Acne Therapy

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ACNE THERAPY Help on accessing alternative formats, such as Portable Document Format (PDF), Microsoft Word and PowerPoint (PPT) files, can be obtained in the alternate format help section. (PDF Version - 65.0 KB) Date 2021-06-25 FOREWORD This monograph is intended to replace the existing Acne Therapy Monograph of October 14, 2016. 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. It may also contain the test methods recommended to be used to comply with the requirements of this monograph. 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. Note: The solidus (/) indicates that the terms and/or the statements are synonymous. Either term or statement may be selected by the applicant. Text in parentheses is additional optional information which can be included on the Product Licence Application form and label at the applicant's discretion. 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 if they contain an ingredient from Table 2. Applicants applying for a DIN can access the appropriate forms and templates at: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions.html. Table 1: NHP medicinal ingredients Proper name(s) 1 Common name(s) 1 Source material(s) 1 Quantity 2 Common name(s) Table 1 Footnotes Table 1 Footnote 1 At least one of the following references was consulted per proper name, common name, and source material: O'Neil et al. 2018; USP 38. Return to Table 1 footnote 1 referrer Table 1 Footnote 2 The following reference was consulted for the dosage: FDA 2015. Return to Table 1 footnote 2 referrer Table 1 Footnote 3 The appropriate dosage range for sulfur in combination with resorcinol or resorcinol monoacetate is 3-8 % (FDA 2010). Return to Table 1 footnote 3 referrer Table 1 Footnote 4 Resorcinol and Resorcinol monoacetate are not permitted as single medicinal ingredients and must be in combination with 3-8 % sulfur (FDA 2010). Return to Table 1 footnote 4 referrer 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 Table 2: Non-prescription drug medicinal ingredient Proper name(s) Common name(s) Source material(s) Quantity Common name(s) Benzoyl peroxide Benzoyl peroxide Benzoyl peroxide 2.5-5% ROUTE(S) OF ADMINISTRATION Topical DOSAGE FORM(S) The following dosage forms are acceptable when used according to the requirements indicated in this monograph: Acceptable dosage forms for Non-prescription drugs (NPDs): Aerosol; Cream; Gel; Lotion; Ointment; Paste; Solution; Wipe Acceptable dosage forms for Natural Health Products (NHPs): Aerosol; Aerosol, spray; Bar, soap; Cream; Foam; Gel; Lotion; Ointment; Paste; Soap, liquid; Solution; Sponge; Spray; Topical liquid; Wipe, medicated USE(S) OR PURPOSE(S) Self-Care Framework Category I Uses or Purposes: For all products, the following statements may be made:

For the treatment/management of acne. Helps treat acne pimples (and allows skin to heal) Dries and helps clear up acne pimples (and allows skin to heal) Reduces the number and/or severity of acne pimples (and allows skin to heal) Penetrates pores to control/reduce acne pimples Helps keep skin clear of new acne pimples Helps prevent new acne pimples from forming Acne treatment Helps prevent acne Helps prevent acne pimples Helps clear acne Acne treatment/medication Helps treat acne/pimples Reduces the number of pimples For products containing benzoyl peroxide, the following statements may be made: Prevents (and)/Kills acne bacteria. Eliminates acne bacteria 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 Quantity(ies) See Tables 1 and 2. Permitted Combinations The only permitted combinations are sulfur and resorcinol or resorcinol monoacetate (FDA 2010): Sulfur: 3 - 8 % + Resorcinol: 2 % Sulfur: 3 - 8 % + Resorcinol monoacetate: 3 % Additional note: Products containing resorcinol or resorcinol monoacetate in combination with sulfur cannot be indicated as body cleansers or as a face wash. Directions for use For all products: For New Users: Apply product to a small area once a day for three days to test if you are sensitive to this product. If no discomfort occurs, cover the entire affected area with a thin layer. Start with one application daily, then gradually increase to two or three times daily, if needed. If dryness or peeling occurs, reduce application to once a day or every other day. For products intended to be applied to the skin and left on: Cleanse skin thoroughly before applying product. For products intended to be applied to the skin and rinsed off: Rinse off (after X minutes). For 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 of Use No statement is required. RISK INFORMATION Caution(s) and Warning(s) For all products: For external use only Ask a doctor or pharmacist/physician or pharmacist/health care practitioner/health care provider/health care professional 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. When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water. Stop use and ask a doctor/physician/health care practitioner/health care provider/health care professional if improvement is not apparent within 6-8 weeks. Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away. For products containing Sulfur or Sulfur in combination with Resorcinol or Resorcinol Monoacetate: When using this product apply only to areas with acne. For products containing Benzoyl Peroxide: When using this product avoid contact with lips, mouth, and nostrils; if contact occurs, rinse with water. When using this product avoid contact with hair and dyed fabrics, which may be bleached by this product. When using this product avoid unnecessary sun exposure and use a sunscreen. Contraindication(s) For products containing Sulfur or Sulfur in combination with Resorcinol or Resorcinol Monoacetate: Do not use on broken skin. Do not use on large areas of the skin. For products containing Benzoyl Peroxide: Do not use on sensitive skin. Do not use if you are allergic to benzoyl peroxide. Known Adverse Reaction(s) For all products: Stop use and ask a doctor/physician/health care practitioner/health care provider/health care professional if you develop severe irritation, burning or itching of the skin. For 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. Note: The alternative terms "physician/health care practitioner/health care provider/health care professional" are only acceptable for NHPs. Non-prescription drug labels must follow the requirements listed in Table 1 of the Guidance document: Labelling Requirements for Non-prescription Drugs . 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 CONDITION(S) No statement required. SPECIFICATIONS This monograph describes those requirements that are specific to this class of non-prescription drugs and to natural health products (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. DRUG FACTS TABLES (Format Optional for Self-Care Category I) References AHFS 2015: American Hospital Formulary Service®. McEvoy GK (ed). AHFS Drug Information 2015®. [Internet] Published by Authority of the Board of the American Society of Health-System Pharmacists®, Bethesda, Maryland. [Accessed 2015 October 07]. Available from: http://online.statref.com 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. FDA 2015: USA Department of Health and Human Services: Food and Drug Administration, 2015 21CFR 333 Subpart D Topical Acne Drug Products. Available from http://www.ecfr.gov/cgi-bin/text-idx?SID=7dd575d6469c84663037eefaae4d0abe&mc=true&node=pt21.5.333&rgn=div5#sp21.5.333.d. [Accessed 2016.07.25]. FDA 2011: USA Department of Health and Human Services: Food and Drug Administration, 2011 Guidance for Industry OTC Acne Product Compliance guide FDA 2010: USA Department of Health and Human Services: Food and Drug Administration, 2010. 21 CFR Part 333. Classification of Benzoyl Peroxide as Safe and Effective and Revision of Labeling to Drug Facts Format; Topical Acne Drug Products for Over-the-Counter Human Use, Final Rule. [Accessed 2015.09.22]. O'Neil MJ, Smith A, Heckelman PE, Budavari S, editors. Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals. 2018 Whitehouse Station (NJ): Merck & Co., Inc; 2018. Sweetman SC, editor. Martindale: The Complete Drug Reference. Online edition. Pharmaceutical Press; 2015 [Accessed 2015.10.07]. USP 38: The United States Pharmacopeia and the National Formulary (USP 38/NF 33). Rockville (MD): United States Pharmacopeial Convention, Inc.; 2015. Report a problem on this page Date modified: 2019-03-01

