

2025-12-19



Acne Therapy Monograph

Health Products and Food Branch

FOREWORD

This monograph is intended to replace the existing Acne Therapy Monograph of June 25, 2021. This monograph describes the requirements necessary to receive market authorization [i.e., a Drug Identification Number (DIN) or a Natural Product Number (NPN)], for topical acne therapy products. The monograph identifies the permitted medicinal and non-medicinal ingredients, concentrations, indications, directions and conditions of use for these products to be market authorized without the submission to Health Canada of additional evidence. Products which do not meet the criteria outlined in this document can apply for market authorization outside of the monograph stream.

Applicants are reminded that acne therapy products, like other non-prescription drugs or natural health products, are subject to the Food and Drug Regulations or the Natural Health Products Regulations administered by the Natural and Non-prescription Health Products Directorate (NNHPD). This includes requirements related to labelling, manufacturing and product specifications. Additional information on labels, outside of those specified in the monograph, such as additional directions for use and/or non-therapeutic claims are acceptable as long as they meet the [Guidelines for the Nonprescription and Cosmetic Industry Regarding Non-therapeutic Advertising and Labelling Claims](#), the [Guidelines for Consumer Advertising of Health products for Nonprescription drugs, Natural Health Products, Vaccines and Medical Devices](#), and are not false, misleading or counterintuitive to the use of the product.

The development of this monograph is the result of a thorough review of existing regulations, guidance documents, policies and current practices within Health Canada and other leading regulatory agencies.

Notes

- Text in parentheses is additional optional information which can be included on the label at the applicant's discretion.
- The solidus (/) indicates that either term and/or statement may be selected on the label.

Medicinal ingredient(s)

Acne therapy products are classified as natural health products (NHPs) if they contain an ingredient listed in Table 1 and do not contain any ingredient listed in Table 2. Applicants seeking to obtain a NPN can access the appropriate forms and guidance at: <https://www.canada.ca/en/health-canada/services/drugs-health-products/natural-non-prescription.html>.

Acne therapy products are classified as non-prescription drugs (NPDs) if they contain an ingredient from Table 2. Applicants applying for a DIN can access the appropriate forms and guidance at: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions.html>.

Proper name(s), Common name(s), Source information

Table 1: NHP medicinal ingredients

Proper name(s) ¹	Common name(s) ¹	Source information ¹	Quantity ²
		Source ingredient(s)	
2-Hydroxybenzoic acid	Salicylic acid	Salicylic acid	0.5 – 2%
Sulfur	Sulfur	Sulfur	3 – 10% ³
1,3-Benzenediol - m-Dihydroxybenzene	Resorcinol	Resorcinol	2% ⁴
1,3-Benzenediol, monoacetate	Resorcinol monoacetate	Resorcinol monoacetate	3% ⁴

¹At least one of the following references was consulted per proper name, common name, and source information: RSC 2025; USP-NF 2024.

²Quantity can be expressed as percentage weight by weight (% w/w) or percentage weight by volume (% w/v), depending on the product formulation. The following references were consulted for the dosage: US FDA 2021; Sweetman 2017.

³The appropriate dosage range for sulfur in combination with resorcinol or resorcinol monoacetate is 3-8 % (US FDA 2021).

⁴Resorcinol and Resorcinol monoacetate are not permitted as single medicinal ingredients and must be in combination with 3-8 % sulfur (US FDA 2021).

Table 2: NPD medicinal ingredient

Proper name	Common name	Quantity
Benzoyl peroxide	Benzoyl peroxide	2.5 – 5%

Route of administration

Topical

Dosage form(s)

Acceptable dosage forms for NHPs

- Aerosol; Aerosol, spray; Bar, soap; Cream; Foam; Gel; Lotion; Ointment; Paste; Soap, liquid; Solution; Sponge; Spray; Topical liquid; Wipe

Acceptable dosage forms for NPDs

- Aerosol; Cream; Gel; Lotion; Ointment; Paste; Solution; Wipe

Use(s) or Purpose(s)

Self-Care Framework Category I Uses or Purposes (for NPDs):

All products

- For the treatment/management of acne (breakouts)
- Acne treatment/medication
- Helps treat acne pimples (and allows skin to heal)
- (Dries and) helps clear (up) (most) acne pimples (and allows skin to heal)
- Reduces the number (and severity)/the severity of acne pimples (and allows skin to heal)
- Penetrates pores to control/reduce the number of acne pimples
- Penetrates pores to eliminate/clear most acne pimples
- Helps keep skin clear of new acne pimples
- Helps prevent (the development of) (new) acne (pimples) (from forming)

Products containing benzoyl peroxide

- Prevents (and)/Kills acne bacteria.
- Eliminates acne bacteria

Notes

- The above uses can be combined on the product label (e.g., Helps treat acne pimples and prevent new acne pimples from forming).
- The term "acne pimples" above can be replaced on the label by any of the following: "acne zits" "acne blemishes", "acne spots", "blackheads", "whiteheads" and "comedones".

