

# Vocabria + Rekambys® | (cabotegravir, rilpivirine)

This leaflet is designed to give you a general idea of the most important things you need to know about your new medicine. It is not supposed to replace the manufacturer's leaflet that comes with the medicine but is intended to be read alongside it. After reading this leaflet if you have any questions please ask your clinic team.

Clinic contact details:

## What are cabotegravir and rilpivirine injections?

Cabotegravir (Vocabria®) and rilpivirine (Rekambys®) injections are a type of long-acting (LA) antiretroviral medication that are used to manage HIV.

Cabotegravir tablets are white, oval-shaped, film-coated with 'SV CTV' on one side. Cabotegravir injection is packaged in a glass vial with an orange plastic flip-cap, containing 3 mL solution for injection. Rilpivirine tablets are white to off-white, round, biconvex, film-coated with "TMC" on one side and "25" on the other side. Rilpivirine injection is packaged in a clear glass vial with a yellow plastic flip-cap, containing 3 mL solution for injection.



Cabotegravir-LA and Rilpivirine-LA are both used together for the treatment of HIV. The two medicines work together and must be given at the same time to be effective at maintaining an undetectable virus level.

Please speak to your clinic team if you would like more information about how these drugs work.

## Who are cabotegravir and rilpivirine injections suitable for?

Injectable treatment is likely to be most suitable for people who struggle with taking daily tablets, for example people with difficulty swallowing tablets, or have practical or emotional difficulties associated with taking tablets, or may struggle to take tablets on time.

There are a few circumstances where injectable treatment is not recommended at present:

- Women who are pregnant or planning to become pregnant
- People living with obesity
- People with an uncommon form of HIV
- People with HIV which is resistant to certain classes of antiretrovirals
- People living with hepatitis B taking tenofovir
- People who have detectable levels of HIV (viral load) in the blood

## Are cabotegravir and rilpivirine injections effective?

The treatment has been shown to be very effective and works well for most people. The studies included people who already had an undetectable viral load on treatment, and who did not have known resistance to either of the medications. However, in the studies, a small number of people (1 in 40) developed a detectable virus level in the blood after 3 years, even if they did not miss any injections.

Although there are limited data this detectable virus level may have implications for U=U. There is a small risk of virological failure and in these cases most people developed resistance to one or both cabotegravir and rilpivirine, leading to fewer future HIV treatment options. For this reason, it is important to get your viral load checked at every visit.

## How should I take cabotegravir and rilpivirine?

### Oral lead-in

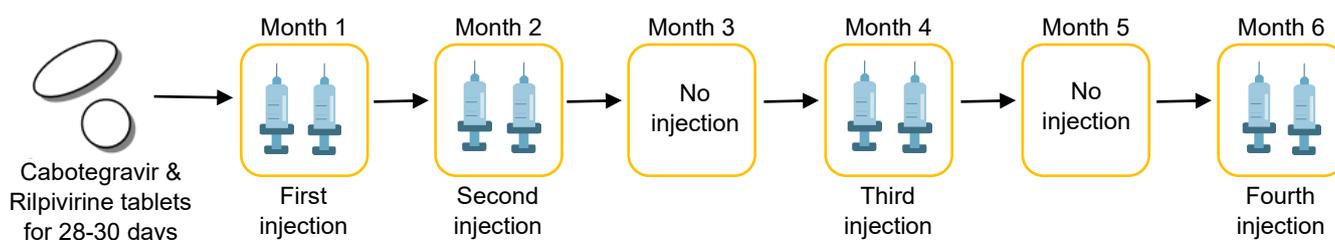
- Your clinic may advise you to take cabotegravir and rilpivirine tablets first for approximately 4 weeks (also known as an oral-lead in), to help the drug reach stable blood levels and to check how well you tolerate the medication.
- The recommended dose is: ONE cabotegravir 30mg tablet ONCE daily and ONE rilpivirine 25mg tablet ONCE daily. Take both tablets together with a main meal around the same time each day.
- If you vomit within 4 hours of taking these medicines take another dose. If you continue to vomit please contact your clinic.
- Please do not crush, if you have trouble swallowing this tablet please contact your clinic team.
- After starting the tablets, you will have a blood test and an appointment to check how you are getting on with your medication. You will take your last dose of cabotegravir and rilpivirine tablets on the date of your **first** injection.

### Direct-to-injection

- A small number of patients **may** start on LA injections immediately. The decision of whether to take tablets initially will depend on individual circumstances and will be decided between you and your clinic doctor.
- Some people may require a slightly different regimen before starting their injections depending on their current circumstance.

### Injections

- If you have started treatment with tablets, you will receive your first injection 28-30 days later.
- If you are starting directly on cabotegravir and rilpivirine LA injections, you will need to take the last dose of your current medication **on the same day** of your first injection.
- A nurse will give you two injections, one cabotegravir and one rilpivirine, into the outer upper muscle of each of your buttocks a few minutes apart (month 1 injection), followed by another set of injections 4 weeks later (month 2 injection).
- Once you have received both month 1 and 2 injections you will then move to 8-weekly injections:



## What if I miss a dose?

HIV medicines work best if there is a constant amount of the medicine in your body. If you are worried about forgetting to take your medicines, speak to your clinic team.