DOSAGE FORM(S)

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RISK INFORMATION

Caution(s) and Warning(s) For all products: For external use onlyAsk a doctor or pharmacist/physician or pharmacist/health care practitioner/health care provider/health care professional before use if youhave severe acne.When using this productskin 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.When using this productavoid contact with eyes. If contact occurs, rinse thoroughly with water.Stop use and ask a doctor/physician/health care practitioner/health care provider/health care professional ifimprovement is not apparent within 6-8 weeks.Keep out of reach of children.If swallowed, call a poison control centre or get medical help right away. For products containing Sulfur or Sulfur in combination with Resorcinol or Resorcinol Monoacetate: When using this productapply only to areas with acne. For products containing Benzoyl Peroxide: When using this productavoid contact with lips, mouth, and nostrils; if contact occurs, rinse with water.When using this productavoid contact with hair and dyed fabrics, which may be bleached by this product.When using this productavoid unnecessary sun exposure and use a sunscreen. Contraindication(s) For products containing Sulfur or Sulfur in combination with Resorcinol or Resorcinol Monoacetate: Do not useon broken skin.Do not useon large areas of the skin. For products containing Benzoyl Peroxide: Do not useon sensitive skin.Do not useif you are allergic to benzoyl peroxide. Known Adverse Reaction(s) For all products: Stop use and ask a doctor/physician/health care practitioner/health care provider/health care professional ifyou develop severe irritation, burning or itching of the skin. For products containing Benzoyl peroxide or Salicylic acid: Allergy alertget medical help right away if you develop hives, swelling of eyes and mouth, blistering, or difficulty breathing. Note: The alternative terms "physician/health care practitioner/health care provider/health care professional" are only acceptable for NHPs. Non-prescription drug labels must follow the requirements listed in Table 1 of theGuidance document: Labelling Requirements for Non-prescription Drugs.

SPECIFICATIONS

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. Note:

The solidus (/) indicates that the terms and/or the statements are synonymous. Either term or statement may be selected by the applicant. Text in parentheses is additional optional information which can be included on the Product Licence Application form and label at the applicant's discretion.

REFERENCES

Return to Table 1 footnote1referrer

Proper name(s)1	Common name(s)1	Source material(s)1	Quantity2
Common name(s)			
Table 1 FootnotesTable 1 Footnote 1At least one of the following references was consulted per proper name, common name, and source material			
2-Hydroxybenzoic acid	Salicylic acid	Salicylic acid	0.5-2%
Sulfur	Sulfur	Sulfur	3-10%3
1,3-Benzenediolm-Dihydroxybenzene	Resorcinol	Resorcinol	2%4
1,3-Benzenediol, monoacetate	Resorcinol monoacetate	Resorcinol monoacetate	3%4

Proper name(s)	Common name(s)	Source material(s)	Quantity
Common name(s)			
Benzoyl peroxide	Benzoyl peroxide	Benzoyl peroxide	2.5-5%