

PART III: CONSUMER INFORMATION

GALEXOS™, for use with sofosbuvir in the treatment of genotype 1 chronic hepatitis C, has been authorized with conditions pending results of studies to verify its clinical benefits. For more information, patients are advised to contact their healthcare provider.

GALEXOS™, for use with peginterferon alfa and ribavirin in the treatment of genotype 1 chronic hepatitis C, has been authorized without conditions.

What is a Notice of Compliance with Conditions (NOC/c)? An NOC/c is a form of market authorization granted to a product on the basis of **promising** evidence of clinical effectiveness following review of the submission by Health Canada.

Products authorized under Health Canada's NOC/c policy are intended for the treatment, prevention or diagnosis of a serious, life-threatening or severely debilitating disease. They have demonstrated promising benefit, are of high quality and possess an acceptable safety profile based on a benefit/risk assessment. In addition, they either respond to a serious unmet medical need in Canada or have demonstrated a significant improvement in the benefit/risk profile over existing therapies. Health Canada has provided access to this product on the condition that sponsors carry out additional clinical trials to verify the anticipated benefit within an agreed upon time frame.

PrGALEXOS™
simeprevir capsules
150 mg simeprevir (as simeprevir sodium)

This leaflet is Part III of a three-part "Product Monograph" published when GALEXOS™ was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about GALEXOS™. Contact your doctor or pharmacist if you have any questions about the drug.

GALEXOS™ is taken along with other medicines for treating chronic hepatitis C infection. It is therefore important that you read the package inserts that are provided with these medicines before you start taking GALEXOS™. If you have any further questions about these medicines, ask your doctor or pharmacist.

ABOUT THIS MEDICATION

What is it used for:

- GALEXOS™ is used to treat hepatitis C infection caused by 'genotype 1' hepatitis C virus (HCV) in adults with stable liver disease who have not been previously treated or who have failed prior treatment.
- GALEXOS™ is a type of anti-HCV drug called a protease inhibitor.

- GALEXOS™ is used with other medicines for the treatment of hepatitis C infection.

What it does:

- GALEXOS™ inhibits a viral enzyme (protease) which prevents the virus from multiplying, thus helping to reduce the infection. When used together with other medicines for treating your hepatitis C infection, GALEXOS™ helps to reduce the HCV in your body.

Does GALEXOS™ reduce the risk of passing HCV to others:

- Hepatitis C can be passed to other individuals through contact with infected blood. Talk with your healthcare provider about ways to prevent spreading the hepatitis C virus.

When it should not be used:

Do not take GALEXOS™ if:

- You are allergic to GALEXOS™, or any of the other ingredients in GALEXOS™ (see **What the nonmedicinal ingredients are**).

Do not take GALEXOS™ with ribavirin if:

- You are a woman who is, may be, or plans to become pregnant.
- You are a man with a female partner who is, may be, or plans to become pregnant.

What the medicinal ingredient is:

Simeprevir (as simeprevir sodium)

What the nonmedicinal ingredients are:

Each GALEXOS™ capsule contains the inactive ingredients colloidal anhydrous silica, croscarmellose sodium, lactose monohydrate, sodium lauryl sulphate, and magnesium stearate.

The capsule coating contains gelatin and titanium dioxide. Capsules are printed with ink containing iron oxide black and shellac.

What dosage forms it comes in:

150 mg capsules

WARNINGS AND PRECAUTIONS

BEFORE you use GALEXOS™ talk to your doctor or pharmacist if:

- you are a woman who is, may be, or plans to become pregnant.
- you are a man with a female partner who is, may be, or plans to become pregnant.
- you have any other liver problems in addition to hepatitis C.
- you have taken the medicines telaprevir or boceprevir.
- you have hepatitis C that is not genotype 1.

- you have Human Immunodeficiency Virus (HIV) infection.
- you have hepatitis B infection.
- you had or are going to have an organ transplant.
- you are breastfeeding or planning to breastfeed. It is not known if GALEXOS™ passes into breast milk. You and your healthcare provider should decide if you will take GALEXOS™ or breastfeed. You should not do both.
- you have a rare hereditary problem of galactose intolerance (severe lactase deficiency or glucose/galactose malabsorption) as this product contains lactose.
- you are of East Asian descent

Blood tests

Your doctor will do blood tests before you start your treatment and regularly during your treatment. These blood tests are done to help your doctor to:

- check if the treatment is working for you.
- decide how long you need to take GALEXOS™ and the other medicines used for treating your hepatitis C infection.

