



**Welcome to your new 2-monthly
long-acting injectable treatment**



This handbook is for people who have been prescribed Vocabria (cabotegravir) + Rekambys (rilpivirine), a long-acting injectable treatment for HIV-1.

Vocabria and Rekambys come with their own Patient Information Leaflets inside of the medicine packaging. Make sure you read them carefully as they contain more detailed information.

Reporting of side effects: if you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet.

▼ These medicines are subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See <https://yellowcard.mhra.gov.uk> for how to report side effects. Side effects should also be reported to GlaxoSmithKline on 0800 221 441.



Contents

- 6 Your treatment overview
- 8 Your treatment steps
- 9 Your treatment schedule
- 10 Get started
- 12 Then injections every 2 months
- 14 Receiving injections
- 16 Managing your treatment
- 20 Delaying injections or stopping treatment
- 21 FAQs
- 22 Contact information

Your treatment overview

Your treatment consists of 2 long acting injections. Instead of taking tablets every day, you will receive your treatment as 2 injections that last **2 months** at a time, after initiation.



What's in my treatment?

Your long-acting treatment is a combination of 2 antiretroviral drugs called cabotegravir and rilpivirine. They both act to suppress HIV in a similar way as other antiretrovirals and is given as 2 injections every 2 months, after initiation.



How do I start my treatment?

There are 2 ways to start your new treatment: either taking tablets of cabotegravir and rilpivirine first, for at least 28 days, or go directly to receiving long-acting injections.

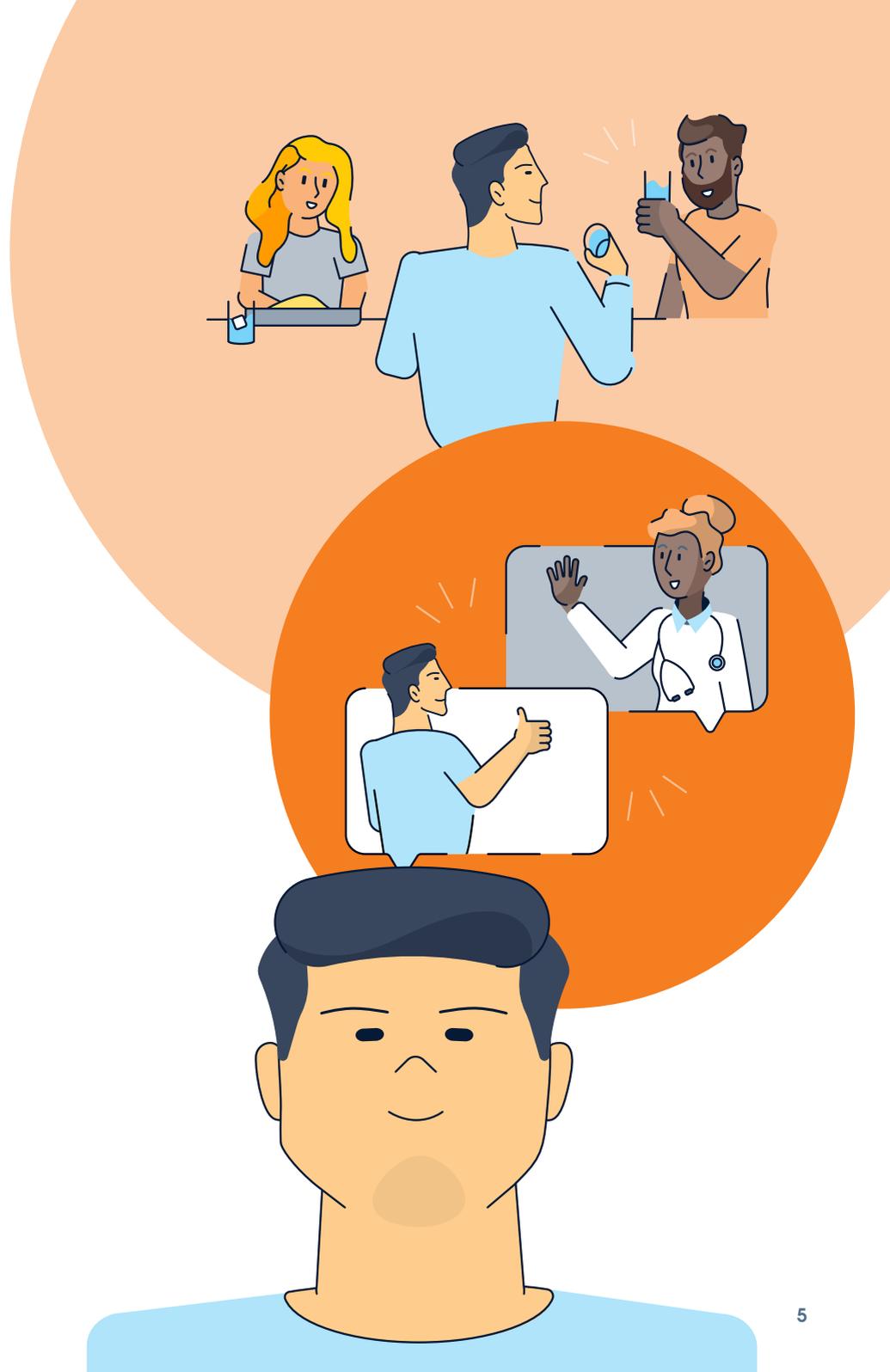
You and your doctor will have decided which option is best for you.



