

# COMMON HIV MEDICINE OPTIONS\*†1

There are many different types of medicines to treat HIV (Human Immunodeficiency Virus). These medicines are called antiretrovirals, and they are grouped into classes. Some tablets may contain more than one class of medicine.











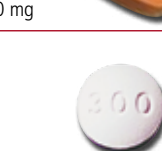
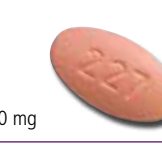




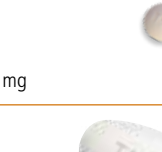

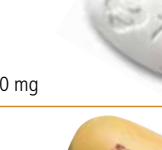
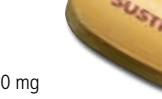
Please be aware that HIV medicines, including EDURANT®, INTELENCE®, PREZCOBIX®, PREZISTA®, and SYMTUZA® do not cure HIV infection or AIDS; and should always be taken as prescribed by your healthcare professional.

- Follow your healthcare professional's directions regarding the use of these medicines
- Discuss any questions you have about your treatment, including side effects and health status, with your healthcare professional
- Products are not shown at actual size

## SINGLE-TABLET REGIMENS (STRs)

<b>SYMTUZA®</b> darunavir/cobicistat/emtricitabine/tenofovir alafenamide (DRV/c/FTC/TAF) 800/150/200/10 mg  SYMTUZA.com	<b>Delstrigo™</b> doravirine/tenofovir disoproxil fumarate/lamivudine 100/300/300 mg 
<b>Atripla®</b> efavirenz/emtricitabine/tenofovir disoproxil fumarate (EFV/FTC/TDF) 600/200/300 mg 	<b>Genvoya®</b> elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide (EVG/c/FTC/TAF) 150/150/200/10 mg 
<b>Biktarvy®</b> bictegravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) 50/200/25 mg 	<b>Juluca®</b> dolutegravir/rilpivirine (DTG/RPV) 50/25 mg 
<b>Complera®</b> rilpivirine/emtricitabine/tenofovir disoproxil fumarate (RPV/FTC/TDF) 25/200/300 mg 	<b>Odefsey®</b> rilpivirine/emtricitabine/tenofovir alafenamide (RPV/FTC/TAF) 25/200/25 mg 
	<b>Stribild®</b> elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate (EVG/c/FTC/TDF) 150/150/200/300 mg 
	<b>Triumeq®</b> dolutegravir/abacavir/lamivudine (DTG/ABC/3TC) 50/600/300 mg 

## NON-STR REGIMENS

PROTEASE INHIBITORS (PIs)	NUCLEOSIDE/NUCLEOTIDE REVERSE TRANSCRIPTASE INHIBITORS (N(t)RTIs/nukes)
<b>PREZCOBIX®</b> darunavir/cobicistat (DRV/c) 800/150 mg  PREZCOBIX.com	<b>Combivir®</b> lamivudine/zidovudine (3TC/ZDV)† 150/300 mg 
<b>PREZISTA®</b> darunavir (DRV) 800 mg  PREZISTA.com	<b>Descovy®</b> emtricitabine/tenofovir alafenamide (FTC/TAF)† 200/25 mg 
<b>Evotaz™</b> atazanavir/cobicistat (ATV/c) 300/150 mg 	<b>Emtriva®</b> emtricitabine (FTC) 200 mg 
<b>Norvir®</b> ritonavir (RTV) 100 mg (Tablet, room temperature) 100 mg (Soft-gel capsules, refrigeration recommended) 	<b>Epivir®</b> lamivudine (3TC) 150 mg 
<b>Reyataz®</b> atazanavir sulfate (ATV) 150 mg 	<b>Epzicom®</b> abacavir sulfate/lamivudine (ABC/3TC)† 600/300 mg 
<b>INTEGRASE INHIBITORS (INSTIs)</b>	<b>Retrovir®</b> zidovudine (ZDV) 300 mg 
<b>Isentress®</b> raltegravir (RAL) 400 mg 	<b>Truvada®</b> emtricitabine/tenofovir disoproxil fumarate (FTC/TDF)† 200/300 mg 
<b>Tivicay®</b> dolutegravir (DTG) 50 mg 	<b>Viread®</b> tenofovir disoproxil fumarate (TDF) 300 mg 
<b>NON-NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS (NNRTIs/non-nukes)</b>	<b>Ziagen®</b> abacavir sulfate (ABC) 300 mg 
<b>EDURANT®</b> rilpivirine (RPV) 25 mg  EDURANT.com	
<b>INTELENCE®</b> etravirine (ETR) 100 mg  INTELENCE.com	
<b>Pifeltro™</b> doravirine 100 mg 	
<b>Sustiva®</b> efavirenz (EFV) 600 mg 	

The brands listed are the trademarks or registered trademarks of their respective owners. EDURANT®, INTELENCE®, PREZCOBIX®, PREZISTA®, and SYMTUZA® are registered trademarks of Janssen Therapeutics, Division of Janssen Products, LP. Information provided is current as of November 2018.

