

VIEKIRA PAK-RBV

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

Consumer Medicine Information (CMI)

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 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 some types of chronic (long-lasting) hepatitis C 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 three different types of tablets for patients with hepatitis C.

These must be taken according to the instructions given by your doctor.

VIEKIRA PAK-RBV includes medicines called direct-acting antiviral agents, and also includes ribavirin to treat your HCV infection.

It 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.

This medicine is only available with a doctor's prescription.

Before you take VIEKIRA PAK-RBV

When you must not take it

Do not take VIEKIRA PAK-RBV if you have an allergy to:

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

Some symptoms of an allergic reaction include

- hives, skin rash or itching of the skin
- 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 or your partner are pregnant.

Your doctor may ask you to take a pregnancy test before, during and

after your treatment with VIEKIRA PAK-RBV.

Ribavirin may cause birth defects 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.

Females and males must use two reliable forms of contraception during this time.

Do not take VIEKIRA PAK-RBV if you have had severe heart problems in the last 6 months.

Tell your doctor if you have experienced any of the serious problems described below, which would indicate that your liver has decompensated: signs of internal bleeding, bruising, swelling or fluid in the feet, legs or stomach, confusion, or jaundice (yellowing of eyes and skin).

Do not take it if you have red blood cell disorders, such as thalassaemia or sickle-cell anaemia.

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

- alfuzosin hydrochloride
- astemizole
- atorvastatin
- blonanserin
- carbamazepine
- cisapride
- colchicine (if you have certain kidney or liver problems)

- dihydroergotamine
- dronedarone
- efavirenz
- ergonovine
- ergotamine
- ethinyloestradiol-containing medications, such as combined oral contraceptives
- fusidic acid
- gemfibrozil
- lovastatin
- lurasidone
- methylergonovine
- midazolam (taken by mouth)
- phenobarbital
- phenytoin
- pimozone
- ranolazine
- rifampicin
- salmeterol
- St John's Wort (*Hypericum perforatum*)
- sildenafil (when used for pulmonary arterial hypertension)
- simvastatin
- terfenadine
- triazolam

* Not all medicines on this list are available in New Zealand.

Do not take VIEKIRA PAK-RBV after the expiry date printed on the pack, or if the packaging is damaged or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal. If you use this medicine after the expiry date has passed it may not work as well.

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 about any other medical conditions you may have, especially if you:

- have liver disease other than hepatitis C
- have never been tested for hepatitis B or have had an infection with the hepatitis B virus
- have HIV infection
- have a liver transplant

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

Your doctor will 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.

Do not take VIEKIRA PAK-RBV if you are breastfeeding or plan to breastfeed.

It is not known whether this medicine passes into the breastmilk. Your doctor will discuss the risks and benefits of using this medicine if you are breastfeeding.

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 have or have had any of the following medical conditions:

- heart problems
- 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 or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Taking other medicines

Tell your doctor or pharmacist if you are taking 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 or diazepam, used to treat anxiety, panic attacks and trouble sleeping.
- candesartan, losartan or valsartan, used to treat high blood pressure or heart problems
- carisoprodol or cyclobenzaprine, used to treat muscle spasms
- colchicine, used to treat gout
- azathioprine, cyclosporine, everolimus, sirolimus or tacrolimus, used to suppress the immune system
- amlodipine, diltiazem, nifedipine or verapamil, used to treat high blood pressure
- amiodarone, bepridil, digoxin, disopyramide, lidocaine, propafenone or quinidine, used for heart problems
- fluticasone, used to treat allergies and asthma
- furosemide, used to treat fluid retention
- hydrocodone, used to treat pain
- ketoconazole or voriconazole, used to treat fungal infections
- atazanavir, atazanavir/ritonavir, darunavir, darunavir/ritonavir, didanosine, lopinavir/ritonavir, rilpivirine, stavudine, or zidovudine, antiviral treatments used to treat HIV infection
- omeprazole, used to treat stomach ulcers and other stomach problems
- quetiapine, used for mental disorders or depression
- pravastatin or rosuvastatin, used to lower blood cholesterol
- fluindione or warfarin, used to prevent blood clots

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.

