

**Important Safety Information on Prescription  
Cough and Cold Products Containing Opioids and the Risk of Opioid Use  
Disorder in Children and Adolescents (< 18 years of age)**



Pendopharm, a Division of Pharmascience Inc.

2020/08/24

**Audience**

Healthcare professionals including general practitioners, family physicians, pediatricians, pediatric respirologists, allergists, nurse practitioners and pharmacists.

**Key messages**

- **Prescription cough and cold products containing codeine, hydrocodone or normethadone are NOT indicated for use in children and adolescents (younger than 18 years of age) since:**
  - **there is a risk of opioid toxicity due to the variable and unpredictable metabolism of codeine or hydrocodone.**
  - **the benefits of symptomatic treatment of cough associated with allergies or the common cold do not outweigh the risks of use of opioids in these patients.**
- **Healthcare professionals are being advised to:**
  - **avoid prescribing products containing opioids (codeine, hydrocodone, and normethadone) for treatment of cough and cold in patients younger than 18 years of age.**
  - **counsel patients and parents/caregivers that cough due to cold or upper respiratory infections is self-limited and generally does not need to be treated.**
  - **use non-opioid alternatives in children and adolescents for whom cough treatment is necessary.**
  - **should the non-opioid alternatives fail, always counsel patients and caregivers/parents on the risks associated with opioid medications and use the lowest effective dose for the shortest duration of time possible.**

- **Health Canada continues to work with the manufacturers of affected prescription opioid-containing products to include this new safety information in their respective Canadian Product Monographs (CPMs).**

### What is the issue?

In 2019, Health Canada published a summary of a [safety review](#) of opioid-containing products indicated for cough and cold, which found limited evidence to support the effectiveness of these products in children and adolescents (under 18 years of age). The review also found limited evidence to link these products with opioid use disorders and related harms in children and adolescents (under 18 years of age). As a precautionary measure, Health Canada has now limited the use of opioid-containing products indicated for cough and cold for adults only (patients 18 years of age and older) and has notified manufacturers of these products to update the indication and other relevant sections of the CPMs to include this new safety information.

### Products affected

DIN	Brand name and Dosage Form	Medicinal Ingredient(s) and Strength(s)	Manufacturer
02224577	COPHYLAC DROPS	normethadone hydrochloride 10 mg/mL p-hydroxyephedrine hydrochloride 20 mg/mL	Bausch Health, Canada Inc.
02324253	PDP-HYDROCODONE SYRUP	hydrocodone bitartrate 5 mg/5 mL	Pendopharm, a Division of Pharmascience Inc.
01934740	ROBITUSSIN AC SYRUP	codeine phosphate 10 mg/5 mL guaifenesin 100 mg/5 mL pheniramine maleate 7.5 mg/5 mL	GlaxoSmithKline Consumer Healthcare ULC
02244079	DIMETANE EXPECTORANT C SYRUP	codeine phosphate 10 mg/5 mL brompheniramine maleate 2 mg/5 mL guaifenesin 100 mg/5 mL phenylephrine hydrochloride 5 mg/5 mL	GlaxoSmithKline Consumer Healthcare ULC
02244080	DIMETANE EXPECTORANT DC SYRUP	hydrocodone bitartrate 1.8 mg/5 mL guaifenesin 100 mg/5 mL brompheniramine maleate 2 mg/5 mL	GlaxoSmithKline Consumer Healthcare ULC