Only brand name medications are depicted.

\*Indications, safety, and efficacy of these products may vary. Please refer to the full Prescribing Information or Patient Information of each medication for more details.

†This chart does not include all HIV treatment formulations, treatment options, or dosing or safety considerations for the use of antiretroviral agents.

‡A pill containing a combination of N(t)RTIs.

Reference: 1. US Department of Health and Human Services. *Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents*. <https://aidsinfo.nih.gov/contentfiles/lvguidelines/AdultandAdolescentGL.pdf>. Accessed December 6, 2018.

Please see next page for Indication and Important Safety Information for EDURANT®, INTELENCE®, PREZCOBIX®, PREZISTA®, and SYMTUZA®, including Boxed Warning for SYMTUZA®.



# PREZCOBIX<sup>®</sup>

(darunavir 800 mg/  
cobicistat 150 mg) tablets

## WHAT IS PREZCOBIX<sup>®</sup> USED FOR?

PREZCOBIX<sup>®</sup> is a prescription HIV-1 (Human Immunodeficiency Virus 1) medicine always used with other antiretroviral medicines to treat HIV-1 infection in adults. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome). PREZCOBIX<sup>®</sup> contains prescription medicines PREZISTA<sup>®</sup> (darunavir) and TYBOST<sup>™</sup> (cobicistat). PREZCOBIX<sup>®</sup> does not cure HIV-1 infection or AIDS. You must keep taking HIV-1 medicines to control HIV-1 infection and decrease HIV-related illnesses. PREZCOBIX<sup>®</sup> should be taken once daily with food.

## Important Safety Information

### What is the most important information I should know about PREZCOBIX<sup>®</sup>?

- **PREZCOBIX<sup>®</sup> may cause liver problems which may be life-threatening. Tell your healthcare provider right away if you have any symptoms such as:**
  - Dark (tea-colored) urine
  - Yellowing of your skin or the whites of your eyes
  - Pale-colored stools (bowel movements)
  - Nausea
  - Vomiting
  - Pain or tenderness on your right side below your ribs
  - Loss of appetite
- **PREZCOBIX<sup>®</sup> may cause severe or life-threatening skin reactions or rashes. Stop taking PREZCOBIX<sup>®</sup> and call your healthcare provider right away if you develop any skin changes with symptoms below:**
  - Fever
  - Tiredness
  - Muscle or joint pain
  - Blisters or skin lesions

– Mouth sores or ulcers

– Red or inflamed eyes, like “pink eye” (conjunctivitis)

- **PREZCOBIX<sup>®</sup>, when taken with some other medications, can cause new or worse kidney problems, including kidney failure.**

### Who should not take PREZCOBIX<sup>®</sup>?

- **Do not take PREZCOBIX<sup>®</sup>** with any medicine that contains: alfuzosin, carbamazepine, cisapride, colchicine (if you have liver or kidney problems), dronedarone, elbasvir and grazoprevir, dihydroergotamine, ergotamine tartrate, lomitapide, lovastatin, lurasidone, methylergonovine, oral midazolam, phenobarbital, phenytoin, pimozide, ranolazine, rifampin, St. John’s wort (*Hypericum perforatum*), sildenafil when used for pulmonary arterial hypertension (PAH), simvastatin, or triazolam.

