



DOCTOR DISCUSSION GUIDE

When choosing an HIV-1 treatment, it's important to talk to your doctor about topics that can be important to your health, including all the medications you are taking and any other concerns you may have.

WHAT ARE ISENTRESS AND ISENTRESS HD?

ISENTRESS is a prescription HIV medicine used with other antiretroviral medicines to treat human immunodeficiency virus-1 (HIV-1) infection in adults, and in children weighing at least 4.4 pounds (2 kg). ISENTRESS HD is a prescription HIV medicine used with other antiretroviral medicines to treat HIV-1 infection in adults, and in children weighing at least 88 pounds (40 kg). HIV is the virus that causes AIDS (Acquired Immune Deficiency Syndrome).

ISENTRESS should not be used in children weighing less than 4.4 pounds (2 kg).

Use this form when visiting your doctor to help get the most out of your conversation and to find the right HIV-1 treatment.

CONCERNED ABOUT SIDE EFFECTS? Ask your doctor about any side effects you may be worried about.

ISENTRESS AND ISENTRESS HD HAVE A LOW RATE OF SIDE EFFECTS

The most common side effects include: trouble sleeping, headache, dizziness, nausea, and tiredness. These are not all possible side effects. Some side effects can be serious:

SEVERE SKIN REACTIONS AND ALLERGIC REACTIONS

Stop using ISENTRESS or ISENTRSS HD and call your doctor or get medical help right away if you develop a rash with:

- Fever Generally ill feeling Extreme tiredness Muscle or joint aches Blisters or sores in mouth
- Blisters or peeling of skin
 Redness or swelling of eyes
 Swelling of the mouth, lips, or face
 Problems breathing

Some of these reactions can be serious and may be life-threatening.

LIVER PROBLEMS

Call your doctor right away if you have any of the following signs or symptoms:

- Yellowing of your skin or the whites of your eyes Dark or tea-colored urine Pale-colored stools (bowel movements)
- Nausea or vomiting Loss of appetite Pain, aching, or tenderness on the right side of your stomach area

CHANGE IN IMMUNE SYSTEM

Your immune system may get stronger and begin to fight infections that have been hidden in your body for a long time. You should tell your doctor right away if you start having new symptoms after starting your HIV-1 medicine.

IMPORTANT SAFETY INFORMATION

Some people who take ISENTRESS or ISENTRESS HD develop severe skin reactions and allergic reactions that can be serious, and may be life-threatening or lead to death. If you develop a rash, call your doctor right away. If you develop a rash with any of the following symptoms, stop using ISENTRESS or ISENTRESS HD and call your doctor or get medical help right away: fever; generally ill feeling; extreme tiredness; muscle or joint aches; blisters or sores in mouth; blisters or peeling of skin; redness or swelling of the eyes; swelling of the mouth, lips, or face; problems breathing.

Sometimes allergic reactions can affect body organs, such as your liver. Call your doctor right away if you have any of the following signs or symptoms of liver problems: yellowing of your skin or whites of your eyes; dark or tea-colored urine; pale-colored stools (bowel movements); nausea or vomiting; loss of appetite; pain, aching, or tenderness on the right side of your stomach area.





TAKING MULTIPLE MEDICATIONS? Tell your doctor about all medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Also tell your doctor about any recreational drugs you may be taking.

ISENTRESS and ISENTRESS HD can be taken with a wide range of non-HIV medications, including statins, opioid analgesics, contraceptives, azole antifungals, and proton pump inhibitors.

SOME MEDICINES INTERACT WITH ISENTRESS.

Tell your doctor if you take: aluminum and/or magnesium, or other drugs such as carbamazepine, phenobarbital, and phenytoin. It is not recommended to take these medicines with ISENTRESS.

SOME MEDICINES INTERACT WITH ISENTRESS HD.

Tell your doctor if you take: antacids containing aluminum, magnesium, or calcium; rifampin; tipranavir/ritonavir; etravirine; or other drugs such as carbamazepine, phenobarbital, and phenytoin. It is not recommended to take these medicines with ISENTRESS HD

Do not start any new medicines without first talking with your doctor. Your doctor will tell you if it's safe to take ISENTRESS or ISENTRESS HD with other medicines.

- Tell your doctor about all medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
- Keep a list of your medicines to show your doctor and pharmacist.
- Ask your doctor or pharmacist for a list of medicines that interact with ISENTRESS and ISENTRESS HD

IMPORTANT SAFETY INFORMATION (CONTINUED)

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 right away if you start having new symptoms after starting your HIV-1 medicine.

People taking ISENTRESS or ISENTRESS HD may still develop infections or other conditions associated with HIV-1 infections.

The most common side effects of ISENTRESS or ISENTRESS HD include: trouble sleeping, headache, dizziness, nausea, and tiredness. Less common side effects include: depression, hepatitis, genital herpes, herpes zoster including shingles, kidney failure, kidney stones, indigestion or stomach area pain, vomiting, suicidal thoughts and actions, and weakness.

Tell your doctor before you take ISENTRESS or ISENTRESS HD if you have a history of a muscle disorder called rhabdomyolysis or myopathy or increased levels of creatine kinase in your blood.

Tell your doctor right away if you get unexplained muscle pain, tenderness, or weakness while taking ISENTRESS or ISENTRESS HD. These may be signs of a rare serious muscle problem that can lead to kidney problems.

These are not all the possible side effects of ISENTRESS or ISENTRESS HD. For more information, ask your doctor or pharmacist. Tell your doctor if you have any side effect that bothers you or that does not go away.

Tell your doctor about all your medical conditions, including if you have any allergies, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed. **Do not breastfeed if you take ISENTRESS or ISENTRESS HD.** Women with HIV should not breastfeed because their babies could be infected with HIV through their breast milk.

Tell your doctor about all the medicines you take, including, prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines interact with ISENTRESS or ISENTRESS HD. Do not start taking a new medicine without telling your doctor. Your doctor can tell you if it is safe to take ISENTRESS or ISENTRESS HD with those other medicines.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call FDA at 1-800-FDA-1088.

Please read the accompanying <u>Patient Information</u> and <u>Instructions for Use</u> for ISENTRESS and ISENTRESS HD and discuss them with your doctor. The physician <u>Prescribing Information</u> also is available.