Sensitivity to sunlight

You may be more sensitive to sunlight (photosensitivity) when taking GALEXOS™. During your treatment with GALEXOS™, use appropriate sun protection (such as a hat, sunglasses, protective clothing, or sunscreen). Especially avoid intense or prolonged exposure to sunlight (including tanning devices).

Rash

The use of GALEXOS™ in combination with peginterferon alfa and ribavirin is associated with skin rash reactions which may be severe.

Contact your doctor if you develop symptoms of skin rash and your doctor will decide if you need treatment for your skin rash and/or if you need to stop taking any of your medications including GALEXOS™.

Children and adolescents

GALEXOS™ should not be used by anyone under 18 years of age because it has not been studied in this age group.

Pregnancy

If you are pregnant, think you might be pregnant or are planning to be pregnant, ask your doctor or pharmacist for advice before taking this medicine.

Pregnant women should not take GALEXOS™ unless specifically directed by the doctor.

When GALEXOS™ is used with ribavirin, please read the package leaflet for ribavirin for information regarding pregnancy. Ribavirin may cause birth defects and death of the fetus.

- You or your female partner **must not become pregnant while taking ribavirin.**

- You or your female partner **must also not become pregnant for 6 months after you have stopped taking ribavirin.**

If you or your female partner become pregnant during this period, you must contact your doctor immediately.

Contraception

- Women must use effective birth control during treatment with GALEXOS™.
- When GALEXOS™ is used with ribavirin, read the package leaflet for ribavirin for information regarding contraception requirements. You and your partner must use two effective methods of birth control during treatment and for six months afterwards. You should discuss with your doctor how you or your partner can prevent getting pregnant.

Driving and using machines

GALEXOS™ combination treatment may affect your ability to drive and use machines. Read the package inserts for the other medicines for information regarding driving and using machines. Do not drive or use machines if you feel faint or have problems with your vision.

INTERACTIONS WITH THIS MEDICATION

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription (e.g., over-the-counter herbal products).

GALEXOS™ and other medicines may affect each other. Tell your doctor if you are taking any of the following medicines.

- medicine to treat irregular heart beat such as amiodarone, digoxin, disopyramide, flecainide, mexiletine, propafenone, quinidine (when taken by mouth)
- medicine to treat bacterial infection such as clarithromycin, erythromycin (when taken by mouth or given by injection), telithromycin
- medicine to prevent blood clots such as warfarin
- medicine to prevent seizures such as carbamazepine, oxcarbazepine, phenobarbital, phenytoin
- medicine to treat fungal infection (when taken by mouth or given by injection) such as itraconazole, fluconazole, ketoconazole, posaconazole, voriconazole
- medicine to treat infections like tuberculosis such as rifabutin, rifampin, rifapentine
- medicine to lower blood pressure such as amlodipine, bepridil, diltiazem, felodipine, nicardipine, nifedipine, nisoldipine, verapamil (when taken by mouth)
- steroids such as dexamethasone when administered by injection or when taken by mouth
- medicine to treat some stomach conditions such as cisapride*

- herbs such as milk thistle (*Silybum marianum*) and St. John's wort (*Hypericum perforatum*) or products containing milk thistle or St. John's wort
- cobicistat: a product that blocks some liver enzymes and increases the levels of some medicines used to treat HIV infections
- medicine to treat HIV such as atazanavir, darunavir with ritonavir, delavirdine mesylate, efavirenz, etravirine, (fos)amprenavir, indinavir, lopinavir, nelfinavir, nevirapine, ritonavir, saquinavir, tripranavir
- medicine to lower cholesterol such as atorvastatin, lovastatin, pitavastatin*, pravastatin, rosuvastatin, simvastatin
- medicine to lower immune response or prevent organ transplant failure such as cyclosporine, sirolimus, tacrolimus
- medicine to treat pulmonary hypertension such as sildenafil, tadalafil
- medicine to treat trouble with sleeping and/or anxiety such as midazolam (when taken by mouth)* and triazolam
- antihistamines astemizole* and terfenadine*

*not marketed in Canada.

