



PRESS RELEASE

AbbVie's HOLKIRA™ PAK Now Reimbursed in Ontario

- *Common Drug Review grants positive recommendation for HOLKIRA PAK*
- *Ontario is the second province in Canada to reimburse HOLKIRA PAK*
- *In Phase 3 clinical trials, HOLKIRA PAK (with or without ribavirin) cured an overall 97 percent of genotype 1 hepatitis C virus patients; additionally, 98 percent of patients completed treatment*

MONTREAL, CANADA, JUNE 29, 2015 – AbbVie, a global biopharmaceutical company, today announced that the Common Drug Review (CDR) has posted the Canadian Drug Expert Committee (CDEC)'s positive recommendation¹ of HOLKIRA PAK for listing with provincial drug formularies. 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.

During their review, the CDEC clearly recognized the clinical value that HOLKIRA PAK brings to people living with hepatitis C and recommended that the treatment be covered under minimal conditions: liver fibrosis stage of ≥ 2 , and treatment should be initiated by physicians with experience in the management of hepatitis C.

Following the positive CDR recommendation announcement, Ontario is the second province to reimburse HOLKIRA PAK on its public formulary through its Exceptional Access Program (EAP) as of June 29, 2015². In Ontario, HOLKIRA PAK will be covered under the following EAP criteria: for treatment-naïve and treatment-experienced adult patients with GT1 chronic HCV infection, with compensated cirrhosis.

“We finally have the tools to address hepatitis C. Although this disease is sometimes overlooked, it is the infectious disease that causes the most years of life lost in Canada. With new, extremely well-tolerated treatments, cure rates are now above 95 per cent,” said Dr. Jordan Feld, a hepatologist at the Francis Family Liver Clinic at Toronto Western Hospital, part of the University Health Network. “Now that we can access these life-saving therapies for those who need them most, we have the possibility to actually eliminate hepatitis C from Canada.”

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 percent of GT1 HCV patients, and 98 percent of patients completed treatment.



“Most patients with hepatitis C have been living with the disease for years or even decades,” said Dr. Morris Sherman, Chairperson, Canadian Liver Foundation. “And after such a long duration of infection they are rapidly running into problems with liver failure and liver cancer. Having therapies that are both highly effective and accessible is critical to curing these individuals and preventing these complications.”

According to the Public Health Agency of Canada, an estimated 242,500 Canadians are living with hepatitis C.³ A significant number of the estimated cases in Canada remain undiagnosed, although the exact proportion is unclear.⁴ There are six different genotypes of hepatitis C; two-thirds of Canadians living with hepatitis C have genotype 1 – either subtype 1a or 1b – which are the most difficult to cure.⁵

“AbbVie is committed to providing the best solution to Canadians living with hepatitis C. With this milestone, we are getting closer to fulfilling this ambition,” said Stéphane Lassignardie, general manager, AbbVie Canada. “Furthermore, Canadians prescribed HOLKIRA PAK will have the opportunity to be enrolled in AbbVie Care, our signature care program designed to provide a wide range of services including reimbursement assistance, education and ongoing disease management support for health care professionals and people living with genotype 1 hepatitis C.”

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, including one trial exclusively in subjects with compensated cirrhosis, with more than 2,300 patients across 25 countries.

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 in cause, 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 at the following location on Health Canada’s website (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer’s website www.abbvie.ca, or by calling 1-888-704-8271.

Additional information about AbbVie’s chronic hepatitis C clinical program can be found on www.clinicaltrials.gov.

Important Safety Information⁶

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 your 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 treatment is over.

Other warnings you should know about:

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, Pharmacyclics, 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 CADTH.

<https://www.cadth.ca/sites/default/files/cdr/complete/cdr-complete-SR0406-Holkira-Pak-June-22-2015-e.pdf>

Accessed on June 26, 2015

² Ontario Ministry of Health and Long-Term Care.

http://www.health.gov.on.ca/en/pro/programs/drugs/edition_42.aspx

Accessed on June 26, 2015

³ Public Health Agency of Canada. Hepatitis C Quick Facts. <http://www.phac-aspc.gc.ca/hepc/index-eng.php>

Accessed on June 26, 2015

⁴ 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

⁵ Hepatitis C Online. <http://www.hepatitisc.uw.edu/go/treatment-infection/treatment-genotype-1/core-concept/all>

Accessed on June 26, 2015

⁶ HOLKIRA PAK (ombitasvir/paritaprevir/ritonavir film-coated tablets; dasabuvir film coated tablets) Product Monograph. Date of Revision: December 22, 2014

http://www.abbvie.ca/content/dam/abbviecorp/ca/english/docs/HOLKIRA_PAK_PM_EN.pdf

Accessed on June 26, 2015

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