Receiving your injections

During your appointments you will receive 2 injections. Each contains 1 part of your treatment. They will be administered by a member of your healthcare team in the upper, outer muscle of your buttock, 1 injection on each side.

Your time in clinic may vary, your healthcare team will monitor you for any side effects until you are ready to leave the clinic.



Your treatment steps

Get started

When you first start treatment you and your doctor may decide to either start treatment with tablets or start treatment directly with injections

Starting with tablets before first injections

- If you are taking tablets before starting your injections, you can find more information on page 10

OR

Starting treatment directly with injections

- You'll receive your first long-acting injections at your clinic
- 1 month later, you'll return for 2 more injections

Then injections every 2-months

From month 4 onwards, you will come back every 2 months to receive your injections or 6 times per year.

Your treatment schedule

Here's an overview of your long-acting treatment schedule for the first 12 months:



Get started >

When you first start treatment you and your doctor may decide to either start treatment with tablets or start treatment directly with injections

Starting tablets before first injection

If you and your doctor have decided that starting your treatment with tablets is the best option for you, here's what you can expect.



What you need to know

One month before starting injections

- You will take 2 tablets once a day for at least 28 days
- Each tablet is 1 part of your treatment (1 cabotegravir tablet and 1 rilpivirine tablet), they should be taken together
- It is important you take your tablets with a meal, around the same time every day
- After at least 28 days of taking tablets you will have an appointment with your healthcare team. Here you will discuss how you've been feeling and any side effects you may have experienced
- Your doctor will assess whether it's appropriate to proceed with injections. If you and your doctor are both happy, on the last day of your tablets you'll receive your first long-acting injections
- 1 month later, you'll receive 2 more injections



Starting treatment directly with injections

If you and your doctor have decided to start treatment directly with injections, here's what you can expect



What you need to know

Month 1

- Injections will be administered by a member of your healthcare team
- You will receive 2 injections
- Each injection contains 1 part of your treatment (1 injection of cabotegravir and 1 injection of rilpivirine)
- The injections will be given in the upper, outer muscle of your buttocks, 1 on each side

1 month later

- You will receive 2 more injections



Then injections every 2 months >



Once you've received your injections in Months 1 and 2, you will move on to a treatment schedule of receiving injections **once every 2-months**.



What you need to know

Every 2-months

- You have to attend an injection appointment once **every 2-months**
- From here onwards, you will receive a total of **6 treatments per year**



Receiving injections



What do I need to know?

After your injections, your healthcare team will monitor you for any side effects until you are ready to leave the clinic.

Injection site reactions

In clinical studies, these were generally mild to moderate and became less frequent over time. Symptoms may include:

- Very common: pain and discomfort, a hardened mass or lump
- Common: redness, itching, swelling, bruising, warmth or discoloration, which may include a collection of blood under skin
- Uncommon: numbness, minor bleeding, an abscess (collection of pus) or cellulitis (heat, swelling or redness)

It's important to tell your healthcare team if you experience any adverse reactions or if the pain persists or worsens over time.



