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GUIDANCE DOCUMENT

Non-prescription Oral Adult Nasal Decongestant Labelling Standard

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Health Products and Food Branch

Canada

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Également disponible en français sous le titre : Ligne directrice : Norme d'étiquetage des médicaments décongestionnants nasaux pour adultes vendus sans ordonnance 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 non-prescription oral decongestant 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. chewable 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/sinus congestion
- sinus pressure
- congestion/stuffiness/stuffy nose due to the common cold/hay fever or other upper respiratory allergies.

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 older¹

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.

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) 10 mg”; “Medicinal Ingredient: Phenylephrine Hydrochloride (relief of nasal congestion) 10 mg”.

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).

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, if a measuring device is provided, 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:

Keep out of the reach of children.

Do not use:

- if you are allergic to phenylephrine or any other ingredient in this product.
- with a monoamine oxidase inhibitor (MAOI) (drugs for depression or Parkinson’s disease) or for two (2) weeks after stopping the MAOI drug.

Ask a doctor before use if you have:

- heart disease, high blood pressure, thyroid disease, diabetes.
- difficulty with urination due to enlargement of the prostate gland.

If pregnant or breast-feeding, ask a healthcare professional before use.

Stop use and ask a doctor if:

- nervousness, dizziness, or sleeplessness occur.
 - symptoms last for more than one (1) week, worsen, or are accompanied by fever (>38°C).
- **In Case of Overdose:** Call a Poison Control Centre or a health care 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: <ul style="list-style-type: none"> nasal/sinus congestion sinus pressure congestion/stuffiness/stuffy nose due to the common cold/hay fever or other upper respiratory allergies 	
Warnings	
Do not use: <ul style="list-style-type: none"> if you are allergic to phenylephrine or any other ingredient in this product. with a monoamine oxidase inhibitor (MAOI) (drugs for depression or Parkinson’s disease) or for two (2) weeks after stopping the MAOI drug. 	
Ask a doctor before use if you have: <ul style="list-style-type: none"> heart disease, high blood pressure, thyroid disease, diabetes. difficulty with urination due to enlargement of the prostate gland. 	
Stop use and ask a doctor if: <ul style="list-style-type: none"> nervousness, dizziness, or sleeplessness occur. symptoms last for more than one (1) week, worsen, or are accompanied by fever (>38°C). 	
If pregnant or breast-feeding, ask a health care professional before use.	
Keep out of reach of children.	
Overdose warning: In case of overdose, call a Poison Control Centre or a health care professional immediately.	
Directions	
Adults and children 12 years and over: <ul style="list-style-type: none"> Take 10 mg every 4 hours. Do not take more than 60 mg in 24 hours. 	
Do not take more than directed.	
Other Information	
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 (3) 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>

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 font 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 ingredient (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 (NHPID) and must meet the limitations outlined in that database, the *Food and Drug Regulations* (FDR), and/or the *Herbs used as Non-medicinal Ingredients in Non-prescription Drugs for Human Use* policy, when relevant.

11. REFERENCES

1. *Guidance Document: Labelling of Pharmaceutical Drugs for Human Use*. Health Canada, January 10, 2014.
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4. *Herbs Used as Non-Medicinal Ingredients in Nonprescription Drugs for Human Use* policy. 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.
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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>