

## USER MANUAL

Bring this booklet to your child's appointments.

**ISENTRESS® 100 mg granules for oral suspension**  
raltegravir

### Instructions for Use *for babies*


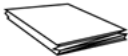


Be sure you read and understand these instructions for use.

#### Before You Start

**Note:** Make sure your doctor shows you how to prepare and give ISENTRESS for oral suspension.

- Be sure you understand these instructions before you start. If you are not sure, call your doctor.
- It is very important that you measure the water and ISENTRESS carefully using the correct syringe.
- Before you give ISENTRESS to your child, check the expiration date. The expiry date is printed on the carton and the ISENTRESS sachets.
- The amount of ISENTRESS depends on your child's age and weight, so it will change over time. Your doctor will tell you the right dose at each check-up after weighing your child. Be sure to keep your doctor's appointments so you get new dosing information as your child grows. During your child's first week of life, you will give ISENTRESS 1 time a day. After that, you will give it 2 times a day.
- This booklet tells you how to:
  - Mix ISENTRESS into a liquid form
  - Measure the right dose using a syringe
  - Give ISENTRESS to your child
  - Clean up

#### Kit Contents

- Outer carton 
- Instructions (this booklet) 
- Prescribing leaflet
- 2 mixing cups 
- 60 sachets of ISENTRESS granules 

- 6 syringes



2 **blue** (10 mL) syringes



2 **green** (3 mL) syringes



2 **white** (1 mL) syringes

The kit has an extra cup and set of syringes in case one is lost or damaged. Do not use any damaged cups or syringes.

### Step 1. Get ready

- Put your child in a safe place. You will need both hands to prepare Isentress.
- Wash your hands with soap and water.
- Take out what you need to make 1 dose and place on a clean surface:



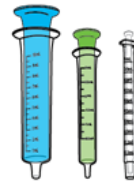
1 mixing cup  
(Using the tab on the mixing cup, pull open the lid)



1 sachet of Isentress granules



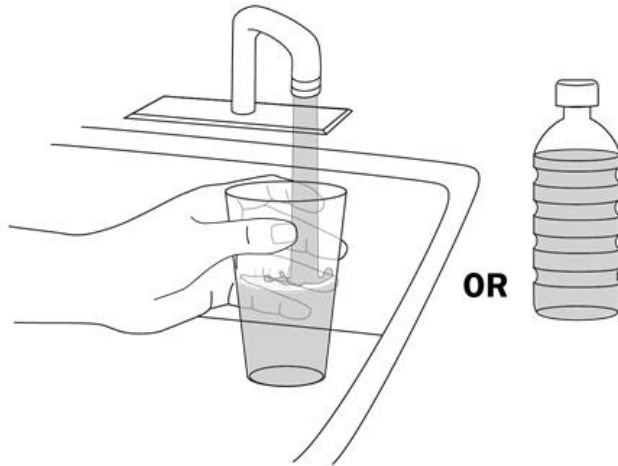
a clean glass



3 syringes  
(Have one of each size ready, but you only need 1 or 2, depending on the size of the dose)

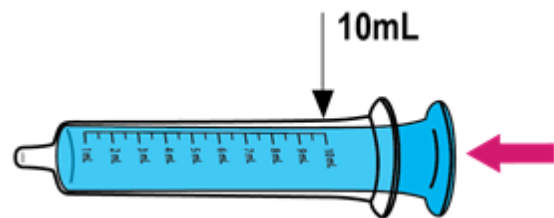
## Step 2. Fill a glass with water

Fill the clean glass with room-temperature drinking water from your tap or using bottled still water.



## Step 3. Fill the blue syringe with water

Push the plunger of the **blue** syringe into the syringe as far as it goes.

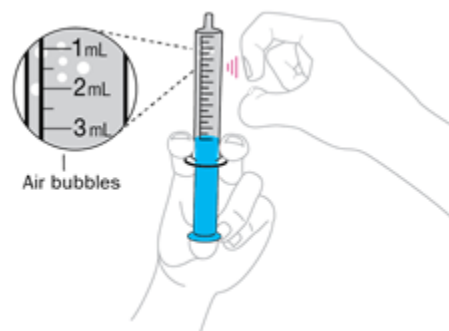


Put the tip of the syringe into the glass of water. Pull back the plunger. Stop when you get to the 10 mL mark.

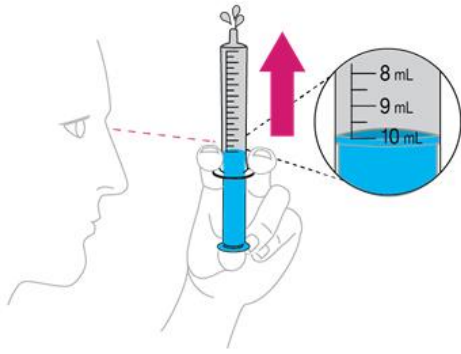


## Step 4. Check for air bubbles

Hold the syringe with tip up. Tap it with your finger to move any air bubbles up.



Slowly push up on the plunger to make the air come out.



Re-check the amount of water in the syringe. If it is less than 10 mL, put the tip back into the water and pull back on the plunger until you get to the 10 mL mark.