<b>DIN</b>	<b>Brand name and Dosage Form</b>	<b>Medicinal Ingredient(s) and Strength(s)</b>	<b>Manufacturer</b>
		phenylephrine hydrochloride 5 mg/5 mL	
02244078	DIMETAPP-C SYRUP	codeine phosphate 10 mg/5 mL brompheniramine maleate 2 mg/5 mL phenylephrine hydrochloride 5 mg/5 mL	GlaxoSmithKline Consumer Healthcare ULC
02049481	NOVAHISTEX DH SYRUP	hydrocodone bitartrate 5 mg/5 mL phenylephrine hydrochloride 20 mg/5 mL	Sanofi-Aventis Canada Inc.
02049473	NOVAHISTINE DH SYRUP	hydrocodone bitartrate 1.7 mg/5 mL phenylephrine hydrochloride 10 mg/5 mL	Sanofi-Aventis Canada Inc.
01916971	TUSSIONEX ORAL SUSPENSION	hydrocodone 5 mg/5 mL phenyltoloxamine 10 mg/5 mL	Sanofi-Aventis Canada Inc.
02198630	CALMYLIN ACE SYRUP	codeine phosphate 10 mg/5 mL guaifenesin 100 mg/5 mL pheniramine maleate 7.5 mg/5 mL	Teva Canada Limited
02169126	TEVA-COTRIDIN SYRUP	codeine phosphate 10 mg/5 mL pseudoephedrine hydrochloride 30 mg/5 mL triprolidine hydrochloride 2mg/5 mL	Teva Canada Limited
02053403	TEVA-COTRIDIN EXPECTORANT SYRUP	codeine phosphate 10 mg/5 mL pseudoephedrine hydrochloride 30 mg/5 mL triprolidine hydrochloride 2mg/5 mL guaifenesin 100 mg/5 mL	Teva Canada Limited
00593435	TEVA-CODEINE TABLETS	codeine phosphate 15mg	Teva Canada Limited

<b>DIN</b>	<b>Brand name and Dosage Form</b>	<b>Medicinal Ingredient(s) and Strength(s)</b>	<b>Manufacturer</b>
00593451	TEVA-CODEINE TABLETS	codeine phosphate 30mg	Teva Canada Limited
00608882	TEVA-EMTEC-30 TABLETS	codeine phosphate 30mg	Teva Canada Limited
		acetaminophen 300mg	
00380571	LINCTUS CODEINE BLANC ORAL SOLUTION	codeine phosphate 10 mg/5 mL	Laboratoire Atlas Inc.
00544884	CODEINE PHOSPHATE INJECTION USP	codeine phosphate 30mg/mL	Sandoz Canada Incorporated
02009757	CODEINE 30 TABLETS	codeine phosphate 30mg	Laboratoire Riva Inc.
02230769	DALMACOL SYRUP	hydrocodone bitartrate 1.65 mg/5 mL	Laboratoire Riva Inc.
		etfedrin hydrochloride 16.65 mg/5 mL	
		sodium citrate 200 mg/5 mL	
		alcohol anhydrous 0.25 mL/5 mL	
		doxylamine succinate 6 mg/5 mL	
00789828	TRIATEC-30 TABLETS	codeine phosphate 30mg	Laboratoire Riva Inc.
		acetaminophen 300mg	
02243063	COVAN SYRUP	triprolidine hydrochloride 2mg/5mL	Pharmascience Inc.
		pseudoephedrine hydrochloride 30mg/5mL	
		codeine phosphate 10mg/5mL	

## **Background information**

Currently in Canada, codeine-containing products have been authorized to relieve pain or suppress cough, while products containing hydrocodone and normethadone have been authorized for cough suppression only.

Following a [safety review](#) of cough and cold products containing opioids (codeine, hydrocodone and normethadone), Health Canada issued a [risk communication](#) on February 18, 2019 recommending children and adolescents (under 18 years of age) not to use cough and cold products that contain opioids. The prescription codeine-containing products indicated for pain relief were not in scope of this specific safety review completed by Health Canada at that time.

While the review did not find any strong evidence linking cough and cold products that contain opioids with opioid use disorders in children and adolescents, it did find that the early use of opioids may be a factor in problematic substance use later in life. The review also found limited evidence to support the effectiveness of these products in children and adolescents (under 18 years of age). Literature suggests that adolescents are at a greater risk of problematic opioid use and overdose, while younger children are at a greater risk of accidental poisoning.

As part of the Government of Canada's ongoing comprehensive strategy to increase awareness and reduce the harms of opioids for Canadians, Health Canada has required the labelling of prescription cough and cold containing opioids to be updated, and continues to work with manufacturers to include enhanced information about the product's risks and limit the use of these products for adults only ( $\geq 18$  years old). Labelling for non-prescription products containing low-dose codeine to treat cough and cold has also been required to be updated with this safety information.

## **Information for consumers**

Cough and cold products containing opioids should not be used in patients younger than 18 years of age. This includes prescription cough and cold products that contain codeine, hydrocodone or normethadone.

Parents and caregivers are encouraged to discuss with their healthcare professionals about the need to treat cough and possible cough treatment alternatives, other than products containing opioids, for children or adolescents (under 18 years of age).

Patients should discuss any questions or concerns about this information with their healthcare professional.

