Important Safety Information on Codeine Antitussive Products

teva | Canada

05-JUNE-2023

Audience
Healthcare professionals including family physicians, general practitioners, and pharmacists.

Key messages

When codeine-containing antitussive medications are used, the following important risks have been identified:

- Abuse, misuse and opioid use disorder
- Respiratory depression
- Overdose
- Neonatal opioid withdrawal syndrome
- Interaction with benzodiazepines and other CNS depressants, including alcohol
- Physical tolerance, dependence, and withdrawal

Important potential risk are:

- Medication errors
- Accidental exposure
- Off-label use
- Diversion

What is the issue?
To respond to the opioid crisis in Canada, Health Canada and manufacturers are working to provide comprehensive risk communications to HCPs in an effort to remind them of the risk of opioid-related harms and proper use of codeine antitussive products.

Products affected
Codeine-Teva (Cotridin)
Codeine-Teva (Cotridin Expectorant)
Codeine-Teva (Calmylin ACE)

Background information

TEVA Canada is the Canadian distributor of 3 codeine-containing antitussive medications: Calmylin ACE, Teva-Cotridin and Teva-Cotridin Expectorant are distributed as prescription medications.

As part of the implementation of risk mitigation strategies to address this opioid crisis, Teva Canada Limited developed an action plan with a focus on risk communications to HCPs in an effort to remind them on the risk of opioid-related harms and proper use of codeine antitussive products.

Information for consumers

Even if you take codeine-containing syrups as prescribed, you are at risk for opioid addiction, abuse and misuse. This can lead to overdose and death.

You may get life threatening breathing problems while taking these syrups. This is less likely to happen if you take it as prescribed by your doctor. Babies are at risk of life-threatening breathing problems if their mothers take opioids while pregnant or nursing.

You should never give anyone your codeine-containing cough syrups. They could die from taking it. If a person has not been prescribed these syrups, taking even one dose can cause a fatal overdose. This is especially true for children.

If you took a codeine-containing syrup while you were pregnant, whether for short or long periods of time or in small or large doses, your baby can suffer life-threatening withdrawal symptoms after birth. This can occur in the days after birth and for up to 4 weeks after delivery. If your baby has any of the following symptoms:

- has changes in their breathing (such as weak, difficult, or fast breathing)
- is unusually difficult to comfort
- has tremors (shakiness)
- has increased stools, sneezing, yawning, vomiting, or fever

Seek immediate medical help for your baby.

Taking codeine-containing syrups with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.

As with all opioids, taking codeine-containing syrups may cause you to become dependent on it. Do not take more than the dose prescribed to you by your doctor.

If you think you have taken too much codeine-containing syrups, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.
You should keep unused or expired codeine-containing syrups in a secure place to prevent theft, misuse or accidental exposure. Codeine-containing syrups should never be thrown into household trash, where children and pets may find it. It should be returned to a pharmacy for proper disposal.

Information for healthcare professionals

Limitations of Use

Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with controlled release opioid formulations, these antitussive syrups should only be used in patients for whom alternative non-opioid treatment options are ineffective, not tolerated, or would be otherwise inadequate to provide appropriate cough management.

Regardless of the clinical setting, the use of codeine-containing syrups is not recommended in patients below the age of 18 years due to increased safety concerns

Addiction, Abuse, and Misuse
Codeine-containing syrups pose risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Each patient's risk should be assessed prior to prescribing. All patients should be monitored regularly for the development of these behaviors or conditions. Medication should be stored securely to avoid theft or misuse.

Life-threatening Respiratory Depression: overdose
Serious, life-threatening, or fatal respiratory depression may occur with use of these syrups. Infants exposed in-utero or through breast milk are at risk of life-threatening respiratory depression upon delivery or when nursed. Patients should be monitored for respiratory depression, especially during initiation of therapy or following a dose increase.

Accidental Exposure/Diversion
Accidental exposure, especially by children, can result in a fatal overdose of these syrups.
Patients should be instructed not to give these syrups to anyone other than the patient for whom it was prescribed, as such inappropriate use may have severe medical consequences, including death.

Neonatal Opioid Withdrawal Syndrome
Prolonged maternal use during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening

Interaction with Alcohol
The co-ingestion of alcohol with these syrups should be avoided as it may result in dangerous additive effects, causing serious injury or death

Risks from Concomitant Use With Benzodiazepines Or Other CNS Depressants
Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death.

- Reserve concomitant prescribing of codeine-containing syrups and benzodiazepines or other CNS depressants for use in patients for whom alternative treatment options are inadequate.
- Limit dosages and durations to the minimum required.
- Follow patients for signs and symptoms of respiratory depression and sedation.

Physical Dependence/Tolerance

As with other opioids, tolerance and physical dependence may develop upon repeated administration of these syrups and there is a potential for development of psychological dependence.

Report health or safety concerns

Managing marketed health product-related side effects depends on health care professionals and consumers reporting them. Any case of addiction, abuse, and misuse, or other serious or unexpected side effects in patients receiving one of the three above mentioned products should be reported to Teva Canada Limited or Health Canada.

Teva Canada Limited
30 Novopharm Ct
Toronto, Ontario M1B 2K9
Phone: 1-800-268-4127, ext. 3

To correct your mailing address or fax number, contact Teva Canada Limited.

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) 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
E-mail: hc.mhpd-dpsc.sc@canada.ca
Telephone: 613-954-6522
Fax: 613-952-7738

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