

Package leaflet: Information for the patient

Viekirax® 12.5 mg/75 mg/50 mg film-coated tablets

Ombitasvir/Paritaprevir/Ritonavir

▼ This medicine is 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 the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

- What Viekirax is and what it is used for
- What you need to know before you take Viekirax
- How to take Viekirax
- Possible side effects
- How to store Viekirax
- Contents of the pack and other information

1. What Viekirax is and what it is used for

Viekirax is an antiviral medicine used to treat adults with chronic (long-term) hepatitis C (an infectious disease that affects the liver, caused by the hepatitis C virus). It contains the active substances ombitasvir, paritaprevir and ritonavir. The combined action of the three active substances stops the hepatitis C virus from multiplying and infecting new cells, thus clearing the virus from your blood over a period of time. Ombitasvir and paritaprevir block two proteins essential for the virus to multiply. Ritonavir acts as a ‘booster’ to prolong the action of paritaprevir in the body.

Viekirax tablets are taken with other antiviral medicines such as dasabuvir and ribavirin. Your doctor will talk with you about which of these medicines to take with Viekirax.

It is very important that you also read the package leaflets for the other antiviral medicines that you take with Viekirax. If you have any questions about your medicines, please ask your doctor or pharmacist.

2. What you need to know before you take Viekirax

Do not take Viekirax

- If you are allergic to ombitasvir, paritaprevir, ritonavir, or any of the other ingredients of this medicine (listed in section 6).
- If you have severe liver problems other than hepatitis C.
- If you are taking any of the medicines listed in the following table. This is because serious or life-threatening effects can occur when Viekirax is taken with these medicines. These medicines can affect the way Viekirax works and Viekirax can affect the way these other medicines work.

Medicines you must not take with Viekirax	
Medicine or active substance	Purpose of the medicine
alfuzosin	for an enlarged prostate
amiodarone	used to correct irregular heartbeats
astemizole, terfenadine	for allergy symptoms. These medicines may be available without a prescription
atorvastatin, lovastatin, simvastatin	to lower blood cholesterol
carbamazepine, phenytoin, phenobarbital	for epilepsy
cisapride	for relieving certain stomach problems
clarithromycin, fusidic acid, rifampicin, telithromycin	for bacterial infections
colchicine in patients who have severe problems with their liver or kidneys	for treating gout attacks
conivaptan	for making the sodium levels in the blood normal
efavirenz, etravirine, lopinavir/ritonavir, saquinavir, tipranavir, nevirapine, indinavir, cobicistat	for HIV infection
enzalutamide	for prostate cancer
ergotamine, dihydroergotamine	for migraine headaches
ergonovine, methylergonovine	used in childbirth
ethinylestradiol-containing medicines such as those contained in most contraceptive pills and vaginal rings used for contraception	for contraception
itraconazole, ketoconazole, posaconazole, voriconazole	for fungal infections
midazolam, triazolam (when taken by mouth)	for anxiety or trouble sleeping
mitotane	for symptoms of malignant tumours of the adrenal glands
pimozide	for schizophrenia
quetiapine	for schizophrenia, bipolar disorder and major depressive disorder
quinidine	for abnormal heart rhythms or malaria
salmeterol	for asthma
sildenafil	when used to treat a heart and lung disorder called "pulmonary arterial hypertension"
St. John’s Wort (<i>hypericum perforatum</i>)	a herbal medicine for anxiety and mild depression. This medicine is available without a prescription
ticagrelor	stops blood from clotting

Do not take Viekirax if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Viekirax.

Warnings and precautions

Talk to your doctor or pharmacist before taking Viekirax if you have liver disease other than hepatitis C.

When taking Viekirax with dasabuvir, tell your doctor if you have the following symptoms as they may be a sign of worsening liver problems:

- Feel sick (nauseous), are sick (vomit) or lose your appetite
- Notice yellowing of your skin or eyes
- Your urine is darker than normal

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Viekirax.