- **Serious problems can happen if you take any of these medicines with PREZCOBIX<sup>®</sup>.**

### What should I tell my healthcare provider before taking PREZCOBIX<sup>®</sup>?

Tell your healthcare provider if you:

- have liver problems, including hepatitis B or hepatitis C, have kidney problems, are allergic to sulfa (sulfonamide), have diabetes, have hemophilia, or have any other medical condition.
- are pregnant, or plan to become pregnant. PREZCOBIX<sup>®</sup> should not be used in pregnant individuals because you may not have enough PREZCOBIX<sup>®</sup> in your body during pregnancy. Your healthcare provider will prescribe different medicines if you become pregnant while taking PREZCOBIX<sup>®</sup>. It is unknown if PREZCOBIX<sup>®</sup> will harm your unborn baby.
- are breastfeeding, or plan to breastfeed. You should not breastfeed if you have HIV-1 because of the risk of passing HIV to your baby. It is unknown if PREZCOBIX<sup>®</sup> can pass into your breast milk.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines interact with PREZCOBIX<sup>®</sup>. Keep a list of your medicines to show your healthcare provider and pharmacist.

**Do not start taking a new medicine without telling your healthcare provider.**

### What are the possible side effects of PREZCOBIX<sup>®</sup>?

PREZCOBIX<sup>®</sup> may cause serious side effects including:

- Diabetes and high blood sugar
- Changes in body fat can happen in people taking HIV-1 medications
- Immune system changes can happen in people who start HIV medications
- Increased bleeding can occur in people with hemophilia who are taking PREZCOBIX<sup>®</sup>

### The most common side effects are:

- Diarrhea
- Nausea
- Rash
- Headache
- Stomach area (abdominal) pain
- Vomiting

These are not all the possible side effects of PREZCOBIX<sup>®</sup>. Tell your healthcare provider if any side effect bothers you or does not go away. For more information, ask your healthcare provider.

**You are encouraged to report negative side effects of prescription drugs to the FDA.**

Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

**You may also report side effects to Janssen Products, LP at 1-800-JANSSSEN (1-800-526-7736).**

**Please read the accompanying Important Brief Summary for PREZCOBIX<sup>®</sup> for more details.**

cp-33793v3

# PREZISTA<sup>®</sup>

(darunavir) tablets

## What is PREZISTA<sup>®</sup>?

PREZISTA<sup>®</sup> (darunavir) is a prescription HIV-1 (Human Immunodeficiency Virus type-1) medicine used with NORVIR<sup>®</sup> (ritonavir) and other antiretroviral medicines to treat HIV-1 infection in adults. HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

PREZISTA<sup>®</sup> should not be used in children under 3 years of age.

When used with other antiretroviral medicines to treat HIV-1 infection, PREZISTA<sup>®</sup> 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.

PREZISTA<sup>®</sup> is always taken with and at the same time as NORVIR<sup>®</sup> (ritonavir) in combination with other HIV-1 medicines for the treatment of HIV-1 infection in adults. PREZISTA<sup>®</sup> should also be taken with food.

**PREZISTA<sup>®</sup> does not cure HIV-1 infection or AIDS.** You must keep taking HIV-1 medicines to control HIV-1 infection and decrease HIV-related illnesses.

Ask your healthcare provider if you have any questions on how to prevent passing HIV to other people.

**Please read the Important Safety Information and talk to your healthcare provider to learn if PREZISTA<sup>®</sup> is right for you.**

- **PREZISTA<sup>®</sup> may cause severe or life-threatening skin reactions or rash.**

Sometimes these skin reactions and skin rashes can become severe and require treatment in a hospital. You should call your healthcare provider immediately if you develop a rash. **Stop taking PREZISTA<sup>®</sup> and ritonavir combination treatment and call your healthcare provider immediately if you develop any skin changes with these symptoms:** fever, tiredness, muscle or joint pain, blisters or skin lesions, mouth sores or ulcers, red or inflamed eyes, like “pink eye.” Rash occurred more often in people taking PREZISTA<sup>®</sup> and raltegravir together than with either drug separately, but was generally mild.

### Who should not take PREZISTA<sup>®</sup>?

**Do not take PREZISTA<sup>®</sup> with any medicine that contains:** alfuzosin, cisapride, colchicine (if you have liver or kidney problems), dronedarone, elbasvir and grazoprevir, ergot-containing medicines (dihydroergotamine, ergotamine tartrate, methylergonovine), lomitapide, lovastatin, lurasidone, midazolam, when taken by mouth, pimozide, ranolazine, rifampin, sildenafil, when used for the treatment of pulmonary arterial hypertension (PAH), simvastatin, St. John’s wort (*Hypericum perforatum*), or triazolam.

Serious problems can happen if you or your child takes any of these medicines with PREZISTA<sup>®</sup>.