What will happen?

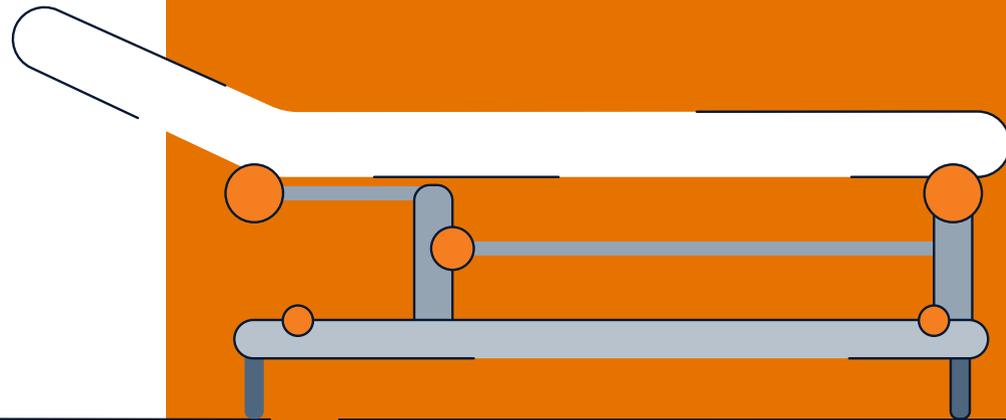


1 You'll most likely be asked to lie down to receive your injections

2 A member of your healthcare team will find the injection site in the upper, outer muscle of your buttock

3 They'll perform the first injection

4 The process will then be repeated in the other buttock





Information to tell your healthcare team about before and during treatment

There are a few things you need to make your healthcare team aware of straight away:

- If you are planning to become pregnant, or are planning to breastfeed. If you become pregnant whilst on this treatment, tell your healthcare team immediately
- If you have or develop an infection with hepatitis B or C
- If you are diagnosed with new liver or kidney problems
- If you are started on any blood-thinning treatment
- If you start taking recreational drugs and/or herbal supplements
- If you are taking any medicines that you have been told may cause a life-threatening irregular heartbeat
- If you get any symptoms of infection e.g. increased temperature
- If you get any symptoms of inflammation e.g. muscle weakness or pain, joint pain or swelling, generalised weakness, palpitations or tremor or excess restlessness
- If you start taking any of these medications:
 - **Carbamazepine, oxcarbazepine, phenytoin, phenobarbital** (to treat epileptic seizures)
 - **Rifabutin, rifampicin or rifapentine** (to treat some bacterial infections such as tuberculosis)
 - **Clarithromycin, erythromycin** (antibiotics)
 - **Dexamethasone** (a steroid)
 - **Methotrexate** (immunosuppressant and chemotherapy)
 - **Omeprazole, lansoprazole, rabeprazole, pantoprazole, esomeprazole, famotidine, cimetidine, nizatidine, ranitidine** (to reduce stomach acid) (applies if you are taking cabotegravir + rilpivirine tablets)
 - **Dabigatran etexilate** (prevents blood from clotting)
 - **Methadone**
 - **St John's wort** (hypericum perforatum – a herbal supplement)

If taking cabotegravir + rilpivirine tablets: antacid medications (including over-the-counter ones) for heartburn, indigestion and stomach ulcers may make cabotegravir and rilpivirine less effective. Please check with your doctor before taking any antacid treatment.

Your long-acting treatment does not affect the combined oral contraceptive pill.

Discuss any concerns you may have with your healthcare team.

Managing your treatment

Once your long-acting treatment is established, it's important to maintain it. Aiming to receive your injections on the same date each time is a big part of this. This is known as your **Target Treatment Date**.



What is your Target Treatment Date?

Your **Target Treatment Date** is the date you should aim for when booking your every 2-month appointments. It's the date that you received your first injections.



Why is it important?

It is important to try to stick to your **Target Treatment Date** as closely as possible. Like with other HIV treatments, following your treatment schedule helps you stay undetectable.



