look at the package to make sure it is not wet or damaged. Do not give the medicine to the child if the package is damaged, return the package to the facility.



Step 2. Check the dose of RALTEGRAVIR written on the box!

Check the dose of RALTEGRAVIR suspension — how many milliliters (mL) and how often to give (once or twice daily) to the baby — is written by the doctor on the box and/or on baby's clinic card.



Step 3. Check the content of the box!

Open the box and check the content to find inside the following items: two mixing plastic cups and two large size blue syringes (measuring 10 mL each), two middle size green syringes (3 mL each), and two small size white syringes (1 mL each).



Now that you checked the box, content, and the dose, you are ready to start preparing the suspension from the granules!

Let us keep following the steps!

Step 4. Prepare to mix the granules!

- Have clean drinking water (for example, cooled boiled water) in the drinking cup available and wash your hands.
- Take one mixing cup out of the box and take one large size blue syringe (10 mL) out of the box.
- Confirm the dose the child should be given and select the right size of the syringe for the suspension – select the smaller-sized white syringe for any dose less than 1 mL and the larger-sized green syringe for any dose between 1 mL and 3 mL. For doses above 3 mL, you will need to use the larger-sized blue syringe (10 mL) that you used to measure the water.
- Remove one foil packet of medicine from the box and place on the clean surface.









Step 5. Mix the RALTEGRAVIR granules with water to make suspension!

- Using the larger-sized blue syringe (10 mL), draw 10 ml of clean water from the drinking cup. When drawing water, be sure to draw the full syringe by turning the syringe up, knocking the syringe with your finger to remove any trapped air (bubbles), and pulling more water into the syringe until it exactly reaches the 10 ml mark.
- Add this 10 mL of clean drinking water in to the mixing cup.
- Open one foil packet of RALTEGRAVIR, pour all of the contents of the packet in the mixing cup that already has 10 mL of clean water, and mix gently for 45 seconds. While mixing the contents of the cup, just count five times to 10 or count to 50 if you do not have a timer at home.
- Do not shake the cup just stir/swirl it in round/circular motion.









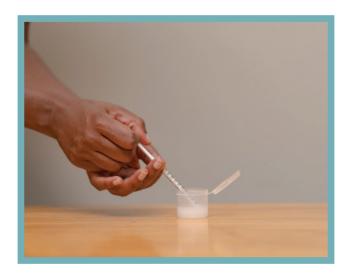






Step 6. Drawing the RALTEGRAVIR dose and giving the medicine to the baby!

- Based on the instructions from the doctor (written either on the box or clinical card), fill the white, green, or blue syringe with the RALTEGRAVIR suspension/mixture to the exact amount of medicine prescribed using the markings on the syringe.
- While filling the syringe precisely to the mark, do not forget to remove all the air in the syringe, the way you did with the water.
- Do not wait too long to give medicine to the baby. Try to do it within 30 minutes (half an hour) after mixing RALTEGRAVIR.
- Place the tip of the syringe in the mouth of the baby (better to do this on the side of their mouth, against the inner cheek) and gently push all of the medicine out of the syringe. It is best to give baby the breast right after the medicine to help wash it down to the baby's stomach.
- Use the same procedure for giving all three medicines the clinic staff prescribed for your baby.





Step 7. Cleaning up and storage!

- Wait 15 minutes after the child has successfully taken RALTEGRAVIR to be sure that baby doesn't vomit, then throw away all the remaining mixture of RALTEGRAVIR after giving the child the required amount of medicine.
- Clean the cup and used syringes with warm water, rinse well, and dry them up on a clean surface for 30 min.
- Place the clean and dried cup and syringes back into the kit/box to store.





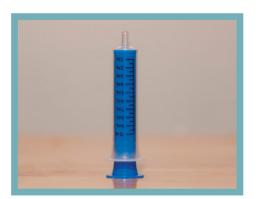




Visual Summary of RALTEGRAVIR Preparation and Administration



























Be proud of the job you have done!

Do not be discouraged if something was not done right, we all make mistakes, just learn from your experience and keep practicing!