### What should I tell my healthcare provider before taking PREZISTA<sup>®</sup>?

**Before taking PREZISTA<sup>®</sup>, tell your healthcare provider if you:**

- have liver problems (including hepatitis B or C), allergy to sulfa medicines, high blood sugar (diabetes), hemophilia, or any other medical conditions.
- are pregnant or planning to become pregnant. Tell your healthcare provider if you become pregnant while taking PREZISTA<sup>®</sup>.
- are breastfeeding or plan to breastfeed. Do not breastfeed if you take PREZISTA<sup>®</sup>. You should not breastfeed if you have HIV because of the risk of passing HIV to your baby. It is not known if PREZISTA<sup>®</sup> can pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby.

**Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicine, vitamins, and herbal supplements. Some medicines interact with PREZISTA<sup>®</sup>. **Keep a list of your medicines to show your healthcare provider and pharmacist. Do not start taking a new medicine without telling your healthcare provider.**

## What are the possible side effects of PREZISTA<sup>®</sup>?

PREZISTA<sup>®</sup> may cause serious side effects, including:

- **High blood sugar, diabetes or worsening of diabetes, and increased bleeding in people with hemophilia** have been reported in patients taking protease inhibitor medicines, including PREZISTA<sup>®</sup>.
- **Changes in body fat** can happen in people who take HIV medicines. The exact cause and long-term health effects of these conditions are not known.
- **Changes in your immune system** can happen when you start taking HIV medicines. Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time.

The most common side effects of PREZISTA<sup>®</sup> include diarrhea, nausea, rash, headache, stomach pain, and vomiting.

These are not all the possible side effects of PREZISTA<sup>®</sup>. For more information, ask your healthcare provider. Tell your healthcare provider if you have any side effect that bothers you or that does not go away. Do not change your dose or stop treatment with PREZISTA<sup>®</sup> without talking to your healthcare provider.

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088. You may also report side effects to Janssen Products, LP at 1-800-JANSSSEN (1-800-526-7736).**

Please refer to the NORVIR<sup>®</sup> (ritonavir) Patient Information Leaflet for additional information on precautionary measures.

**Please read the accompanying Important Brief Summary for PREZISTA<sup>®</sup> for more details.**

cp-07235v2

# Symtuza<sup>®</sup>

darunavir/cobicistat/emtricitabine/  
tenofovir alafenamide tablets  
800mg/150mg/200mg/10mg

## WHAT IS SYMTUZA<sup>®</sup>?

SYMTUZA<sup>®</sup> is a prescription medicine that is used without other antiretroviral medicines to treat Human Immunodeficiency Virus-1 (HIV-1) infection in adults who:

- have not received anti-HIV-1 medicines in the past, or
- when their healthcare provider determines that they meet certain requirements.

HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS).

## Important Safety Information

### WHAT IS THE MOST IMPORTANT INFORMATION I SHOULD KNOW ABOUT SYMTUZA<sup>®</sup>?

**SYMTUZA<sup>®</sup> can cause serious side effects including:**

- **Worsening of hepatitis B virus infection.** Your healthcare provider will test you for hepatitis B virus (HBV) before starting treatment with SYMTUZA<sup>®</sup>. If you have HBV infection and take SYMTUZA<sup>®</sup>, your HBV may get worse (flare-up) if you stop taking SYMTUZA<sup>®</sup>.

- o Do not stop taking SYMTUZA<sup>®</sup> without first talking to your healthcare provider.
- o Do not run out of SYMTUZA<sup>®</sup>. Refill your prescription or talk to your healthcare provider before your SYMTUZA<sup>®</sup> is all gone.

- o If you stop taking SYMTUZA<sup>®</sup>, your healthcare provider will need to check your health often and do blood tests regularly for several months to check your HBV infection or give you a medicine to treat your HBV infection. Tell your healthcare provider about any new or unusual symptoms you may have after you stop taking SYMTUZA<sup>®</sup>.

- **Change in liver enzymes.** People with a history of hepatitis B or C virus infection or who have certain liver enzyme changes may have an increased risk of developing new or worsening liver problems during treatment with SYMTUZA<sup>®</sup>. Liver problems can also happen during treatment with SYMTUZA<sup>®</sup> in people without a history of liver disease. Your healthcare provider may need to do tests to check your liver enzymes before and during treatment with SYMTUZA<sup>®</sup>.