This is not a complete list of medicines. Know the medicines you take. Keep a list of your medicines and show it to your doctor and pharmacist when you get a new medicine. Your doctor and your pharmacist can tell you if you can take these medicines with GALEXOS™.

Some of these medicines may be obtained without a prescription. It is important that you carefully read the package leaflets that are provided with these medicines.

PROPER USE OF THIS MEDICATION

- Always take GALEXOS™ exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- You must take GALEXOS™ along with other medicines for treating your hepatitis C infection. Read the package inserts of these medicines for the dosage and how to take instructions.

Usual adult dose:

- The recommended dose of GALEXOS™ is one capsule (150 mg) once a day.
- Your doctor will decide how long you should take your medicines.
- Always take GALEXOS™ with food. The type of food is not important.
- Take this medicine by mouth.
- Swallow the capsule whole with water or liquid.
- Try to take GALEXOS™ at the same time each day.

Overdose:

In case of drug overdose, contact a healthcare practitioner (doctor), hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Missed dose:

- If you miss a dose of GALEXOS™ by less than 12 hours of your usual dose time, take your missed dose as soon as possible with food. Then continue taking GALEXOS™ at the usual scheduled time.
- If you miss a dose of GALEXOS™ by more than 12 hours of your usual dose time, skip your missed dose and then take the next GALEXOS™ dose at the usual scheduled time.
- Do not take a double dose of GALEXOS™ to make up for a missed dose.

Do not stop taking GALEXOS™

Do not stop taking GALEXOS™ in order to ensure that your medicine continues to work against the virus, unless your doctor tells you to.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Read the package inserts for the other medicines used for treating your hepatitis C infection for side effects reported with these medicines.

Like all medicines, GALEXOS™ can cause side effects. The following side effects may happen with this medicine when used in combination with peginterferon alfa and ribavirin:

Very common side effects (may affect more than 1 in 10 people):

- itching of the skin.
- skin rash.

Common side effects (affect fewer than 1 in 10 people):

- increased bilirubin levels in your blood.
- being sensitive to sunlight (photosensitivity).
- constipation.

In clinical studies, the following side effects were reported in more than 1 in 10 patients taking this medicine in combination with sofosbuvir: feeling very tired, headache, nausea, difficulty sleeping and itching of the skin.

If any of the side effects gets serious, or you notice any side effects not listed in this leaflet, please tell your doctor.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect	Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
	Only if severe	In all cases	

Common	Sensitivity to <u>sunlight</u> sunburn, blistering, redness of the skin, swelling of the skin	✓		
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This is not a complete list of side effects. For any unexpected effects while taking GALEXOS™, contact your doctor or pharmacist.

HOW TO STORE IT

- Store at room temperature between 15-30°C.
- Store in the original package in order to protect from light.
- Keep GALEXOS™ and all medications out of the reach and sight of children.
- Do not use this medicine after the expiry date which is stated on the package after EXP.
- 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 protect the environment.

GENERAL ADVICE

Do not give GALEXOS™ to other people even if they have the same condition you have. It may harm them.

This leaflet provides a summary of the most important information about GALEXOS™. If you would like more information, talk to your doctor. You can ask your doctor or pharmacist for information about GALEXOS™ that is written for health professionals.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following three ways:

- **Report online at**
www.healthcanada.gc.ca/medeffect
- **Call toll-free at 1-866-234-2345**
- **Complete a Canada Vigilance Reporting Form and:**
 - **Fax toll-free to 1-866-678-6789, or**
 - **Mail to: Canada Vigilance National Office
Health Canada
Postal Locator 0701E
Ottawa, Ontario K1A 0K9**

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect® Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full Product Monograph, prepared for health professionals can be found at:
<http://www.janssen.ca> or by contacting the sponsor, Janssen Inc., at 1-800-567-3331 or 1-800-387-8781.

This leaflet was prepared by Janssen Inc.
Toronto, Ontario M3C 1L9

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Last revised: January 2015

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