

VIEKIRA PAK-RBV

A combination therapy containing paritaprevir, ritonavir, ombitasvir, dasabuvir and ribavirin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Viekira Pak-RBV.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Viekira Pak-RBV is used for

Viekira Pak-RBV is used to treat chronic (lasting a long time) hepatitis C infection in adults including those with cirrhosis (scarring of the liver).

Hepatitis C is a liver disease caused by a virus which infects and damages liver cells.

This treatment consists of 3 different types of tablets. These must be taken according to the instructions given by your doctor.

Viekira Pak-RBV works by lowering the amount of hepatitis C virus in your body. It removes the virus from your blood over a period of time.

Ask your doctor or pharmacist if you have any questions about why it has been prescribed for you.

Your doctor may have prescribed it for another purpose.

Before you take Viekira Pak-RBV

When you must not take it

Do not take Viekira PAK-RBV if you are pregnant or your female partner is pregnant (if you are male).

Ribavirin may cause birth defects and/or death of an unborn baby. Extreme care must be taken to avoid pregnancy during treatment and for 6 months after completion of treatment with ribavirin.

Two reliable forms of contraception must be used during this time.

Do not take Viekira Pak-RBV if you have an allergy to:

- any medicine containing paritaprevir, ritonavir, ombitasvir, dasabuvir or ribavirin; or
- any of the ingredients listed at the end of this leaflet.

Some symptoms of an allergic reaction include:

- hives, skin rash or itching;
- shortness of breath, wheezing, difficulty breathing or a tight feeling in your chest;
- swelling of the face, lips or tongue, which may cause difficulty in swallowing or breathing.

Do not take Viekira PAK-RBV if you take a medicine that contains:

- alfuzosin hydrochloride
- ranolazine
- amiodarone, quinidine, dronedarone or disopyramide
- astemizole, terfenadine

- blonanserin, lurasidone
- carbamazepine, phenytoin or phenobarbital
- cisapride
- colchicine if you have kidney or liver cirrhosis
- efavirenz
- ergotamine, dihydroergotamine,
- ergonovine or methylergonavine
- ethinyloestradiol-containing medications such as combined oral contraceptives
- fusidic acid
- gemfibrozil, lovastatin simvastatin or atorvastatin
- mitotane, enzalutamide
- oral midazolam, triazolam
- pimozide
- rifampicin
- salmeterol
- Hypericum perforatum (St John's Wort)
- sildenafil (when used for pulmonary arterial hypertension)
- ticagrelor

Do not take Viekira Pak-RBV if you have severe heart problems or have experienced any heart problems in the last 6 months.

Do not take Viekira Pak-RBV if you have severe liver disease or decompensated liver disease.

Do not take Viekira Pak-RBV if you have red blood cell disorders such as thalassaemia or sickle-cell anaemia.

Do not take it after the expiry date printed on the pack or if the packaging is damaged or shows signs of tampering.

If you use this medicine after the expiry date has passed it may not work as well.

If it has expired or is damaged return it to your pharmacist for disposal.

Use in Children

Do not give Viekira Pak-RBV to children or adolescents under 18 years of age.

The use of Viekira Pak-RBV in children and adolescents has not yet been studied.

Before you start to take it

Tell your doctor if you have never been tested for hepatitis B or know you have or have had an infection with the hepatitis B virus.

Your doctor may want to monitor you more closely.

Tell your doctor or pharmacist if you are taking contraceptives that include ethinyloestradiol either to prevent pregnancy or for other reasons.

Your doctor may ask you to stop or change to a different method of birth control (progestin-only or non-hormonal methods) during your treatment with Viekira Pak-RBV.

Viekira Pak-RBV may cause severe liver problems in some patients.

Let your healthcare provider know if you develop the following:

- fatigue or weakness,
- nausea,
- vomiting,
- loss of appetite,

- yellowing of your skin or eyes, or
- darkening of your urine while on treatment with Viekira Pak-RBV.

Do not take Viekira Pak-RBV if you are breastfeeding or plan to breastfeed.

It is not known whether this medicine passes into the breast milk.

Your doctor will discuss the risks and benefits of using this medicine if you are breastfeeding.

Tell your doctor or pharmacist if you have or have had any of the following medical conditions:

- HIV infection
- Heart conditions
- Gout
- Severe liver disease
- Kidney disease

If you have not told your doctor or pharmacist about any of the above, tell them before you take Viekira Pak-RBV.

Tell your doctor if you had a liver transplant.

• If you are taking everolimus, you should not take Viekira Pak-RBV since the dose of everolimus cannot be adjusted to give the correct drug levels when taking Viekira Pak-RBV.

• If you are taking tacrolimus or sirolimus, talk to your doctor about the risks and benefits of taking both tacrolimus or sirolimus and Viekira Pak-RBV at the same time.