- **Severe liver problems.** In rare cases, severe liver problems can happen that can lead to death. **Tell your healthcare provider right away if you get these symptoms:**
  - o Skin or the white part of your eyes turn yellow
  - o Dark “tea-colored” urine
  - o Light-colored stools

o Loss of appetite for several days or longer

- o Nausea
- o Vomiting
- o Stomach area pain

**SYMTUZA<sup>®</sup> may cause severe or life-threatening skin reactions or rashes** which may sometimes require treatment in a hospital. Call your healthcare provider right away if you develop a rash. **Stop taking SYMTUZA<sup>®</sup>** and call your healthcare provider right away if you develop any skin changes with symptoms below:

- Fever
- Tiredness
- Muscle or joint pain
- Blisters or skin lesions
- Mouth sores or ulcers
- Red or inflamed eyes, like “pink eye” (conjunctivitis)

### Who should not take SYMTUZA<sup>®</sup>?

• Do not take SYMTUZA<sup>®</sup> with any of the following medicines: alfuzosin, carbamazepine, cisapride, colchicine (if you have liver or kidney problems), dronedarone, elbasvir and grazoprevir, ergot-containing medicines (such as: dihydroergotamine, ergotamine tartrate, methylergonovine), lovastatin or a product that contains lovastatin, lurasidone, oral midazolam (when taken by mouth), phenobarbital, phenytoin, pimozide, ranolazine, rifampin, St. John’s wort (*Hypericum perforatum*) or a product that contains St. John’s wort, sildenafil when used for pulmonary arterial hypertension (PAH), simvastatin or a product that contains simvastatin, or triazolam.

• Serious problems can happen if you take any of these medicines with SYMTUZA<sup>®</sup>.

**Before taking SYMTUZA<sup>®</sup>, tell your healthcare provider about all of your medical conditions, including if you:**

- have liver problems (including hepatitis B or hepatitis C), have kidney problems, are allergic to sulfa (sulfonamide), have diabetes, have hemophilia, or have any other medical condition.
- are pregnant (if you become pregnant while taking SYMTUZA<sup>®</sup>), or plan to become pregnant. It is unknown if SYMTUZA<sup>®</sup> will harm your unborn baby.
- o SYMTUZA<sup>®</sup> should not be used during pregnancy.
- are breastfeeding or plan to breastfeed. Do not breastfeed if you take SYMTUZA<sup>®</sup>.

**Tell your healthcare provider about all the medicines you take,** including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines interact with SYMTUZA<sup>®</sup>. **Keep a list of your medicines to show your healthcare provider and pharmacist. Do not start taking a new medicine without telling your healthcare provider.**

### HOW SHOULD I TAKE SYMTUZA<sup>®</sup>?

- Take SYMTUZA<sup>®</sup> 1 time a day with food.

### WHAT ARE THE POSSIBLE SIDE EFFECTS OF SYMTUZA<sup>®</sup>?

SYMTUZA<sup>®</sup> may cause serious side effects including:

- See **“What is the most important information I should know about SYMTUZA<sup>®</sup>?”**
- **Immune system changes** can happen in people who start HIV medications.
- **New or worse kidney problems, including kidney failure.**
- o Your healthcare provider should do blood and urine tests to check your kidneys before you start and while you are taking SYMTUZA<sup>®</sup>.

- **Too much lactic acid in your blood (lactic acidosis).**

o Too much lactic acid is a serious but rare medical emergency that can lead to death. **Tell your healthcare provider right away if you get these symptoms:** weakness or being more tired than usual, unusual muscle pain, being short of breath or fast breathing, stomach pain with nausea and vomiting, cold or blue hands and feet, feel dizzy or lightheaded, or a fast or abnormal heartbeat.

- **Diabetes and high blood sugar (hyperglycemia).** Some people who take protease inhibitors including SYMTUZA<sup>®</sup> can get high blood sugar, develop diabetes, or your diabetes can get worse. Tell your healthcare provider if you notice an increase in thirst or if you start urinating more often while taking SYMTUZA<sup>®</sup>.
- **Changes in body fat** can happen in people taking HIV-1 medications.
- **Increased bleeding** can occur in people with hemophilia who are taking SYMTUZA<sup>®</sup>.

**The most common side effects of SYMTUZA<sup>®</sup> are:** Diarrhea, rash, nausea, fatigue, headache, stomach problems, and gas.

These are not all of the possible side effects of SYMTUZA<sup>®</sup>.