What happens if I need to rearrange an appointment?

Wherever possible, your appointments should be scheduled on your **Target Treatment Date**. Where this is not possible, there is normally some flexibility (appointments can be booked up to 1 week before or after your **Target Treatment Date**).

There may be occasions when you can't attend your scheduled appointment. If that's the case, **talk to your doctor if you think you will not be able to receive your injections at the usual time. Your doctor may recommend you take tablets instead until you are able to receive the injections again.**



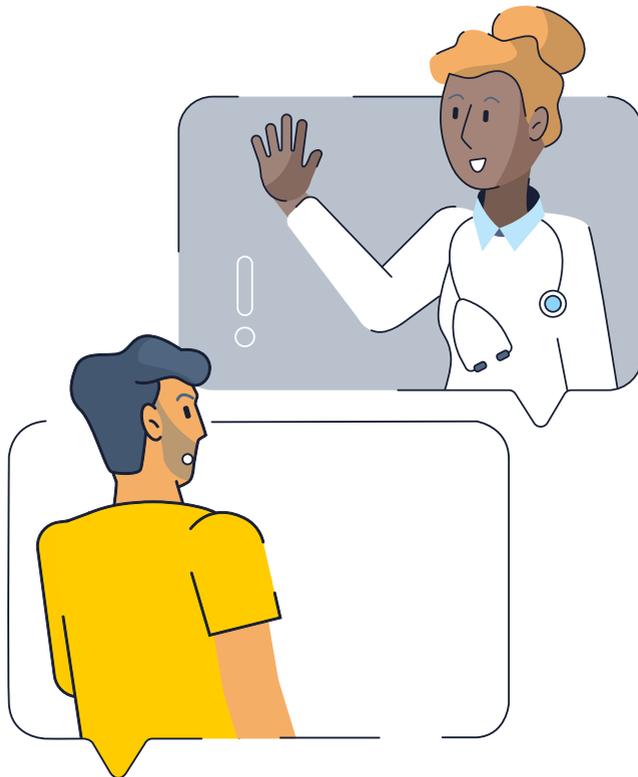
Will I have any side effects?

It's important you tell your healthcare team about any changes to your health or how you're feeling. All medications can have side effects. You can find a list of potential side effects in the **Patient Information Leaflets** that come in the boxes with your medication. Make sure you read them before starting your treatment.

Please ask your healthcare team if you have any questions.

Effects on some blood tests

Your treatments can also result in some changes to blood test results that check your liver and pancreas function, the levels of cells in your blood and your cholesterol/lipid profile. Your healthcare team will be monitoring you for these during your treatment



There are some side effects that are very common and may affect **more than 1 in 10 people**.

You may experience headaches or feel hot/feverish (which may occur within one week after injections). Once you start receiving injections you may experience injection site reactions.

You may also experience some side effects that affect **less than 1 in 10 people** such as:

- **Changes in your energy, mood or sleep**

You may notice you have a lack of energy, feel anxious, depressed, tired, weak, drowsy or experience dizziness. You may also experience abnormal dreams or have difficulty sleeping (insomnia)

Treatment can make you dizzy and have other side effects that make you less alert. Don't drive or use machines unless you are sure you're not affected

- **Changes in your digestive system**

There's a chance you may have a decreased appetite, have a dry mouth, feel sick (nausea), experience vomiting, have more wind (flatulence), have stomach pain, diarrhoea or experience weight gain

- **Other changes to look out for**

These could include an unexplained rash, feeling generally unwell and muscle pain

Some rare side effects may occur. If you experience any of the following, see a doctor straight away:

- If you experience signs of an allergic reaction, such as a skin rash, a high temperature, lack of energy, swelling, sometimes of the face or mouth, causing difficulty in breathing, muscle or joint aches
- If you get any symptoms of infection and inflammation or if you notice any of the symptoms of autoimmune disorders such as, muscle weakness and/or muscle pain, joint pain or swelling, weakness beginning in the hands and feet and moving up towards the trunk of the body, palpitations or tremor, hyperactivity (excessive restlessness and movement)
- If you get severe pain in the tummy (abdomen), especially if the pain spreads and gets worse. This may be caused by inflammation of your pancreas (pancreatitis)

Delaying injections or stopping treatment

If after trying long-acting treatment you're unsure if it is right for you, discuss your concerns with your healthcare team before making a decision.