Not taking the medicine as directed or stopping the medicine too early may affect your response to the medicine or to future treatments.

If you do not understand the instructions on the labelling, 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.

For combination ombitasvir/paritaprevir/ritonavir 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, which are blue tablets with “3RP” on one side and “200” on the other – your doctor will prescribe the right amount of ribavirin for you based on your weight and other factors.

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

Follow the instructions of your doctor and pharmacist. Also refer to the Dosing 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, ask your doctor or pharmacist.

How to take it

Swallow the tablets whole with a glass of water.

When to take it

Take VIEKIRA PAK-RBV after meals, at about the same times every day.

Taking it at the same times 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.

Most patients should take their VIEKIRA PAK-RBV for 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 combination ombitasvir/paritaprevir/ritonavir 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.

If you miss a dose of ribavirin tablets (blue tablets marked with “3RP”) – take the next dose as per the usual dosing schedule.

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 0800 764766 [0800 POISON]), or go to the Accident and Emergency Department 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 ribavirin component may cause birth defects and/or death of an unborn baby.

Male or female patients taking VIEKIRA PAK-RBV and their partners should use two 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 the HBV infection.

Tell your doctor if, for any reason, you have not used VIEKIRA PAK-RBV exactly as prescribed.

VIEKIRA PAK-RBV may cause severe liver problems in some patients. Let your doctor know if you develop any of the following signs of liver problems while on treatment with VIEKIRA PAK-RBV:

- fatigue or weakness
- nausea
- vomiting
- loss of appetite
- yellowing of your skin or eyes
- confusion
- swelling of the stomach area
- darkening of your urine

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 the '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.

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
- Having trouble sleeping
- Unusual weakness or lack of energy
- Tiredness, headaches, being short of breath when exercising, dizziness or looking pale. These are symptoms of anaemia
- Diarrhoea or vomiting
- Decreased appetite
- Dizziness
- Headache
- Cough
- Shortness of breath, difficulty breathing or chest tightness
- Dry skin or rash

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

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

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:

- Combination ombitasvir/paritaprevir/ritonavir tablets are pink coloured, oblong shaped with "AV1" on one side
- Dasabuvir tablets are beige coloured, oval-shaped with "AV2" on one side
- Ribavirin tablets are blue-coloured, oblong-shaped with

“3RP” on one side and “200”
on the other side

Ingredients

Combination ombitasvir/paritaprevir/ ritonavir tablets

Active Ingredients

- Ombitasvir/paritaprevir/ritonavir
12.5/75/50 mg

Inactive ingredients

- copovidone
- tocofersolan
- propylene glycol monolaurate
- sorbitan monolaurate
- silicon dioxide
- sodium stearyl fumarate
- polyvinyl alcohol
- macrogol
- purified talc
- titanium dioxide (E171)
- iron oxide red (E172)

Dasabuvir tablets

Active Ingredient

- dasabuvir 250 mg

Inactive ingredients

- microcrystalline cellulose
- lactose
- copovidone
- croscarmellose sodium
- colloidal anhydrous silica
- magnesium stearate
- polyvinyl alcohol
- titanium dioxide (E171)
- macrogol
- purified talc
- iron oxide yellow, red and black
(E172)

Ribavirin Tablets

Active Ingredient

- ribavirin 200 mg

Inactive ingredients

- microcrystalline cellulose
- lactose
- croscarmellose sodium
- povidone
- magnesium stearate
- polyvinyl alcohol
- titanium dioxide
- macrogol
- purified talc
- indigotine aluminium lake (200
mg tablets) or brilliant blue FCF
aluminium lake (400 mg and 600
mg tablets)
- carnauba wax

VIEKIRA PAK-RBV does not
contain gluten, sucrose, tartrazine or
any other azo dyes.

Supplier

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 August
2017.

Version 7