

PRESS RELEASE

AbbVie's HOLKIRA™ PAK Now Reimbursed in Quebec

- *HOLKIRA PAK is now listed in the drug formularies covered by Quebec's public prescription drug insurance program for patients with genotype 1 hepatitis C virus infection.*
- *In Phase 3 clinical trials, HOLKIRA PAK (with or without ribavirin) cured an overall 97% of the genotype 1 hepatitis C virus patients; additionally, 98% of the patients completed the treatment.*

MONTREAL, CANADA, JULY 24, 2015 – AbbVie, a global biopharmaceutical company, today announced that its treatment against hepatitis C, HOLKIRA PAK, is now listed in the drug formularies covered by Quebec's public prescription drug insurance plan (RPAMQ)¹. HOLKIRA PAK (ombitasvir/paritaprevir/ritonavir film-coated tablets; dasabuvir film-coated tablets) is an all-oral, short-course (12 weeks for the majority of patients), interferon-free treatment, with or without ribavirin (RBV), for the treatment of patients with genotype 1 (GT1) chronic hepatitis C virus (HCV) infection, including those with compensated cirrhosis.

After reviewing the HOLKIRA PAK submission, the Institut national d'excellence en santé et en service sociaux (INESSS)² determined that HOLKIRA PAK meets the therapeutic value and economic and pharmaco-economic value criteria for the treatment of genotype 1 chronic hepatitis C in patients who have or have not previously been treated.

"We are witnessing a revolution in the treatment of hepatitis C. We can now confidently tell our patients that hepatitis C can be cured in as little as 12 weeks, thanks to treatments that are very well tolerated," explains Dr. Emmanuelle Huchet, general practitioner, Director of Clinical Services at the Clinique médicale l'Actuel. "We appreciate the government's understanding in making these new treatments available."

It is estimated that 50,000 people in Quebec are living with hepatitis C. However, a large number of these estimated cases have gone undiagnosed, but the exact proportion is not known with certainty³. According to the Institut national de santé publique du Québec, close to 2,000 new cases of hepatitis C are reported each year in Quebec⁴.

"We had been eagerly waiting for this news for Quebecers living with hepatitis C," notes Laurence Mersilian, general manager, Centre Associatif Polyvalent d'Aide Hépatite C (CAPAHC). "These new treatments, which have proven to be extremely effective, offer new hope, since hepatitis C has devastating consequences. Today, thanks to the commitment by the Ministère de la Santé et des Services sociaux, we can finally conceive of the possible eradication of hepatitis C."



HOLKIRA PAK combines three direct-acting antivirals to attack the virus at three separate stages of its replication process. In Phase 3 clinical trials, HOLKIRA PAK (with or without ribavirin) cured an overall 97% of the GT1 HCV patients, with 98% of the patients completing the treatment.

"Our aim at AbbVie is advancing the science within hepatitis for all people living with this disease, which is an increasing global health concern," said Stéphane Lassignardie, general manager, AbbVie Canada. "AbbVie is proud to be working with governments and associations to better understand their needs and priorities and in turn learn how we can help improve standards of care for Canadians living with hepatitis C."

Canadians prescribed HOLKIRA PAK will have the opportunity to enrol in AbbVie Care, an AbbVie signature support program, designed to provide a wide range of personalized services for disease management throughout and after their treatment.

HOLKIRA PAK was approved by Health Canada on December 22, 2014. The approval of HOLKIRA PAK was supported by a robust clinical development program that was designed to study the safety and efficacy of the regimen in six pivotal Phase 3 studies with more than 2,300 patients across 25 countries, including one trial exclusively in subjects with cirrhosis.

About HOLKIRA PAK

HOLKIRA PAK consists of the fixed-dose combination of ombitasvir/paritaprevir/ritonavir, taken once daily, and dasabuvir taken twice daily. HOLKIRA PAK is administered with or without ribavirin, depending on the type of hepatitis C virus, the treatment history of the patient and the presence/absence of cirrhosis. The combination of three different mechanisms of action interrupts the hepatitis C virus replication process with the goal of optimizing sustained virologic response across different patient populations.

