cabotegravir (Vocabria)

WHAT IS CABOTEGRAVIR?

Cabotegravir, also known as cabotegravir sodium or CAB (brand name Vocabria), is a drug used as part of antiretroviral therapy (ART). The FDA approved cabotegravir in 2021 as an antiretroviral drug (ARV) for people with HIV infection. Cabotegravir is manufactured by ViiV Healthcare.

Cabotegravir is a type of drug called an integrase inhibitor. Integrase inhibitors block integrase (an HIV enzyme). HIV uses integrase to insert (integrate) its viral DNA into the DNA of host CD4 cells. Blocking integrase prevents HIV from replicating.

When used with rilpivirine (Edurant) to treat HIV infection, cabotegravir may help:

- Reduce the amount of HIV in your blood. This is called viral load.
- Increase the number of CD4 cells in your blood, that help fight off other infections.

Reducing the amount of HIV and increasing CD4 cells in your blood may help improve your immune system. This may reduce your risk of death or getting opportunistic infections (OIs) that can happen when your immune system is weak. Read more about viral suppression.

Cabotegravir does not cure HIV infection or AIDS. You must keep taking HIV medicines to control HIV infection and decrease HIV-related illnesses.

WHO SHOULD TAKE CABOTEGRAVIR?

Cabotegravir is a prescription HIV medicine that is used in combination with another ARV called rilpivirine (Edurant) for short-term treatment of HIV infection in adults to replace their current ARVs when their healthcare provider determines that they meet certain requirements.

Cabotegravir is used in the following ways:

- To assess the tolerability of cabotegravir before receiving the long-acting combination HIV medicine cabotegravir/rilpivirine (Cabenuva) extended-release injectable suspensions.
- As oral therapy for people who will miss planned injection dosing with Cabenuva.

The safety and effectiveness of cabotegravir has not been established in children under 18 years of age. Cabotegravir has not been carefully studied in the elderly (65 years of age and older).

All people living HIV should be on ART to keep healthy AND not transmit the virus to others. You and your healthcare provider should consider your CD4 cell count, your viral load, any symptoms you are having, and your preferences when deciding which HIV medications are right for you. Read more about U.S. ART guidelines.

WHO SHOULD NOT TAKE CABOTEGRAVIR?

Do not take cabotegravir if you are allergic to cabotegravir or any of the ingredients in this drug.

Do not take cabotegravir if you are taking any of the following medicines. Taking cabotegravir with these medicines may affect how cabotegravir works. Cabotegravir may cause serious or life-threatening side effects or death when used with these medicines:

- Seizure medicines: carbamazepine, oxcarbazepine, phenobarbital, phenytoin
- Tuberculosis (TB) medicines: rifampin, rifapentine

Ask your healthcare provider or pharmacist if you are not sure if your medicine is one that is listed above. If you have taken any of these medicines in the past four weeks, talk to your healthcare provider or pharmacist before starting treatment with cabotegravir.

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE TAKING CABOTEGRAVIR?

Before you take cabotegravir tell your healthcare provider about all of your medical conditions, and in particular if you:

- Have ever had a skin rash or an allergic reaction to medicines that contain cabotegravir
- Have ever had liver problems

- Have ever had mental health problems

Talk to your healthcare provider if you are pregnant, you plan to become pregnant, you become pregnant, or think you may be pregnant during treatment with cabotegravir. It is not known if cabotegravir will harm your unborn baby. There is a pregnancy registry for people who take ARVs during pregnancy. The purpose of this registry is to collect information about the health of you and your baby and monitor outcomes in people exposed to ARVs during pregnancy. Talk to your healthcare provider about how you can take part in this registry. Read more about pregnancy and HIV.

Talk to your healthcare provider if you are breastfeeding or plan to breastfeed during treatment with cabotegravir. It is not known if cabotegravir can pass to your baby in your breastmilk. You should not breastfeed if you have HIV because of the risk of passing HIV to your baby. Talk with your healthcare provider about the best way to feed your baby.