Unacceptable use(s) or purpose(s)

Statement(s) to the effect of:

- Controls oil (oily skin)
- Cures acne
- Severe acne

Applications for products that recommend a sequential treatment regime or products co-packaged with another non-prescription drug, natural health product or cosmetic product (as defined in the [Guidance Document: Labelling of Pharmaceutical Drugs for Human Use](#)) will be reviewed outside the monograph.

Dose(s)

Subpopulation(s)

Adolescents 12 to 17 years, Adults 18 years and older

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Quantity(ies)

See Tables 1 and 2.

Permitted combinations

The only permitted combinations are sulfur and resorcinol or resorcinol monoacetate (US FDA 2021):

- Sulfur: 3 - 8 % + Resorcinol: 2 %
- Sulfur: 3 - 8 % + Resorcinol monoacetate: 3 %

Additional note: Resorcinol or resorcinol monoacetate in combination with sulfur cannot be included in rinse off products (e.g. body cleansers or face wash products).

Direction(s) for use

All products

- Cover the entire affected area with a thin layer (US FDA 2021).
- Start with 1 application daily, then gradually increase to 2 or 3 times daily, if needed (US FDA 2021).
- If dryness or peeling occurs, reduce application to once a day or every other day (US FDA 2021).

Optional

For New Users: Apply product to a small area once a day for 3 days to test if you are sensitive to this product. If no discomfort occurs, use as directed (US FDA 2021).

Products intended to be left on the skin

Cleanse/clean (the) skin thoroughly before applying (the) product (US FDA 2021).

Products intended to be applied to the skin and rinsed off

Rinse off (after X minutes) (US FDA 2021).

Aerosols, aerosol sprays and sprays

- Do not spray directly onto face. Spray on hands then apply to face.
- Avoid inhaling or exposing others to spray.

Duration(s) of use

No statement is required.

Risk information

Caution(s) and warning(s)

All products

- **For external use only** (US FDA 2021).
- **Ask a health care practitioner/health care provider/health care professional/doctor/physician/pharmacist before use** if you have severe acne.
- **When using this product** avoid contact with eyes. If contact occurs, rinse thoroughly with water (US FDA 2021).
- **When using this product** skin irritation and dryness are more likely to occur when using another topical acne product at the same time. If irritation occurs, use only one product at a time (US FDA 2021).
- **Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician** if improvement is not apparent within 6-8 weeks (Krinsky et al. 2017; Sweetman 2017).
- **Keep out of reach of children.** If swallowed, call a poison control centre or get medical help right away.

Products containing Sulfur

When using this product apply only to areas with acne (US FDA 2021).

Products containing Benzoyl Peroxide

- **When using this product** avoid contact with lips, mouth, and nostrils; if contact occurs, rinse with water (US FDA 2021).
- **When using this product** avoid contact with hair and dyed fabrics, which may be bleached by this product (US FDA 2021).
- **When using this product** avoid unnecessary sun exposure and use a sunscreen (US FDA 2021).

Contraindication(s)

Products containing Sulfur

- **Do not use** on broken skin (US FDA 2021).
- **Do not use** on large areas of the skin (US FDA 2021).

Products containing Benzoyl Peroxide

- **Do not use** on sensitive skin (US FDA 2021).
- **Do not use** if you are allergic to benzoyl peroxide (US FDA 2021).

Known Adverse Reaction(s)

All products

Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if you develop severe irritation, burning or itching of the skin (US FDA 2021; HC 2015).

Products containing Benzoyl peroxide or Salicylic acid

Allergy alert get medical help right away if you develop hives, swelling of eyes and mouth, blistering, or difficulty breathing (HC 2015).

Non-medicinal ingredients

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 the current [Cosmetic Ingredient Hotlist](#), when relevant.

Storage conditions

Must be established in accordance with the requirements described in the *Natural Health Products Regulations* or the *Food and Drug Regulations*.

Specifications

This monograph describes those requirements that are specific to this class of non-prescription drugs and to NHPs. 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 monograph.

For products containing Table 1 NHP medicinal ingredients only

The finished product specifications must be established in accordance with the requirements described in the NNHPD [Quality of Natural Health Products Guide](#). The medicinal ingredient must comply with the requirements outlined in the [NHPID](#).

For products containing Table 2 non-prescription drug medicinal ingredients

Requirements described in the Regulations to the *Food and Drugs Act* must be met.

EXAMPLE OF PRODUCT FACTS (for NHPs):Consult the Guidance Document, [Labelling of Natural Health Products](#) for more details.