The complete HOLKIRA PAK Product Monograph is available through Health Canada's website at <http://hc-sc.gc.ca/index-eng.php>, through the manufacturer's website at www.abbvie.ca, or by calling 1-888-704-8271.

Additional information about AbbVie's clinical development program in the treatment of chronic hepatitis C can be found on www.clinicaltrials.gov.

Important Safety Information⁵

To help avoid possible side effects and ensure proper use, talk to your health care professional before you take HOLKIRA PAK. Talk about any health conditions or problems you may have, including if you:

- Are using a medicine containing ethinyl estradiol for contraception or for other reasons. You must not use medicines that contain ethinyl estradiol while taking HOLKIRA PAK. Your doctor will ask you to stop or consider changing to a different type of contraceptive medicine during your treatment.
- Have liver problems other than hepatitis C infection.
- Have any other medical condition.



- Have had a liver transplant.
- Are breastfeeding or plan to breastfeed. It is not known if HOLKIRA PAK passes into breast milk. You and your health care provider should decide if you will take HOLKIRA PAK or breastfeed. You should not do both.
- You or your partner should not become pregnant while taking HOLKIRA PAK with ribavirin and for six months after the end of treatment.

Other warnings:

Let your health care provider know if you develop nausea, vomiting, loss of appetite, yellowing of your skin or eyes, or darkening of your urine while on treatment with HOLKIRA PAK.

If HOLKIRA PAK is administered with ribavirin, the warnings and precautions for ribavirin also apply to this combination regimen. Refer to the ribavirin Patient Medication Information for a full list of the warnings and precautions for ribavirin.

It is not known if taking HOLKIRA PAK is safe and effective in children under 18 years of age.

Your doctor may 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.

Tell your health care professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

HOLKIRA PAK should not be administered with other ritonavir-containing medicines (NORVIR[®], KALETRA[®]). When co-administered with HOLKIRA PAK, atazanavir or darunavir should be taken without ritonavir.

About AbbVie

AbbVie is a global, research-based biopharmaceutical company formed in 2013 following separation from Abbott Laboratories. The company's mission is to use its expertise, dedicated people and unique approach to innovation to develop and market advanced therapies that address some of the world's most complex and serious diseases. Together with its wholly-owned subsidiary, Pharcacyclics, AbbVie employs more than 28,000 people worldwide and markets medicines in more than 170 countries. For further information on the company and its people, portfolio and commitments, please visit www.abbvie.ca and www.abbvie.com. Follow [@abbvie](https://twitter.com/abbvie) on Twitter or view careers on our [Facebook](#) or [LinkedIn](#) page.

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¹ Régie de l'assurance maladie du Québec. Consulted July 24, 2015 at https://www.prod.ramq.gouv.qc.ca/DPI/PO/Commun/PDF/Liste_Med/Liste_Med/liste_med_2015_07_24_fr.pdf

² Institut national d'excellence en santé et en service sociaux (INESSS). Consulted July 24, 2015 at https://www.inesss.qc.ca/fileadmin/doc/INESSS/Inscription_medicaments/Avis_au_ministre/Juillet_2015/Harvoni-et-Holkira-Pak_2015_07_cav.pdf

³ An update on the management of chronic hepatitis C: Consensus guidelines from the Canadian Association for the Study of the Liver, Canadian Journal of Gastroenterology, Vol. 26 No. 6, June 2012.

⁴ The Institut national de santé publique du Québec. Consulted July 24, 2015 at <https://www.inspq.qc.ca/formation/institut/itss/virus-hepatite-c-prise-en-charge-en-reseaux>

⁵ HOLKIRA PAK (ombitasvir/paritaprevir/ritonavir film-coated tablets; dasabuvir film coated tablets) Product Monograph. Date of Revision: December 22, 2014. Consulted July 24, 2015 at http://www.abbvie.ca/content/dam/abbviecorp/ca/english/docs/HOLKIRA_PAK_PM_EN.pdf

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