

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed according to a physician's prescription only

Vocabria Tablets

Film-coated tablets

Each tablet contains:

cabotegravir (as sodium) 30 mg

For the list of the inactive and allergenic ingredients in the medicine, see section 2 - "Important information about some of the ingredients in the medicine" and section 6 – "Additional information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Vocabria Tablets are indicated, in combination with rilpivirine tablets, for the short-term treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults who are virologically suppressed (HIV-1 RNA < 50 copies/mL) on a stable anti-retroviral regimen without present or past evidence of viral resistance to, and no prior virological failure with agents of the NNRTI and INI class, for:

- oral lead-in to assess tolerability of Vocabria and rilpivirine prior to administration of long acting cabotegravir injection plus long acting rilpivirine injection.
- oral therapy for adults who will miss planned dosing with cabotegravir injection plus rilpivirine injection.

Therapeutic group:

Vocabria contains the active ingredient cabotegravir. Cabotegravir belongs to a group of anti-retroviral medicines called *integrase inhibitors (INIs)*.

Vocabria Tablets does not cure HIV infection; it keeps the amount of virus in your body at a low level. This helps maintain the number of CD4+ cells in your blood. CD4+ cells are a type of white blood cells that are important in helping your body to fight infection. Your physician will advise you to take Vocabria tablets before administration of the Vocabria injection for the first time.

If you are being given a Vocabria injection, but you are not able to receive your injection, your physician can also recommend that you take the Vocabria tablets instead, until you are able to receive the injection again.

Vocabria tablets are always given in combination with another anti-retroviral medicine called rilpivirine tablets to treat HIV infection. Vocabria and rilpivirine tablets will replace your current anti-retroviral medicines. Refer to the rilpivirine patient leaflet for information on that medicine.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- you have ever developed a severe skin rash, skin peeling, blistering and/or mouth sores.
- you are hypersensitive (allergic) to the active ingredient (cabotegravir) or to any of the additional ingredients contained in this medicine (listed in section 6).
- you are taking any of these medicines as they may affect the way Vocabria works:
 - **carbamazepine, oxcarbazepine, phenytoin and phenobarbital** (medicines to treat epilepsy and prevent fits)
 - **rifampicin or rifapentine** (medicines to treat some bacterial infections such as tuberculosis)

→ **Tell your physician** if you think any of these may apply to you.

Special warnings regarding use of the medicine

Severe skin reaction

The serious skin reactions, Stevens-Johnson syndrome and toxic epidermal necrolysis, have been reported very rarely in association with Vocabria. Stop taking Vocabria and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions.

→ **Read the information** in section 4 of this leaflet (“Side effects”).

Allergic reaction

Vocabria contains the active ingredient cabotegravir, which is an integrase inhibitor. Integrase inhibitors, including cabotegravir, can cause a serious allergic reaction known as a hypersensitivity reaction. You need to know about important signs and symptoms to look out for while you’re taking Vocabria.

→ **Read the information** in section 4 of this leaflet (“Side effects”).

Liver problems including hepatitis B and/or C

Tell your physician if you have or have had problems with your liver, including hepatitis B and/or C. Your physician may evaluate how severe your liver disease is before deciding if you can take Vocabria.

Look out for important symptoms

Some people taking medicines for HIV infection develop other conditions, which can be serious. You need to know about important signs and symptoms to look out for while you’re taking Vocabria. These include:

- symptoms of infections
- symptoms of liver damage

→ **Read the information** in section 4 of this leaflet (“Side effects”).

If you get any symptoms of infection or liver damage:

→ **Tell your physician immediately**. Don’t take other medicines for the infection without your physician’s advice.

Children and adolescents

This medicine is not for use in children or adolescents less than 18 years of age. There is no information about the safety and efficacy of using this medicine in children and adolescents less than 18 years old.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the physician or pharmacist.

Vocabria must not be given with some other medicines (see "Do not use the medicine" earlier in section 2):

Some medicines can affect how Vocabria works or make it more likely that you will have **side effects**. Vocabria can also affect how some other medicines work.

Tell your physician if you are taking one of the medicines in the following list:

- **Medicines called antacids, to treat indigestion and heartburn.** Antacids can stop the medicine in Vocabria tablets from being absorbed into your body.

Do not take these medicines in the 2 hours before you take Vocabria Tablets or for at least 4 hours after you take it.