Product Facts	
Medicinal ingredient (w/v)	
Salicylic acid	XX %
Uses • Helps treat acne pimples. • Helps prevent acne pimples from forming. • Dries and helps clear up acne pimples and allows skin to heal. • Reduces the number and severity of acne pimples.	
Warnings	
If applicable¹: Allergens: food allergen, gluten (gluten source), sulphites, etc. Contains aspartame	
For external use only	
Allergy alert get medical help right away if you develop hives, swelling of eyes and mouth, blistering, or difficulty breathing.	
Ask a health care practitioner before use if you have severe acne.	
When using this product • skin irritation and dryness are more likely to occur when using another topical acne product at the same time. If irritation occurs, use only one product at a time • avoid contact with eyes. If contact occurs, rinse thoroughly with water.	
Stop use and ask a health care practitioner if • improvement is not apparent within 6-8 weeks • you develop severe irritation, burning or itching of the skin.	
Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away.	
Directions Adults and Adolescents 12 years and older: • Cleanse skin thoroughly before applying product • For New Users: Apply product to a small area once a day for 3 days to test if you are sensitive to this product. If no discomfort occurs, use as directed • Cover the entire affected area with a thin layer • Start with one application daily, then gradually increase to 2 or 3 times daily, if needed • If dryness or peeling occurs, reduce application to once a day or every other day.	
Other information (Add storage information)	
Non-medicinal ingredients List all NMIs	
Questions? (Call) 1-XXX-XXX-XXXX	

¹This section can be removed from the table if the product contains no allergen or aspartame.²Optional.

DRUG FACTS TABLES (for NPDs; Format Optional for Self-Care Category I)

Drug Facts	
Active ingredient (w/w)	Purpose
Benzoyl peroxide XX %	Acne treatment
Uses • For the treatment/management of acne (breakouts) • Acne treatment/medication • Helps treat acne pimples (and allows skin to heal) • (Dries and) helps clear (up) (most) acne pimples (and allows skin to heal) • Reduces the number (and severity)/the severity of acne pimples (and allows skin to heal) • Penetrates pores to control/reduce the number of acne pimples • Penetrates pores to eliminate/clear most acne pimples • Helps keep skin clear of new acne pimples • Helps prevent (the development of) (new) acne (pimples) (from forming) • Prevents (and)/ Kills acne bacteria • Eliminates acne bacteria.	
Warnings For external use only Allergy alert get medical help right away if you develop hives, swelling of eyes and mouth, blistering, or difficulty breathing Do not use • on sensitive skin • if you are allergic to benzoyl peroxide. Ask a doctor before use if you have severe acne. When using this product • skin irritation and dryness are more likely to occur when using another topical acne product at the same time. If irritation occurs, use only one product at a time • avoid contact with eyes, lips, mouth, and nostrils. If contact occurs, rinse thoroughly with water • avoid contact with hair and dyed fabrics, which may be bleached by this product • avoid unnecessary sun exposure and use a sunscreen. Stop use and ask a doctor if • improvement is not apparent within 6-8 weeks • you develop severe irritation, burning or itching of the skin. Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away.	
Directions Adults and children 12 years and older: • For New Users: Apply product to a small area once a day for 3 days to test if you are sensitive to this product. If no discomfort occurs, use as directed ¹ • Cover the entire affected area with a thin layer • Start with one application daily, then gradually increase to 2 or 3 times daily, if needed • If dryness or peeling occurs, reduce application to once a day or every other day [For products intended to be left on the skin]: • Cleanse skin thoroughly before applying product. [For products intended to be applied to the skin and rinsed off]: • Rinse off (after X minutes).	
Other information [If no other information, delete this section]	
Inactive ingredients List NMIs	
Questions? 1-XXX-XXX-XXXX (or other contact information)	

¹Optional.

References

HC 2015: Health Canada. Summary Safety Review: Over-the-counter topical acne products containing either benzoyl peroxide or salicylic acid – Assessing the potential risk of serious allergic reactions (serious hypersensitivity reactions). Ottawa (ON): Health Canada; 2015. [Accessed 2025 October 7]. Available from: <https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/safety-reviews/summary-safety-review-over-counter-topical-acne-benzoyl-peroxide-salicylic-risk-serious-allergic.html>.

Krinsky DL, Ferreri SP, Hemstreet B, Hume AL, Newton GD, Rollins CJ, Tietze KJ. Handbook of Nonprescription Drugs: An interactive approach for Self-Care, 18th edition. Washington (DC): American Pharmaceutical Association; 2015.

RSC 2025: Royal Society of Chemistry: The Merck Index Online; 2025. [Accessed 2025 February 18]. Available from: <https://merckindex.rsc.org/>

Sweetman SC, editor. Martindale: The Complete Drug Reference, 39th edition. Grayslake (IL): Pharmaceutical Press; 2017.

US FDA 2021: U.S. Food and Drug Administration. Over-the-Counter (OTC) Monograph M006: Topical acne drug products for over-the-counter human use. Washington (DC): U.S. Food and Drug Administration, Department of Health and Human Services; 2021. [Accessed 2025 October 7]. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/omuf/monographs/OTC%20Monograph_M006-Topical%20Acne%20drug%20products%20for%20OTC%20Human%20Use%2011.23.2021.pdf

USP-NF 2024: United States Pharmacopeia and the National Formulary. Rockville (MD): United States Pharmacopeial Convention, Inc.; 2024.