**Please read the accompanying Important Brief Summary for SYMTUZA<sup>®</sup> for more details.**

cp-62077v1

# ONCE-DAILY EDURANT<sup>®</sup>

(rilpivirine) tablets

## About EDURANT<sup>®</sup>

• EDURANT<sup>®</sup> (rilpivirine) is a prescription medicine that is used with other antiretroviral medicines to treat Human Immunodeficiency Virus-1 (HIV-1) in people 12 years of age and older and who weigh at least 77 lbs (35 kg).

– Have **never** taken HIV medicines before, **and**

– Have an amount of HIV in their blood (called “viral load”) that is no more than 100,000 copies/mL

• EDURANT<sup>®</sup> is not recommended for patients less than 12 years of age or who weigh less than 77 lbs (35 kg)

**Please read Important Safety Information below, and talk to your healthcare provider to learn if EDURANT<sup>®</sup> is right for you.**

## Important Safety Information

### Who should not take EDURANT<sup>®</sup>?

**Do not take EDURANT<sup>®</sup> if you also take:**

- anti-seizure medicines:
  - carbamazepine – phenobarbital
  - oxcarbazepine – phenytoin
- anti-tuberculosis (anti-TB) medicines:
  - rifampin – rifapentine
- proton pump inhibitor (PPI) medicine for certain stomach or intestinal problems:
  - esomeprazole – omeprazole – rabeprazole
  - lansoprazole – pantoprazole sodium
- more than 1 dose of the steroid medicine dexamethasone or dexamethasone sodium phosphate
- St. John’s wort (*Hypericum perforatum*)

### What should I tell my healthcare provider before taking EDURANT<sup>®</sup>?

**Before taking EDURANT<sup>®</sup>, tell your healthcare provider about all your medical conditions, including if you:**

- have or had liver problems, including hepatitis B or C virus infection
- have kidney problems
- have ever had a mental health problem
- are pregnant or plan to become pregnant. It is not known if EDURANT<sup>®</sup> will harm your unborn baby. Tell your healthcare provider if you become pregnant during treatment with EDURANT<sup>®</sup>

- are breastfeeding or plan to breastfeed. **Do not breastfeed if you take EDURANT<sup>®</sup>**

– You should not breastfeed if you have HIV-1 because of the risk of passing HIV-1 to your baby.

– It is not known if EDURANT<sup>®</sup> passes into your breast milk. Talk with your healthcare provider about the best way to feed your baby during EDURANT<sup>®</sup> treatment.

**Tell your healthcare provider about all the medicines you take, including** prescription and over-the-counter medicines, vitamins, and herbal supplements.

**Do not start taking a new medicine without telling your healthcare provider.** Your healthcare provider can tell you if it is safe to take EDURANT<sup>®</sup> with other medicines

### How should I take EDURANT<sup>®</sup>?

- Take EDURANT<sup>®</sup> every day exactly as your healthcare provider tells you to.
- **Take EDURANT<sup>®</sup> 1 time each day with a meal.** A protein drink alone does not replace a meal.
- Do not change your dose or stop taking EDURANT<sup>®</sup> without first talking with your healthcare provider. Stay under the care of your healthcare provider during treatment with EDURANT<sup>®</sup>.
- Do not miss a dose of EDURANT<sup>®</sup>.

• If you take an H<sub>2</sub>-receptor antagonist (famotidine, cimetidine, nizatidine, or ranitidine), you should take these medicines at least 12 hours before or at least 4 hours after you take EDURANT<sup>®</sup>.

• If you take antacids, or other products that contain aluminum, calcium carbonate, or magnesium hydroxide, you should take these medicines at least 2 hours before or at least 4 hours after you take EDURANT<sup>®</sup>.

• If you miss a dose of EDURANT<sup>®</sup> within 12 hours of the time you usually take it, take your dose of EDURANT<sup>®</sup> with a meal as soon as possible. Then, take your next dose of EDURANT<sup>®</sup> at the regularly scheduled time. If you miss a dose of EDURANT<sup>®</sup> by more than 12 hours of the time you usually take it, wait and then take the next dose of EDURANT<sup>®</sup> at the regularly scheduled time.

• Do not take more than your prescribed dose to make up for a missed dose.

• If you take too much EDURANT<sup>®</sup>, call your healthcare provider or go to the nearest hospital emergency room right away.