- **rifabutin** (to treat some bacterial infections such as tuberculosis).

→ **Tell your physician or pharmacist** if you are taking one of these medicines. Your physician may decide that you need extra check-ups.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby:

→ **ask your physician for advice** before using Vocabria.

Pregnancy

- **Vocabria is not recommended during pregnancy.** If needed, your physician will consider the benefit to you and the risk to your baby of receiving Vocabria while you're pregnant. If you are planning to have a baby, **talk to your physician in advance.**
- If you have become pregnant, do not stop taking Vocabria without consulting your physician.

Breast-feeding

Breast-feeding **is not recommended** in women living with HIV because HIV infection can be passed on to the baby in breast milk.

It is not known whether the ingredients of Vocabria can pass into breast milk.

If you're breast-feeding, or thinking about breast-feeding, you should **discuss it with your physician as soon as possible.**

Driving and using machines

Vocabria 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.

Important information about some of the ingredients in the medicine

If you have been told by your physician that you have an intolerance to some sugars, contact your physician before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially sodium-free.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the physician's instructions. Check with the physician or pharmacist if you are uncertain about the preparation dosage and treatment regimen.

The dosage and treatment regimen will be determined by the physician only.

Vocabria Tablets must always be taken with another HIV medicine (rilpivirine tablets).

You should also follow the instructions for rilpivirine carefully.

The leaflet is supplied in the rilpivirine carton.

The recommended dosage is usually:

Dosing schedule for Vocabria Tablets followed by monthly injections:

Which medicine	When		
	Month 1 (at least 28 days)	At Month 2 following one month of tablets.	Month 3 onwards
Vocabria	30 mg tablet once a day	600 mg injection	400 mg injection every month
Rilpivirine	25 mg tablet once a day	900 mg injection	600 mg injection every month

Dosing schedule for Vocabria Tablets followed by every 2 months injections:

Which medicine	When		
	Month 1 (at least 28 days)	At Month 2 and Month 3 following one month of tablets	Month 5 onwards
Vocabria	30 mg tablet once a day	600 mg injection	600 mg injection every 2 months

Rilpivirine	25 mg tablet once a day	900 mg injection	900 mg injection every 2 months
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When you first start treatment with Vocabria, you and your physician may decide to either start treatment with Vocabria tablets or start treatment directly with a Vocabria injection: If you decide to start treatment with tablets, your physician will tell you:

- to take one 30 mg Vocabria tablet and one 25 mg rilpivirine tablet, once a day, **for approximately one month.**
- after that, receive **monthly or every 2 months** injections.

The first month of Vocabria and rilpivirine tablets is called the oral lead-in-period. It allows your physician to assess whether it's appropriate to proceed with injections.

How to take the tablets

Vocabria Tablets should be swallowed with a small amount of water.

Vocabria can be taken with or without food. If you take a Vocabria tablet at the same time as rilpivirine, both tablets should be taken with a meal.

No information is available about crushing/splitting/chewing.

If you cannot receive your Vocabria injection

If you are not able to receive your Vocabria injection, your physician may recommend you take Vocabria tablets or another HIV treatment instead, until you can receive an injection again.

Do not exceed the recommended dose.

Antacid medicines

Antacids, to treat **indigestion and heartburn**, can stop Vocabria Tablets being absorbed into your body and make it less effective.

Do not take an antacid during the two hours before you take Vocabria Tablets or for at least 4 hours after you take it. Talk to your physician for further advice on taking acid-lowering (antacid) medicines with Vocabria Tablets.

If you accidentally have taken a higher dosage

If you accidentally took too many Vocabria tablets, **contact your physician or pharmacist for advice.** If possible, show them the Vocabria package.

If you have taken an overdose or if a child accidentally ingested the medicine, immediately refer to your physician or the emergency room of a hospital and bring the package of medicine with you.

If you forgot to take the medicine

If you notice that you forgot to take the dose within 12 hours of the time you usually take Vocabria Tablets, 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.

If you vomit less than 4 hours after taking Vocabria Tablets, take another tablet. If you vomit more than 4 hours after taking Vocabria Tablets, you do not need to take another tablet until your next scheduled dose.

Adhere to the treatment regimen recommended by your physician.