• If you are taking ciclosporin, speak to your doctor to confirm the dose and frequency of your ciclosporin while you are taking Viekira Pak-RBV, when you have completed Viekira Pak-RBV or if you have to stop Viekira Pak-RBV for any reason.

Tell your doctor or pharmacist if you have any allergies to any other medicines, foods, preservatives or dyes.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food store.

Some medicines and Viekira Pak-RBV may interfere with each other.

Tell your doctor if you are taking:

- alprazolam, a medicine used for anxiety, panic attacks and trouble sleeping.
- Ciclosporin, everolimus, sirolimus or tacrolimus, medicines used to suppress the immune system
- colchicine, a medicine used to treat gout
- warfarin, fluindione or dabigatran or other similar medicines called vitamin K antagonists that are used to thin the blood
- deferasirox to help reduce iron levels in the blood
- amlodipine, amiodarone, bepridil, digoxin, lidocaine, propafenone or quinidine, medicines used for heart problems
- diazepam, a medicine used for anxiety, alcohol withdrawal or muscle spasm

- erythromycin, a medicine to treat infections
- diltiazem, verapamil or nifedipine, medicines to treat angina
- fexofenadine, a medicine to treat hay fever
- fluticasone, a medicine to treat asthma
- furosemide, a medicine used to prevent fluid retention
- imatinib, a medicine to treat some cancers
- hydrocodone, a medicine to treat pain
- ketoconazole and voriconazole, medicines used to treat fungal infections
- levothyroxine, a medicine to treat thyroid problems
- atazanavir, darunavir, lopinavir, ritonavir or rilpivirine, zidovudine, stavudine, didanosine, medicines used to treat HIV infection
- omeprazole, esomeprazole or lansoprazole, medicines used to treat stomach ulcers and other stomach problems
- quetiapine, a medicine used to treat mental disorders or depression
- repaglinide or metformin, medicines to treat diabetes
- rosuvastatin and pravastatin, medicines used to lower blood cholesterol
- s-mephenytoin, a medicine used to treat epilepsy
- teriflunomide, a medicine used to treat multiple sclerosis
- trazodone, a medicine used to treat depression
- sulfasalazine, a medicine used to treat and manage inflammatory bowel disease or rheumatoid arthritis
- valsartan, losartan or candesartan, medicines used to treat high blood pressure.

These medicines may be affected by Viekira Pak-RBV, or may affect how well it works. You may need to use different amounts of your medicine, or take different medicines. Your doctor or pharmacist has more information on medicines to be careful with or to avoid while taking Viekira Pak-RBV.

How to take Viekira Pak-RBV

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

It is important you follow the instructions your doctor provides about how to take Viekira Pak-RBV and for how long. Not taking the medicine as directed or stopping the medicine too early may cause you to not respond to the medicine and may affect your response to future treatments. If you do not understand the instructions on the box/bottle, ask your doctor or pharmacist for help.

How much to take

Take Viekira Pak-RBV exactly as your doctor has prescribed.

Your doctor will tell you how many tablets to take and at what time of the day.

The usual dose is as follows:

For paritaprevir/ritonavir/ombitasvir tablets which are pink-coloured with "AV1" on one side - Take 2 in the morning.

For dasabuvir tablets which are beige-coloured with "AV2" on one side - Take 1 in the morning and 1 in the evening

For ribavirin tablets (blue tablets with "3RP" on one side and either "200" or "600" on the other) the recommended dose depends on how much you weigh. Instructions are shown below.

- **Weight less than 75kg**
Take two 200mg tablets in the morning and three 200mg tablets in the evening.
- **Weight 75kg or more**
Take one 600mg tablet in the morning and one 600mg tablet in the evening.

Ask your doctor or pharmacist if you are unsure.

Your doctor may change the dose of RBV you take based on test results during treatment.

Follow the instructions of your doctor and pharmacist. Also refer to the Tips card and the packaging for instructions on which tablets to take in the morning and which to take in the evening.

If you are not sure how much and when to take it, ask your doctor or pharmacist.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Take Viekira Pak-RBV during or immediately after a meal, at about the same time every day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

Continue taking your medicine for as long as your doctor or pharmacist tells you

You will take Viekira Pak-RBV for either 12 or 24 weeks. Your doctor will tell you how long your treatment will last.

If you become pregnant while taking Viekira Pak-RBV, you should immediately stop using it and tell your doctor.

If you forget to take it

It is important not to miss a dose of this medicine. If you do miss a dose of paritaprevir/ritonavir/ombitasvir tablets (pink tablets marked with "AV1") and it is:

- **More than 12 hours**
until your next dose - take the missed dose with food as soon as possible.
- **Less than 12 hours**
until your next dose - do not take the missed dose, take your next dose as usual with food.

If you miss a dose of dasabuvir tablets (beige tablets marked with "AV2") and it is:

- **More than 6 hours**
until your next dose - take the missed dose with food as soon as possible.
- **Less than 6 hours**
until your next dose - do not take the missed dose, take your next dose as usual with food.