Occasionally you may forget a dose. If this happens, please follow the guidance below and speak with your clinic as soon as possible for advice.



### Oral cabotegravir and rilpivirine

- If you forget to take a cabotegravir and/or rilpivirine tablet and notice within 12 hours of the time you usually take it, take the missed tablet as soon as possible.
- If you notice after 12 hours, then skip that dose and take the next dose as usual.
- Do not take a double dose to make up for a forgotten tablet.
- Report any forgotten doses to your clinic team when you have your first injection



### Injectable cabotegravir and rilpivirine

- If you plan to miss a scheduled injection appointment by more than 7 days, you may take ONE cabotegravir 30 mg tablet and ONE rilpivirine 25 mg tablet ONCE daily for up to 2 **consecutive** months to replace one injection visit.
- This is known as oral bridging and can be used when you are planning to travel or will be away from your clinic for a period of time.
- Please be aware that oral bridging **cannot** be used for more than 2 months. If you expect to be away for a longer period of time, please discuss this with your clinic team as you will need to switch to an alternative oral treatment.
- Depending on the length of time since your last injection, you may be able to resume your 8-weekly injections as normal or have to restart with initiation injections.

**It is important to have your injections on the scheduled date.** If too long is left between receiving your injections, the amount of medicine may not be enough and the virus may develop resistance to the medicine. You may then require a change in your treatment.

- You will be told the date you are next due an injection during your appointment. It may be helpful to keep it in a diary to remind you.
- If you are not able to make it to your injection appointment for the date it is scheduled there is some flexibility as to when you can re-arrange it. Typically, this is within a two-week window, which starts 1 week before and finishes 1 week after the date you were due to have the injection.
- Speak to your clinic team if you think you will not be able to make your appointment as soon as possible. This will give them time to re-arrange it to an appropriate date.

## What are the common side effects with cabotegravir and rilpivirine?

If you experience any side effects, and either they are troubling you or you develop any new symptoms after you start cabotegravir and rilpivirine, do not stop taking your medication, instead please contact your clinic team so they can discuss other treatment options with you and/or advise you how to stop safely.

Some examples of the most common side effects are listed below (for a full list of side effects please check the manufacturer information leaflet):



Injection site reactions: pain, swelling, redness, itching or a small lump where the injection was given. This tends to go away within a week for most people. It is possible that you will have this side effect.



Stomach side effects: feeling sick, vomiting, diarrhoea, reduced appetite, weight gain.



Head side effects: headache, difficulty sleeping, abnormal dreams, drowsiness, feeling low in mood, feeling anxious.



Other: Rash, muscle aches, temperature.

If you are concerned with any side effects or new symptoms after starting treatment you experience, please tell your doctor, nurse or pharmacist who can advise you further.

### What medicines should I avoid with cabotegravir and rilpivirine?

It is important that you tell anyone prescribing you medication about any medicines you are taking. This includes prescribed medicines, recreational or party drugs, and/or supplements you buy over the counter. Always tell your clinic team if you are taking (note this is not an exhaustive list of medicines):

Medicine	Why this is important
<b>Anti-TB drugs:</b> Rifampicin, rifapentine & rifabutin	Do not use these drugs as they can reduce the levels of cabotegravir and rilpivirine tablets <b>and</b> injections in the body and can cause it to stop working properly. Do not start taking these medicines and inform your doctor.
<b>Drugs used to prevent seizures:</b> Carbamazepine (also used for pain), oxcarbazepine, phenobarbital & phenytoin	
<b>St. John's wort:</b> (herbal drug used to treat depression)	
Multivitamins, supplements or antacids that contain: Calcium, magnesium, aluminium, zinc, or iron.	These can stop you from absorbing cabotegravir <b>tablets</b> properly. They should be taken at least 2 hours before or 4 hours after cabotegravir tablets. <b>This interaction only applies to the tablets, so once you have moved over to the injections this interaction is no longer relevant.</b>
Medicines that affect stomach acid e.g. omeprazole, lansoprazole, famotidine	Drugs that reduce stomach acidity can stop rilpivirine <b>tablets</b> from being absorbed properly. <ul style="list-style-type: none"> <li>• Proton pump inhibitors e.g. omeprazole, lansoprazole and pantoprazole, should <b>not</b> be taken with rilpivirine tablets.</li> <li>• H2-receptor antagonists such as famotidine may be an alternative to proton pump inhibitors and can be taken with rilpivirine. However, it must be taken <b>ONCE</b> daily and at least 4 hours after, and 12 hours before, taking rilpivirine tablets.</li> <li>• If you are taking antacids (for indigestion) or calcium supplements, these should be taken at least 2 hours before or 4 hours after both rilpivirine and cabotegravir <b>tablets</b>.</li> <li>• Always speak to your doctor or pharmacist for more information about this before you start to take any acid suppression medication.</li> </ul> <b>This interaction only applies to the tablets, so once you have moved over to the injections this interaction is no longer relevant.</b>