Blood tests

Your doctor will test your blood before, during and after your treatment with Viekirax. This is so that your doctor can:

- Decide what other medicines you should take with Viekirax and for how long.
- Confirm if your treatment has worked and if you are free of the hepatitis C virus.
- Check for side effects of Viekirax or other antiviral medicines your doctor has prescribed for you to use with Viekirax (such as “dasabuvir” and “ribavirin”).

Children and adolescents

Do not give Viekirax to children and adolescents under 18 years of age. The use of Viekirax in children and adolescents has not yet been studied.

Other medicines and Viekirax

Tell your doctor or pharmacist if you are taking, have recently taken and before starting any other medicines.

There are some medicines you **must not take** with Viekirax see the previous table “Medicines you must not take with Viekirax”.

Tell your doctor or pharmacist before taking Viekirax, if you are taking any of the medicines in the table below. The doctor may need to change your dose of these medicines. Tell your doctor or pharmacist before taking Viekirax also if you are using hormonal contraceptives. See the section on contraception below.

Medicines you must tell your doctor about before taking Viekirax	
Medicine or active substance	Purpose of the medicine
alprazolam	for anxiety, panic attacks and trouble sleeping
ciclosporin, tacrolimus	to suppress the immune system
colchicine	for treating gout attacks
digoxin, amlodipine, nifedipine, valsartan, diltiazem, verapamil	for heart problems or high blood pressure
furosemide	for the build-up of too much fluid in the body
levothyroxine	for thyroid problems
rilpivirine, darunavir, atazanavir	for HIV infection
omeprazole, lansoprazole, esomeprazole	for stomach ulcers and other stomach problems
imatinib	for the treatment of some cancers of the blood
fluvastatin, pitvastatin, pravastatin, rosuvastatin	to lower blood cholesterol
dabigatran, warfarin	to thin the blood
fezofenadine	for hay fever
s-mephenytoin	for epilepsy
sulfasalazine	for inflammatory bowel disease
repaglinide	for lowering blood sugar
erythromycin	for bacterial infections
steroid or corticosteroid medicines (such as fluticasone)	for many different conditions including serious illnesses and allergies
trazodone	for anxiety and depression

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Viekirax.

Pregnancy

Women must not become pregnant while they or their partner are being treated with Viekirax and ribavirin. This is because ribavirin can cause birth defects or the death of your unborn baby.

- Do not start treatment if you are pregnant.
- Do not become pregnant during treatment.
- If you or your partner becomes pregnant during treatment with Viekirax or in the following 6 months, contact your doctor straight away.

Ask your doctor or pharmacist for advice if you are taking Viekirax with or without ribavirin, and you or your partner are planning to become pregnant.

Read the “Pregnancy” sections of the package leaflets for the other antiviral medicines that you take with Viekirax (such as “dasabuvir” and “ribavirin”). It is important that both men and women read the information.

Contraception

- If you are taking Viekirax with ribavirin, you or your partner must use an effective method of contraception during treatment and for 6 months after treatment is finished. Ask your doctor about the best contraception for you.
- Talk to your doctor before taking Viekirax if you are using a contraceptive medicine that contains ethinylestradiol. Your doctor will ask you to stop and change to a different type of contraceptive medicine during your treatment with Viekirax.

Read the “Contraception” section of the package leaflets for the other antiviral medicines that you take with Viekirax (such as “dasabuvir” and “ribavirin”). It is important that both men and women read the information.

Breastfeeding

You should not breast-feed during treatment with Viekirax. It is not known whether the active substances in Viekirax (ombitasvir, paritaprevir and ritonavir) pass into breast milk.

Driving and using machines

Some patients have reported feeling very tired when taking Viekirax with other medicines for their hepatitis C infection. If you feel tired, do not drive or use machines.

3. How to take Viekirax

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Viekirax tablets are usually taken with other anti-viral medicines such as “dasabuvir” and “ribavirin”.

How much to take

The recommended dose is two tablets taken together in the morning.

How to take

- Take the tablets in the morning with food. The type of food is not important.
- Swallow the tablets whole.
- Do not chew, crush or break the tablets as they may have a bitter taste.