Do not take a double dose of ribavirin tablets to make up for the dose that you missed.

This may increase the chance of getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for advice.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 764766 [0800 POISON]), or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Viekira Pak-RBV.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using Viekira Pak-RBV

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Viekira Pak-RBV.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon that you are taking this medicine.

Tell your doctor or pharmacist immediately if you become pregnant while taking Viekira Pak-RBV.

Extreme care must be taken to avoid pregnancy during treatment and for 6 months after completion of treatment. The RBV component may cause birth defects and/or death of an unborn baby.

Female patients taking Viekira Pak-RBV should use 2 effective forms of contraception.

Male patients taking Viekira Pak-RBV and their female partners should use 2 effective forms of contraception.

Tell your doctor if you have or have had an infection from Hepatitis B virus (HBV). You may experience a reactivation of a HBV infection

Tell your doctor if, for any reason, you have not taken Viekira Pak-RBV exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not use this medicine to treat any other complaints unless your doctor or pharmacist tells you to.

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not stop taking Viekira Pak-RBV, or change the dosage, without checking with your doctor or pharmacist.

Do not stop using contraceptives whilst taking Viekira Pak-RBV (except for contraceptives that contain

ethinyloestradiol). See 'Before you start to take it' section of this leaflet.

You must not take medicines that contain ethinyloestradiol while taking Viekira Pak-RBV).

Things to be careful of

Be careful driving or operating machinery until you know how Viekira Pak-RBV affects you.

The effect of Viekira Pak-RBV on your ability to drive or use machines is not known.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Viekira Pak-RBV.

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. You may need medical attention if you get some of the side-effects.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Feeling very tired
- Feeling sick
- Itching
- Trouble sleeping
- Unusual weakness or lack of energy
- Tiredness, headaches, being short of breath when exercising, dizziness and looking pale.
- Diarrhoea and vomiting
- Decreased appetite
- Cough
- Muscle spasm if you have received a liver transplant.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

Skin rash, redness, blisters or peeling skin, accompanied by fever, chills, headache, cough, difficulty breathing or swallowing, dizziness or light-headedness, swelling of the face, lips, tongue or throat, severe itching of the skin with a red rash or raised bumps.

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

After using Viekira Pak-RBV

Storage

Keep your tablets in the pack/bottle until it is time to take them.

Keep the medicine in a cool, dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a windowsill. Do not leave it in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop taking this medicine, or the medicine has passed its expiry date, return any of this unused or date-expired medicine to your pharmacist for disposal.

Product description

What it looks like

Viekira Pak-RBV comes in three types of tablets:

- Paritaprevir/ritonavir/ombitasvir tablets which are pink-coloured, oblong shaped with "AV1" debossed on one side
- Dasabuvir tablets which are beige-coloured, oval-shaped with "AV2" debossed on one side
- Ribavirin tablets are blue-coloured, oblong-shaped with "3RP" on one side and either "200" or "600" on the other side, depending on strength of the tablet.

Ingredients

Viekira Pak-RBV comes in three types of tablets

Paritaprevir/ritonavir/ombitasvir tablets

Active Ingredient

- paritaprevir,ritonavir/ombitasvir 75/50/12.5mg

Inactive ingredients

- copovidone
- tocofersolan
- propylene glycol monolaurate
- sorbitan monolaurate
- silicon dioxide
- sodium stearyl fumarate
- polyvinyl alcohol
- macrogol 3350
- purified talc
- titanium dioxide
- iron oxide red

Dasabuvir tablets

Active Ingredient

- dasabuvir 250mg

Inactive ingredients

- microcrystalline cellulose
- lactose
- copovidone
- croscarmellose sodium
- colloidal anhydrous silica
- magnesium stearate
- polyvinyl alcohol
- titanium dioxide
- polyethylene macrogol 3350
- purified talc
- titanium dioxide
- iron oxide yellow, red and black

Ribavirin Tablets

Active Ingredient

- ribavirin 200mg or 600mg

Inactive ingredients

- microcrystalline cellulose
- lactose
- croscarmellose sodium
- povidone

- magnesium stearate
- purified water
- polyvinyl alcohol
- titanium dioxide
- macrogol 3350
- purified talc
- indigo carmine aluminium lake or brilliant blue FCF aluminium lake

Viekira Pak-RBV does not contain gluten, sucrose, tartrazine or any other azo dyes.

Supplier

Viekira Pak-RBV is supplied in Australia by:

AbbVie Pty Ltd
Level 7, 241 O'Riordan Street
Mascot NSW 2020
Australia

Viekira Pak-RBV is supplied in New Zealand by:

AbbVie Limited
6th Floor, 156-158 Victoria St
Wellington, 6011
New Zealand

This leaflet was prepared in December 2017

Australian Registration Number(s)
AUST R 224637 and 234442.

Version 9