### What are the possible side effects of EDURANT<sup>®</sup>?

**EDURANT<sup>®</sup> can cause serious side effects including:**

- **Severe skin rash and allergic reactions.** Skin rash is a common side effect of EDURANT<sup>®</sup>. Skin rash can be serious. Call your healthcare provider right away if you

get a rash. In some cases, rash and allergic reaction may need to be treated in a hospital. If you get a rash with any of the following symptoms, **stop taking EDURANT<sup>®</sup> and get medical help right away:**

- fever – redness or swelling of the eyes (conjunctivitis)
- skin blisters – swelling of the face, lips, mouth, tongue, or throat
- mouth sores – trouble breathing or swallowing
- pain on the right side of the stomach (abdominal) area
- dark-colored urine “tea colored”

- **Change in liver enzymes.** People with a history of hepatitis B or C virus infection or who have certain liver function test changes may have an increased risk of developing new or worsening liver problems during treatment with EDURANT<sup>®</sup>. Liver problems have also happened during treatment with EDURANT<sup>®</sup> in people without a history of liver disease. Your healthcare provider may need to do tests to check your liver enzymes before and during treatment with EDURANT<sup>®</sup>.

- **Depression or mood changes. Tell your healthcare provider right away if you have any of the following symptoms:**

- feeling sad or hopeless
- feeling anxious or restless
- have thoughts of hurting yourself (suicide) or have tried to hurt yourself

- **Changes in body fat** can happen in people who take HIV medicine. These changes may include increased amount of fat in the upper back and neck (“buffalo hump”), breast, and around the middle of your body (trunk). Loss of fat from the legs, arms, and face may also happen. The exact cause and long-term health effects of these problems are not known.

- **Changes in your immune system (Immune Reconstitution Syndrome)** can happen when you start taking HIV 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 healthcare provider right away if you start having any new symptoms after starting your HIV-1 medicine.

**The most common side effects of EDURANT<sup>®</sup> include** depression, headache, trouble sleeping (insomnia), and rash.

This is not a complete list of all side effects. If you experience these or other symptoms, contact your healthcare professional right away. Do not stop taking EDURANT<sup>®</sup> or any other medications without first talking to your healthcare professional.

**Please read the accompanying Important Brief Summary for EDURANT<sup>®</sup> for more details.**

cp-51056v1

# INTELENCE<sup>®</sup>

(etravirine) tablets

## About INTELENCE<sup>®</sup> (etravirine)

• INTELENCE<sup>®</sup> is a prescription medicine that is used in combination with other antiretroviral medicines to treat human immunodeficiency virus-1 (HIV-1) infection in adults and children 2 years of age and older, who have taken HIV-1 medicines in the past. HIV-1 is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

• INTELENCE<sup>®</sup> is not recommended for use in children less than 2 years of age.

**INTELENCE<sup>®</sup> does not cure HIV infection or AIDS.** You must stay on continuous HIV therapy to control your HIV infection and decrease HIV-related illnesses.

Ask your healthcare professional if INTELENCE<sup>®</sup> is right for you.

## Important Safety Information

### What are the possible side effects of INTELENCE<sup>®</sup>?

**INTELENCE<sup>®</sup> can cause serious side effects including:**

- **Severe skin rash and allergic reactions.** Skin rash is a common side effect of INTELENCE<sup>®</sup>. Rash can be serious. Call your healthcare provider right away if you get a rash. In some cases, severe rash and allergic reaction may need to be treated in a hospital and may lead to death

- If you get a rash with any of the following symptoms, stop taking INTELENCE<sup>®</sup> and call your healthcare provider right away:

- o fever
- o generally ill feeling
- o extreme tiredness
- o muscle or joint aches
- o blisters or sores in mouth
- o blisters or peeling of the skin
- o redness or swelling of the eyes
- o swelling of the mouth, lips, or face
- o problems breathing

• Sometimes allergic reactions can affect body organs, such as your liver. Call your healthcare provider right away if you have any of the following signs or symptoms of liver problems:

- o yellowing of your skin or whites of your eyes
- o dark or tea-colored urine
- o pale-colored stools (bowel movements)
- o nausea or vomiting
- o loss of appetite
- o pain, aching, or tenderness on the right side of your stomach area

• **Changes in your immune system** can happen when you start taking HIV medicines. Your immune system may get stronger and begin to fight infections that have been hidden

• **Changes in body fat** can happen in people taking HIV-1 medicines. The cause and long-term health effects of this condition is not known

• The most common side effects of INTELENCE<sup>®</sup> in adults include rash as well as numbness, tingling or pain in the hands or feet

• The most common side effects of INTELENCE<sup>®</sup>