Health Canada Santé Canada

GUIDANCE DOCUMENT

Non-prescription Oral Adult Decongestant Cough and Cold Labelling Standard

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Health Products and Food Branch

Canada

Our mission is to help the people of Canada maintain and improve their health. *Health Canada*	The Health Products and Food Branch's mandate is to take an integrated approach to the management of the risks and benefits to health related products and food by: • minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and, • promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health. *Health Products and Food Branch*

Également disponible en français sous le titre : Ligne directrice : Norme d'étiquetage des médicaments décongestionnants pour adultes vendus sans ordonnance contre la toux et le rhume administrés par voie orale

FOREWORD

Guidance documents are meant to provide assistance to industry and health care professionals on **how** to comply with governing statutes and regulations. They also provide assistance to staff on how Health Canada mandates and objectives should be implemented in a manner that is fair, consistent and effective.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. These alternate approaches to the principles and practices described in this document ***may be*** acceptable provided they are supported by adequate justification. Alternate approaches should be discussed in advance with the relevant program area to avoid the possible finding that applicable statutory or regulatory requirements have not been met.

As a corollary to the above, it is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document, in order to allow the Department to adequately assess the safety, efficacy or quality of a therapeutic product. Health Canada is committed to ensuring that such requests are justifiable and that decisions are clearly documented.

This document should be read in conjunction with the accompanying notice and the relevant sections of other applicable guidance documents and regulations.

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1. INTRODUCTION

This labelling standard describes the requirements necessary to receive marketing authorization (a Drug Identification Number (DIN)) for oral decongestant non-prescription products containing phenylephrine hydrochloride as a single ingredient for use in adults and children 12 years of age and older. This labelling standard does not apply to products for use by children under 12 years of age.

2. MEDICINAL INGREDIENT

TABLE 1: Drug medicinal ingredient

Therapeutic Class	Medicinal Ingredient Preferred Name
Decongestant	Phenylephrine hydrochloride

3. PHARMACEUTICAL FORMS

3.1 Acceptable:

- Immediate release solid oral dosage forms such as tablets, caplets, capsules, chewable tablets, effervescent tablets, powders, lozenges.
- Oral liquid formulations such as suspension, syrup, elixir.

3.2 Unacceptable:

- Modified dose release (e.g. liquid extended release, solid oral sustained release, bi-layer formulations or enteric coated products).
- Products that require evaluation of animal sourced ingredients (e.g. animal tissue based gelatin capsules, where a valid European Directorate for the Quality of Medicines (EDQM) Certificate of Suitability or equivalent is not provided).
- Other dosage forms: e.g., liquid filled capsule, powder dosage form intended for direct application to the mouth, thin strips, lollipops, popsicles/freezer pops etc.

4. USES

4.1 Acceptable Uses

Nasal Decongestant

Temporary relief of nasal congestion due to:
- the common cold.
- hay fever or other upper respiratory allergies

Temporary relief of:
- stuffy nose
- sinus pressure/congestion

4.2 Unacceptable Uses

The following indications for decongestant products are excluded and would require a review outside of this labelling standard. These include but are not limited to:

- sinusitis
- bronchitis
- influenza/flu

5. DOSAGE DIRECTIONS

5.1 Dosage for Adults and children 12 years of age and older[1]

TABLE 2:

Therapeutic Class	Medicinal ingredient preferred name	Recommended Single Dose[2]	Dose Interval	Maximum Daily Dose
Decongestant	Phenylephrine Hydrochloride	10 mg	every 4 hours	60 mg

Do not take more than 60 mg of Phenylephrine in 24 hours.

[1] Doses and dosing frequency are those recommended by the Expert Advisory Committee on Nonprescription Cough and Cold Remedies (First Report, August 1988).

[2] For liquid formulations, the single dose must be contained and labelled in standard units (e.g., millilitres).

5.2 Dosing Considerations

1. The quantitative declaration of the medicinal ingredients on any panel of the inner and outer labels should be prominently displayed and should be further identified by the therapeutic class or indication listed under **Section 4.1**, e.g.: "Medicinal Ingredient: Phenylephrine Hydrochloride (decongestant) 10mg"; "Medicinal Ingredient: Phenylephrine Hydrochloride (relief of nasal congestion) 10mg".

2. The labels should declare the recommended single and maximum daily dose, as well as the dosing interval for the product. Maximum daily dose may be expressed in terms of dosage units (e.g. do not exceed X tablets per day).

3. For liquid formulations, the following statement should be included with the directions for use: "Use only the measuring device provided."

5.3 Combinations

Applicants should apply outside of the labelling standard if they wish to combine phenylephrine hydrochloride with other medicinal ingredients.

6. WARNINGS

For outer and inner label

Do not use with a monoamine oxidase inhibitor (MAOI) or for 2 weeks after stopping the MAOI drug.

Ask a doctor before use if you have:
- heart disease, high blood pressure, thyroid disease, diabetes
- difficulty in urination due to enlargement of the prostate gland
- pregnant or breastfeeding

Ask a doctor or pharmacist before use if you:
- are allergic to phenylephrine or any other ingredient in this product

Stop use and ask a doctor if:
- nervousness, dizziness, or sleeplessness occur
- symptoms last for more than 1 week, worsen, or are accompanied by fever

These could be signs of a serious condition.

In Case of Overdose: Call a Poison Control Centre or a healthcare professional immediately, even if you do not notice any signs or symptoms.