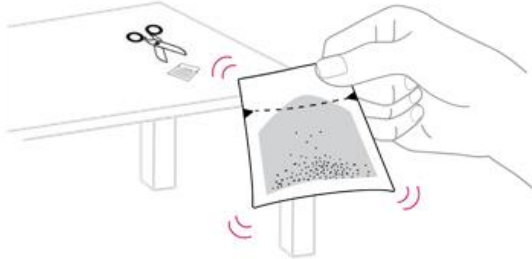
**Step 5. Add the 10 mL of water to the mixing cup**



## Step 6. Add Isentress to the cup

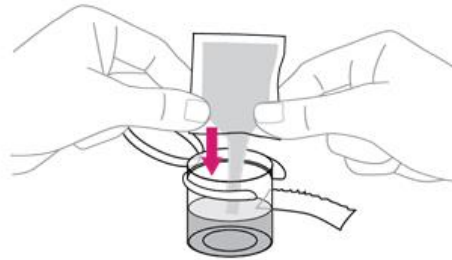
### *Note before adding Isentress:*

Make sure you and your child are ready! After mixing Isentress, use it within 30 minutes. Throw away any leftover Isentress after you have given the dose to your child.



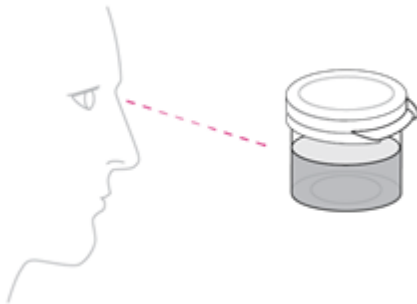
Tear or cut open the sachet and add all of the granules to the water in the mixing cup. Make sure the sachet is completely empty.

Take 1 sachet of ISENTRESS and shake the granules to the bottom of the sachet.



## Step 7. Mix Isentress and water

Snap the lid of the mixing cup shut. Gently swirl the mixing cup for 45 seconds in a circular motion to mix the granules and water. Use a clock or timer to time for 45 seconds. **DO NOT SHAKE** the mixture



Check to make sure the granules are mixed.  
If it is not mixed, swirl it some more.  
The mixture should look cloudy.

## Step 8. Check your prescription

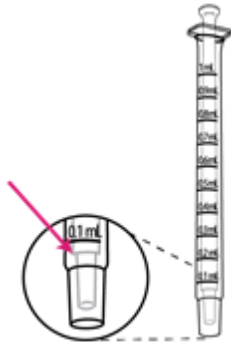
Use the dose amount in 'mL' prescribed by the doctor.

Remember that the dose may change each time you go to the doctor, so make sure you have all the recent information. Be sure to go to all of your doctor's appointments so your child gets the right dose!

### Step 9. Choose the syringe you need

Choose the correct syringe for your child's dose:

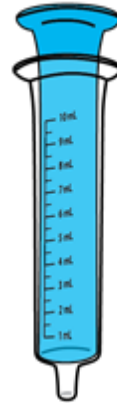
**WHITE**  
(1 mL)  
for 1 mL or less



**GREEN**  
(3 mL)  
for 1.5 mL to 3 mL



**BLUE**  
(10 mL)  
for 3.5 mL to 10 mL



Move this part of the plunger to the correct mark on the syringe

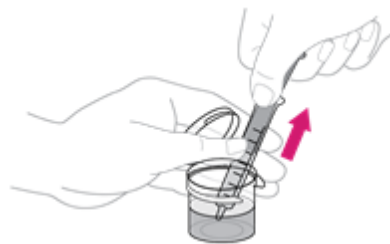
Then find the mL mark on the syringe barrel that matches your child's dose.

### Step 10. Measure Isentress

Push the plunger into the barrel of the syringe as far as it goes.



Put the tip of the syringe into the cup of the prepared Isentress and pull back on the plunger.



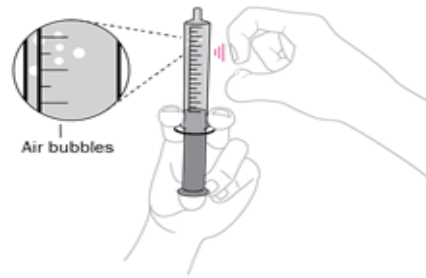
Stop when you get to the line that matches your child's prescribed dose.

### **IMPORTANT:**

- Your child's dose may be different from the one shown in this figure.
- There will usually be some leftover, prepared Isentress in the mixing cup.

### Step 11. Check for air bubbles

Hold the syringe with tip up.  
Tap it with your finger  
to move any air bubbles up.



Slowly push the plunger to make the air come out.



Re-check the amount of Isentress in the syringe.  
If it is less than the prescribed dose, put the tip back into the cup of prepared Isentress and pull back  
on the plunger until you get to the right dose mark.

### Step 12. Give Isentress to your baby

Place the tip of the syringe  
inside your child's mouth  
so that it touches either the  
right or left cheek.



Slowly push in the plunger to give the prepared Isentress. If your child fusses, take the tip of the syringe out of the mouth and try again. It is important that your child takes all of the prescribed dose (a little left in the syringe tip is OK).

**IMPORTANT:** If your child does not take all of the prescribed dose or spits some of it out, call your doctor to find out what to do.

### **Step 13. Clean up**

Pour the leftover prepared Isentress into the rubbish.  
**Do not pour it into the sink.**

Pull the plungers out of any syringes you used.

Hand wash the syringes, plungers, and mixing cup with warm water and dishwashing soap.  
Do not wash in the dishwasher.

Rinse with water and air dry.  
Put everything in a clean, dry place.

### **How should I store Isentress?**

Store in the original package in order to protect from moisture.  
Do not open the Isentress sachets until you are ready to prepare a dose.



**Be sure to keep your doctor's appointments so you always know how much Isentress to give.**

**This instructions for use was last revised in February 2021**

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