



This material was developed by Sanofi Canada Inc., as part of the Canadian Specific Opioids targeted Risk Management Plan (CSO-tRMP) for TUSSIONEX, NOVAHISTINE DH and NOVAHISTEX DH. It is not intended for promotional use.

## OPIOID COUGH MEDICINES Educational Brochure for Healthcare Professionals on Opioid - Related Harm

Dear Healthcare Professional:

This educational material is intended for physicians who are prescribing opioid cough medicines and is designed to highlight the importance of balancing the use of opioid cough medicines with the risks of fatal or non-fatal adverse events (such as addiction, abuse, and misuse, which can lead to overdose and death). It can also assist you with counseling patients and/or caregivers on safe use, serious risks and proper storage and disposal of opioid products to ensure appropriate use.

Your patients should receive the **OPIOID MEDICINES – INFORMATION FOR PATIENTS AND FAMILIES** at the time of dispensing of the opioid cough medicine. In addition, the Patient Package Insert (PPI) should be provided to the patient/caregiver. These documents will further enhance the patient's/caregiver's understanding of the potential for opioid-related harm and improve patient, household and community safety.

### KEY POINTS TO CONSIDER WHEN PRESCRIBING OPIOID COUGH MEDICINES

#### Patient selection

Consider if an opioid cough medicine is an appropriate treatment option. Each patient should be assessed for their clinical risks for opioid abuse or addiction prior to being prescribed opioids, as the likelihood of experiencing serious adverse events can depend upon the type of opioid and duration of treatment, the patient's own level of tolerance as well as risk factors for opioid use disorder (OUD). The risk factors include patient or family history of addiction, abuse, physical dependence, drug withdrawal syndrome, psychiatric history, lifestyle risk factors and age group.

Hydrocodone cough products are not indicated for use in patients younger than 18 years of age because of existing concerns about safety of opioid use in children and known serious adverse events with use of opioid antitussives in children. A benefit/risk assessment for opioid cough medicine indicates that the benefits of symptomatic treatment of cough associated with allergies or the common cold do not outweigh the risks for use of opioid cough medicine in this patient population.

Use opioid cough medicines only when alternative treatment options are not available.

Hydrocodone is not recommended for use in pregnant women unless the potential benefits outweigh the risks. Prolonged maternal use of opioid cough medicines during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening.

#### Dosing

As with other opioids, tolerance and physical dependence (with or without psychological dependence) tend to occur with chronic administration of opioids. Consider prescribing "as needed" vs. "around-the clock" dosing, and the minimum quantity of medication necessary to treat the cough and for the shortest time, based on the expected duration of cough. Patients should not use the hydrocodone products for longer than 7 days. An evaluation should be done about the possibility of splitting the total quantity into smaller volume if this can contribute to a better monitoring of patient. Patients on prolonged therapy could experience withdrawal symptoms following abrupt discontinuation of therapy or upon administration of an opioid antagonist.

#### Monitoring

All patients receiving opioids should be routinely monitored for signs of misuse and abuse, and their cough should be assessed regularly to determine the most appropriate dose and the need for further use of opioid cough medication. Adjust/reduce dosage or discontinue cough medicine accordingly.

Assess your patient's compliance with the prescribed dosage and identify any signs and symptoms of opioid misuse, abuse and OUD. Be familiar with the available screening tools for risk of abuse (e.g. <http://www.lynnwebstermd.com/opioid-risk-tool/>) and how to begin the process of early intervention upon suspicion of an OUD.

Access the resources that are available to you in your province of practice to understand the provincial clinical guidelines on the management of OUD. Additional resources on the treatment of OUD are available and include the Canadian Research Initiative on Substance Misuse National Guideline for the Clinical Management of the OUD ([https://crism.ca/wp-content/uploads/2018/03/CRISM\\_NationalGuideline\\_OUD-ENG.pdf](https://crism.ca/wp-content/uploads/2018/03/CRISM_NationalGuideline_OUD-ENG.pdf)).

Life-threatening, or fatal respiratory depression may occur with the use of hydrocodone. Infants exposed *in-utero* or through breast milk are at risk of life-threatening respiratory depression upon delivery or when nursed. Concomitant use of opioids with benzodiazepines or other central nervous system depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Monitor patients for respiratory depression, especially during initiation of hydrocodone or following a dose increase. Instruct patients on the hazards related to taking opioids including fatal overdose.

In addition, monitor for the potential occurrence of medication errors in your patients by asking detailed questions regarding dosage and administration of the product.

### Patient/Caregiver Counselling

- Emphasize the potential risk of opioid-related harm and advise your patient/caregiver to read the **OPIOID MEDICINES – INFORMATION FOR PATIENTS AND FAMILIES** provided at the time of dispensing and the PPI.
- Remind patient/caregiver to report any adverse events to you or to their other healthcare professional.
- Provide clear dosing instructions to your patient/caregiver including the daily maximum dose.
- Discuss the safe storage and disposal of the opioid cough medicine with your patient/caregiver, to reduce risk of accidental exposure/ingestion by household contacts, especially children/teens and to reduce risk of theft. Accidental exposure to hydrocodone, especially by children, can result in a fatal overdose of hydrocodone.
- Inform patient/caregiver of the availability of “free take-home naloxone kits” in their respective provinces: Refer to: <https://www.canada.ca/en/health-canada/services/substance-use/problematic-prescription-drug-use/opioids/naloxone.html>

### Adverse Events Reporting

To report any suspected adverse events associated with the use of the opioid cough medicines:

- Visit the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or call toll-free at 1-866-234-2345. Contact Sanofi-Aventis Canada Inc. by phone at 1-800-265-7927 or by visiting the contact us page on Sanofi’s website at [www.sanofi.ca](http://www.sanofi.ca).

### Continuing Opioid Training

Maintain your knowledge concerning the risks of opioid-related harm, weighing these risks before prescribing an opioid and properly managing patients who are prescribed opioids, both for short and long-term use. Always be aware of the current conditions of use for the hydrocodone products as detailed in their respective Canadian Product Monographs.

Please refer to the links below for examples of the available Opioid Online Training.

- College of Family Physicians of Canada: <https://selflearning.cfpc.ca/#/lng-en/>
- Ontario Pharmacies Association: <https://www.opatoday.com/Tags/Addictions>
- McMaster University: [https://machealth.ca/programs/opioids\\_clinical\\_primer/](https://machealth.ca/programs/opioids_clinical_primer/)
- Centre for Addiction and Mental Health: <https://www.camh.ca/en/education/continuing-education-programs-and-courses>

This educational material is not a comprehensive description of the risks associated with the use of opioid cough medicines. Refer to the full Product Monograph of TUSSIONEX, NOVAHISTINE DH and NOVAHISTEX DH or contact Sanofi Medical Information (1-800-265-7927 or [SanofiMedInfoCA@sanofi](mailto:SanofiMedInfoCA@sanofi)) for complete prescribing information.

Regards,



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