7. PRODUCT FACTS TABLE: RECOMMENDED (NOT MANDATORY)[3]

Product Facts

Medicinal ingredient (in each dosage unit) **Purpose**

Phenylephrine Hydrochloride XX mg.....Nasal Decongestant

Uses **Temporary relief of nasal congestion due to** • •	**Temporary relief of:** • •

Warnings

Do not take more than 60 mg of Phenylephrine in 24 hours

Do not use with a monoamine oxidase inhibitor (MAOI) or for 2 weeks after stopping the MAOI drug.

Ask a doctor before use if you have

- heart disease, high blood pressure, thyroid disease, diabetes
- difficulty in urination due to enlargement of the prostate gland
- pregnant or breastfeeding

Ask a doctor or pharmacist before use if you are allergic to phenylephrine or any other ingredient in this product

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- symptoms last for more than 1 week, worsen, or are accompanied by fever

These could be signs of serious condition.

Directions
Adults and children 12 years and over
Do not take more than directed

- Take 10 mg every 4 hours
- Do not take more than 60 mg in 24 hours

Overdose warning: In case of overdose, get medical help or call a Poison Control Centre immediately.

Non-medicinal ingredients
< List all NMIs>

Questions? Concerns? Call 1-877-XXX-XXXX

[3] The regulatory amendment for a Fact Table for non-prescription drug products would come into force three years after the day of registration in Canada Gazette Part II.
http://gazette.gc.ca/rp-pr/p2/2014/2014-07-02/html/sor-dors158-eng.php
http://www.hc-sc.gc.ca/dhp-mps/consultation/drug-medic/pll_fact_tab_rens_elc-eng.php

8. OTHER LABELLING REQUIREMENTS

Declaration of ingredients for all products:

Section C.01.004 of the *Food and Drug Regulations* indicates that for single ingredient products and/or products for which a compendial standard exists, the following must be shown on the inner and outer labels:

- the proper name on the principal display panel immediately preceding or following the brand name in a font size not less than 1/2 the size of the brand name
- a quantitative list of the medicinal ingredients by their proper names, or common names if they have no proper names
- a qualitative list of non-medicinal ingredients clearly distinguished from the medicinal ingredients.

Health Canada's *Guidance Document: Labelling of Pharmaceutical Drugs for Human Use* should be consulted for applicable labelling requirements

Legibility:

Although no specific type size is mentioned in the *Regulations*, Section A.01.016 specifies that all information required to appear on a label must be:

- Clearly and prominently displayed, and
- Readily discernible to the purchaser or consumer under the customary conditions of purchase and use.

A person with normal vision, or those with corrective glasses that restore normal vision, should be able to read the information without straining. The colour, contrast, the position, and the spacing of the information are all to be taken into consideration in complying with these requirements.

9. SPECIFICATIONS

This labelling standard describes those requirements that are specific to this class of drug.

- Products must comply with the requirements in the *Food and Drugs Act* and associated *Regulations*. It is also noted that all products are subject to Part C, Division 2 of the *Food and Drug Regulations*.

- All ingredients (medicinal and non-medicinal) and finished product specifications must meet or exceed the standards described in the publications referred to in Schedule B of the *Food and Drugs Act*, or equivalent standards.

- Where no Schedule B monograph exists for the finished product's dosage form, specifications should be similar to those of a comparable compendial dosage form demonstrating the product's identity, potency, purity and quality.

- Finished product specifications should include tests for identification and an assay with suitable limits for the medicinal ingredient(s). The specifications for all dosage forms should include a description of the dosage form, including organoleptic properties as well as physico-chemical testing (e.g., pH, specific gravity, viscosity) appropriate to the dosage form. Where antimicrobial preservatives are added, an assay with suitable limits should be included. Antimicrobial preservative effectiveness should be determined in order to establish that the product is capable of resisting microbial contamination.

- Any change to the manufacturing process that impacts the safety and efficacy of the ingredients, such as the use of novel technology (e.g. nanotechnology), requires supporting data and will be reviewed outside the labelling standard.

10. NON-MEDICINAL INGREDIENTS

Non-medicinal ingredients must be chosen from the current Natural Health Products Ingredients Database and must meet the limitations outlined in that database.

Non-medicinal ingredients must be restricted to those substances, necessary for the formulation of the dosage form. Their concentration must not exceed the minimum required to provide their intended effect. They must be harmless in the amounts used, their presence must not affect the therapeutic efficacy or safety of the medicinal ingredients and they must not interfere with assays and tests for the medicinal ingredients and, if present, antimicrobial preservatives. Sponsors should be aware that ingredients of botanical origin added as non-medicinal ingredients must comply with the Health Canada Policy entitled *Herbs Used as Non-Medicinal Ingredients in Non-prescription Drugs for Human Use* (1995).

11. REFERENCES

1. *Guidance Document: Labelling of Pharmaceutical Drugs for Human Use*. Health Canada, January 10, 2014.

2. *Guidance for Industry: Impurities in Existing Drug Substances and Products*. Health Canada, September 2005.

3. *Guidance to Industry: Product Monograph*. Health Canada, October, 2004.

4. *Herbs Used as Non-Medicinal Ingredients in Nonprescription Drugs for Human Use*. Health Canada, September 1995.

5. First report of the expert advisory committee on non-prescription cough and cold remedies. *Health and Welfare Canada, August 1988.*

6. United States Food and Drug Administration: Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products For Over-The-Counter Human Use; Final Monograph for OTC Decongestant Drug Products Code of Federal Regulations Part 310, 341, and 369, Volume 59, No. 162, Tuesday, August 23, 1994. http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/DevelopmentResources/Over-the-CounterOTCDrugs/StatusofOTCRulemakings/ucm116167.pdf

7. United States Food and Drug Administration: Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products For Over-The-Counter Human Use; Code of Federal Regulations Part 341, Title 21, Volume 5, Revised as of April 1, 2014. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=341.14