If you stop taking the medicine

Don't stop taking Vocabria Tablets without advice from your physician

Take Vocabria Tablets for as long as your physician recommends. Don't stop unless your physician advises you to.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the physician or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Vocabria Tablets may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

Stop taking Vocabria and seek medical attention immediately if you notice any of the following symptoms:

- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of the mouth, throat, nose, genitals, and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-

Johnson syndrome, toxic epidermal necrolysis). These serious skin reactions are very rare (may affect **up to 1 in 10,000** people).

Allergic reactions

Vocabria tablets contains cabotegravir, which is an integrase inhibitor. Integrase inhibitors, including cabotegravir, can cause a serious allergic reaction known as a hypersensitivity reaction. These hypersensitivity reactions are uncommon (may affect up to **1 in 100** people).

If you get any of the following symptoms:

- skin reaction (*rash, hives*)
- a high temperature (*fever*)
- lack of energy (*fatigue*)
- swelling, sometimes of the face or mouth (*angioedema*), causing difficulty in breathing
- muscle or joint aches.

→ **Tell your physician immediately.** Your physician may decide to carry out tests to check your liver, kidneys or blood, and may tell you to stop taking Vocabria.

Very common side effects

These may affect **more than 1 in 10** people:

- headache
- fever.

Common side effects

These may affect **up to 1 in 10** people:

- depression
- anxiety
- abnormal dreams
- difficulty in sleeping (*insomnia*)
- dizziness
- feeling sick (*nausea*)
- vomiting
- stomach pain (*abdominal pain*)
- wind (*flatulence*)

- diarrhoea
- rash
- muscle pain (*myalgia*)
- lack of energy (*fatigue*)
- feeling weak (*asthenia*)
- generally feeling unwell (*malaise*)
- weight gain.

Uncommon side effects

These may affect **up to 1 in 100** people:

- suicide attempt and suicidal thoughts (particularly in patients who have had depression or mental health problems before)
- allergic reaction (*hypersensitivity*)
- hives (*urticaria*)
- swelling, sometimes of the face or mouth (*angioedema*), causing difficulty in breathing
- feeling drowsy (*somnolence*)
- liver damage (signs may include yellowing of the skin and the whites of the eyes, loss of appetite, itching, tenderness of the stomach, light-coloured stools or unusually dark urine)
- changes in liver blood tests (increase in transaminases or increase in bilirubin).

Other side effects that may show up in blood tests

- an increase in lipases (a substance produced by the pancreas)

Other possible side effects

People receiving Vocabria and rilpivirine therapy for HIV may get other side effects.

Pancreatitis

If you get severe pain in the abdomen (tummy), this may be caused by inflammation of your pancreas (pancreatitis).

→ **Tell your physician**, especially if the pain spreads and gets worse.

Symptoms of infection and inflammation

People with advanced HIV infection (AIDS) have weak immune systems and are more likely to develop serious infections (*opportunistic infections*). When they start

treatment, the immune system becomes stronger, so the body starts to fight infections.

Symptoms of infection and inflammation may develop, caused by either:

- old, hidden infections flaring up again as the body fights them
- the immune system attacking healthy body tissue (autoimmune disorders).

The symptoms of autoimmune disorders may develop many months after you start taking medicine to treat your HIV infection.

Symptoms may include:

- **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 any symptoms of infection and inflammation or if you notice any of the symptoms above:

→ **Tell your physician immediately.** Don't take other medicines for the infection without your physician's advice.

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the physician.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il/>

5. HOW TO STORE THE MEDICINE?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.

- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Do not discard medicines in the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

- In addition to the active ingredients, the medicine also contains:
Microcrystalline cellulose, lactose monohydrate, sodium starch glycolate (Type A), hypromellose 2910, 3 and 6 mPa*s, magnesium stearate, titanium dioxide (E171), macrogol 400 (E1521).
- What the medicine looks like and the contents of the package:
Vocabria film-coated tablets are white, oval, film-coated tablets, debossed with "SV CTV" on one side.
The tablets are provided in bottles that contain 30 tablets. The bottle is closed with child-resistant closures.
- Instructions for opening: to remove the cap, press down while twisting the cap left (counterclockwise direction) at the same time.
- Instructions for closing: place the cap at the open end of the bottle and twist right (clockwise direction) until fully closed.
- License holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: ViiV Healthcare UK Ltd., London, England.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 169-80-36947.

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