WHAT ABOUT DRUG RESISTANCE?

Many new copies of HIV are mutations. These new copies are slightly different from the original virus. Some mutations can keep multiplying even when you are taking an ARV. When this happens, the drug will stop working. This is called developing resistance to the drug. Sometimes, if your virus develops resistance to one ARV, it will also have resistance to other ARVs. This is called cross-resistance. Read more about HIV drug resistance.

Resistance can develop quickly. It is very important to take ARVs according to instructions, on schedule, and not to skip or reduce doses.

HOW IS CABOTEGRAVIR TAKEN?

Cabotegravir is taken by mouth as a tablet. The recommended dosage of cabotegravir for adults is one 30 mg tablet once daily, in combination with one 25 mg tablet of rilpivirine (Edurant).

Take one cabotegravir tablet and one rilpivirine tablet once daily for one month (at least 28 days) exactly as your healthcare provider tells you. You will receive treatment with oral cabotegravir and rilpivirine tablets for one month (at least 28 days) before you receive Cabenuva extended-release injectable suspensions for the first time. This will allow your healthcare provider to assess how well you tolerate these medicines. Your final dose of cabotegravir and rilpivirine tablets should be taken on the same day you receive your first injections of Cabenuva.

If you miss or plan to miss a scheduled monthly injection of Cabenuva by more than 7 days, call your healthcare provider right away to discuss your treatment options.

Take cabotegravir at the same time each day with or without food. If you take cabotegravir at the same time as rilpivirine, you should take it with a meal.

If you take antacid products that contain aluminum, magnesium hydroxide, or calcium carbonate, they should be taken at least 2 hours before or 4 hours after you take cabotegravir. Do not miss a dose of cabotegravir. If you miss a dose of cabotegravir, take it as soon as you remember.

Cabotegravir is also available in 1 combination medication. Combination HIV medicines contain 2 or more HIV medicines from 1 or more drug classes.

- cabotegravir/rilpivirine (Cabenuva)

WHAT ARE THE SIDE EFFECTS?

When you start any ARV, you may have temporary side effects such as headaches, nausea, indigestion, or a general sense of feeling ill. These side effects usually get better or disappear over time.

The most common side effects of cabotegravir are headaches, nausea, abnormal dreams, anxiety, and sleep disorders.

Cabotegravir can cause serious side effects including:

Allergic reactions. Call your healthcare provider right away if you develop a rash with cabotegravir. Stop taking cabotegravir and get medical help right away if you develop a rash with any of the following signs or symptoms:

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

Liver problems. Liver problems have happened in people with or without history of liver problems or other risk factors. Your healthcare provider may do blood tests to check your liver function. Call your healthcare provider right away if you develop any of the following signs or symptoms of liver problems:

- Your skin or the white part of your eyes turns yellow (jaundice)
- Dark or “tea-colored” urine
- Light-colored stools (bowel movements)
- Nausea or vomiting
- Loss of appetite
- Pain, aching, or tenderness on the right side of your stomach area
- Itching

Depression or mood changes. Call your healthcare provider or get emergency medical help right away if you have any of the following symptoms:

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

These are not all the possible side effects of cabotegravir. For more information, ask your healthcare provider or pharmacist. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

HOW DOES CABOTEGRAVIR REACT WITH OTHER DRUGS?

All ARVs can interact with other drugs or supplements you are taking. These interactions can change the amount of each drug in your bloodstream and cause an under- or overdose. New interactions are constantly being identified. **Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your healthcare provider can tell you if it is safe to take cabotegravir with other medicines.

See above for a list of medicines that should not be taken with cabotegravir.

MORE INFORMATION

Download the full Prescribing Information, including the Patient Information leaflet.

You should also read the Patient Information that comes with rilpivirine (Edurant).

Visit the Cabenuva website.

Check out the ViiV Healthcare Patient Assistance Program.

Get a ViiV Healthcare Savings Card.

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