## **Information for healthcare professionals**

Healthcare professionals are being advised that:

- Prescription cough and cold products containing opioids are no longer indicated in patients younger than 18 years of age since:
  - there is a risk of opioid toxicity due to the variable and unpredictable

metabolism of codeine or hydrocodone; and

- the benefits of symptomatic treatment of cough associated with allergies or the common cold do not outweigh the risks for use of opioids in these patients.
- Parents should be advised that cough due to cold or upper respiratory infections is self-limited and generally does not need to be treated.
- For those children and adolescents requiring cough treatment, non-opioid alternatives are available.
- Should the non-opioid alternatives fail, always advise patients and parents/caregivers of the risks associated with opioid medications and use the lowest effective dose for the shortest duration of time possible.

### **Action taken by Health Canada**

Health Canada continues to work with respective manufacturers to update the labelling of prescription cough and cold products containing opioids to include the restriction of the indication to adults only ( $\geq 18$  years old).

Health Canada is communicating this important safety information to healthcare professionals and Canadians via the [Recalls and Safety Alerts Database on the Healthy Canadians Web Site](https://recallsandsafetyalerts.gc.ca/) (<https://healthycanadians.gc.ca/recall-alert-rappel-avis/index-eng.php>). This communication update will be further distributed through the MedEffect™ e-Notice email notification system, as well as through social media channels, including LinkedIn and Twitter.

### **Report health or safety concerns**

Health Canada's ability to monitor the safety of marketed health products depends on healthcare professionals and consumers reporting adverse reactions and medical device incidents. Any case of serious or unexpected side effects in patients receiving cough and cold products containing codeine, hydrocodone or normethadone should be reported to the respective manufacturer or Health Canada.

**GlaxoSmithKline  
Consumer Healthcare  
ULC**  
Mississauga, ON  
1-888-275-9938

**Laboratoire Riva  
Inc.**  
Blainville, Québec  
1-800-363-7988

**Teva Canada Ltd.**  
Toronto, Ontario  
1-800-268-4127,  
option 3

**Sanofi-aventis Canada  
Inc.**  
Laval, Québec,  
1-800-265-7927

**Pharmascience Inc.  
and Pendopharm, a  
Division of  
Pharmascience**  
Montreal, Québec  
1-888-550-6060

**Laboratoire Atlas  
Inc,**  
Anjou, Quebec  
514-254-7188

**Sandoz Canada Inc.**  
110, rue de Lauzon  
Boucherville, Quebec  
1-800-343-8839

**Bausch Health, Canada  
Inc.**  
2150 boulevard St-Elzéar  
ouest West  
Laval, Québec H7L 4A8  
1-800-361-4261

**To correct your mailing address or fax number, contact one of the companies listed above.**

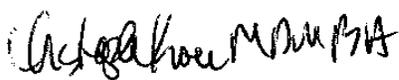
You can report any suspected adverse reactions associated with the use of health products to Health Canada by:

- Calling toll-free at 1-866-234-2345; or
- Visiting MedEffect Canada's Web page on [Adverse Reaction Reporting](https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html) (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax.

For other health product inquiries related to this communication, contact Health Canada at:

Marketed Health Products Directorate (MHPD)  
E-mail: [hc.mhpd-dpsc.sc@canada.ca](mailto:hc.mhpd-dpsc.sc@canada.ca)  
Telephone: 613-954-6522  
Fax: 613-952-7738

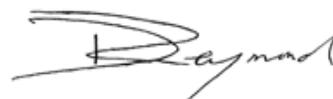
Sincerely,



Christopher Kocun, MD, MBA  
Chief Medical Officer  
GlaxoSmithKline Consumer  
Healthcare ULC



Olivier St-Denis  
President, Laboratoire Riva  
Inc.



Didier Reymond, MD  
Country Medical  
Director  
Teva Canada Ltd.



Sophia Kajla  
Medical Head, General  
Medicines  
sanofi-aventis Canada Inc.



Brian des Islet, PhD  
Vice-President Scientific  
Affairs  
Pharmascience Inc.  
Pendopharm, a Division of  
Pharmascience Inc.



Jean Noory  
QC director  
Laboratoire Atlas Inc.



---

Mauricio Ede  
Chief Medical and Scientific  
Officer  
Sandoz Canada Inc.



---

Tibor Kapusy, MD  
Director, Regulatory Affairs  
Bausch Health, Canada  
Inc.