Delaying injections

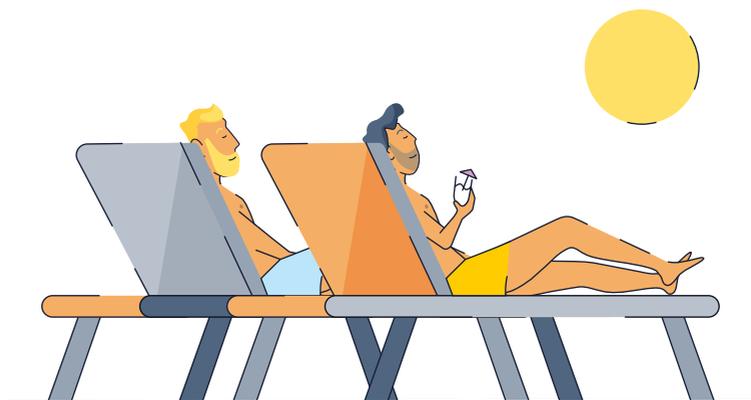
Talk to your doctor if you think you will not be able to receive your injections at the usual time. Your doctor may recommend you take tablets instead, until you are able to receive your injection again.



Stopping your long-acting treatment

If you decide you would like to stop taking your long-acting treatment, let your healthcare team know as soon as possible. **Don't stop taking your treatment without talking to your healthcare team first.**

To reduce the risk of developing viral resistance, you will need to start an alternative treatment within 2 months after your final every 2-month injections (or within 1 month, if you decide to stop after receiving your first injections).



FAQs

What if I miss an injection appointment?

If you miss Vocabria + Rekambys Injections

Contact your doctor immediately to make a new appointment, it is important that you keep your regular planned appointments to receive your injection to control your HIV. Talk to your doctor if you are thinking about stopping treatment.

Talk to your doctor if you think you will not be able to receive your injections at the usual time. Your doctor may recommend you take tablets instead, until you are able to receive injections again.

If I'm starting with tablets before my first injections, what happens if I miss a dose?

If you forget to take a tablet, try to take it as soon as you remember. If you are due to take your next dose in less than 12 hours, don't take your tablets, simply wait to take your next dose as planned. Never take a double dose to make up for the dose you forgot.

If you vomit within 4 hours of taking your tablets, take another 2 with a meal. If you vomited more than 4 hours after taking your tablets, wait until you are scheduled to take your next dose. Don't take a double dose.

Can I give myself the injections somewhere else on my body?

No, the injections must be administered in the upper, outer

buttock muscles and are not suitable for self-injection.

They require a member of your healthcare team to administer them. Speak to your healthcare team if you would like more information.

How long will the treatment stay in my body?

Your treatment is long-acting, so it will stay in your body for longer than the HIV medication in tablets.

Cabotegravir and rilpivirine will stay in your body for a prolonged period of time (at least 1 year) after you've received injections, but the amount will decrease over time.

Having low levels of treatment in your body will not protect you against the virus, and may also increase your risk of developing viral resistance.

You must receive injections every 2-months for your treatment to be effective.

Talk to your healthcare team if you have any concerns.

Can I drink alcohol/take recreational drugs or herbal supplements while on treatment?

Other substances and drugs may interact with your treatment which could make it less effective and increase the risk of developing side effects.

Make sure you tell your healthcare team about any recreational drugs or herbal supplements you are taking and/or if you drink alcohol.

Additional content

**Patient video - what is in your treatment.
Please click below link to access the video.**

<https://videos.gskstatic.com/viiv/VX/UK/videos/mp4/patient-support-video.mp4>



Rekamby (rilpivirine long acting), including the trademark, is owned by the Janssen Pharmaceutical Companies and used under license by the ViiV Healthcare group of companies. All other trademarks are owned by the ViiV Healthcare group.

©2024 ViiV Healthcare group of companies or its licensor.

NP-GB-CBR-BKLT-240002, October 2024