How long to take Viekirax for

You will take Viekirax for either 12 or 24 weeks. Your doctor will tell you how long your treatment will last. Do not stop taking Viekirax unless your doctor tells you to. It is very important that you complete the full course of treatment. This will give the medicines the best chance to clear the hepatitis C virus infection.

If you take more Viekirax than you should

If you accidentally take more than the recommended dose, you should contact your doctor or go to the nearest hospital straight away. Keep the medicine pack with you so that you can easily describe what you have taken.

If you forget to take Viekirax

It is important not to miss a dose of this medicine. If you do miss a dose 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. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Tell your doctor or pharmacist if you notice any of the following side effects.

Side effects when taking Viekirax with dasabuvir: Common: may affect up to 1 in 10 people

- Itching

Side effects when taking Viekirax with dasabuvir and ribavirin:

- Very common:** may affect more than 1 in 10 people
 - Feeling very tired (fatigue)
 - Feeling sick (nausea)
 - Itching
 - Trouble sleeping (insomnia)
 - Feeling weak or lack of energy (asthenia).

Common: may affect up to 1 in 10 people

- Anaemia (low number of red blood cells).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. Healthcare professionals are asked to report any suspected adverse reactions via the local reporting system. By reporting side effects you can help provide more information on the safety of this medicine.

In Saudi Arabia:

The National Pharmacovigilance and Drug Safety Centre (NPC)

- Fax: +966-11-205-7662
- Call NPC at +966-11-2038222.
- Exts: 2317-2356-2353-2354-2334-2340.
- Toll free phone: 8002490000
- E-mail: npc.drug@sfga.gov.sa
- Website: www.sfga.gov.sa/npc

By reporting side effects, you can help provide more information on the safety of this medicine.

For rest of the countries:

Bahrain, United Arab Emirates, Yemen, Kuwait, Oman, Qatar:

- Fax: +9714 424 1313
- Email: pv.gulf@abbvie.com

Iraq, Jordan, Lebanon, Syria, Iran:

- Hotline: +961 70122946
- Email: Pharmacovigilance_levant@abbvie.com

5. How to store Viekirax

Keep this medicine out of the sight and reach of children.

Do not use the medicine after the expiry date which is stated on the carton after ‘EXP’. The expiry date refers to the last day of that month.

Store below 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Viekirax contains

- Each tablet contains 12.5 mg of ombitasvir, 75 mg of paritaprevir and 50 mg of ritonavir.
- The other ingredients are:
 - Tablet core: copovidone, vitamin E, polyethylene glycol succinate, propylene glycol monolaurate, sorbitan monolaurate, colloidal anhydrous silica (E551), sodium stearyl fumarate.
 - Tablet film-coating: polyvinyl alcohol (E1203), polyethylene glycol 3350, talc (E553b), titanium dioxide (E171) and red iron oxide (E172).

What Viekirax looks like and contents of the pack

Viekirax tablets are pink, oblong film-coated tablets of dimmensions 18.8 mm x 10.0 mm, marked with ‘AV1’. Viekirax tablets are packed into foil blisters containing 2 tablets. Each carton contains 56 tablets (multipack carton containing 4 inner cartons of 14 tablets each).

Marketing Authorisation Holder

AbbVie Ltd
Maidenhead
SL6 4XE
United Kingdom

Manufactured by:

Fournier Laboratories Ireland Limited
Anngrove, Carrigtwohill
Co. Cork Ireland

Packaged & released by:

AbbVie Deutschland GmbH & Co. KG
Knollstrasse
67061 Ludwigshafen
Germany

This leaflet was last revised in 01/2015.

Council of Arab Health Ministers

This is a Medicament
<ul style="list-style-type: none">Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you. Follow strictly the doctor’s prescription, the method of use and the instructions of the pharmacist who sold the medicament. The doctor and the pharmacist are the experts in medicines, their benefits and risks. Do not by yourself interrupt the period of treatment prescribed for you. Do not repeat the same prescription without consulting your doctor. Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab Pharmacists