Ground Ivy - Topical

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GROUND IVY - GLECHOMA HEDERACEA - Topical 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 - 47.4 KB) This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredient. Notes Text in parentheses is additional optional information which can be included on the label at the applicant's discretion. The solidus (/) indicates that the terms and/or statements are synonymous. Either term or statement may be selected by the applicant on the label. Date February 28, 2025 Proper name(s), Common name(s), Source information Table 1. Proper name(s), Common name(s), Source information Proper name(s) Common name(s) Source information Source material(s) Part(s) Preparation(s) Glechoma hederacea Ground ivy Glechoma hederacea Herb top Dry References: Proper name: USDA 2024; Common name: Gardner and McGuffin 2013; Source information: Barnes et al. 2007; Grieve 1971. Route of Administration Topical Dosage Form(s) Acceptable dosage forms when used according to the requirements indicated in this monograph: Cream; Gel; Liquid; Loose; Lotion; Ointment; Paste; Powder; Salve; Solution; Topical liquid; Wipe. Use(s) or Purpose(s) (Traditionally) used in Herbal Medicine (as a vulnerary) to help heal minor wounds (such as cuts) (Barnes et al. 2007; Williamson et al. 1988; Grieve 1971). Notes For multi-ingredient products: To prevent the product from being represented as a “traditional medicine”, any indicated traditional use claim must refer to the specific medicinal ingredient(s) and recognized traditional system of medicine from which the claim originates when 1) both traditional and modern claims are present or 2) when claims originate from multiple systems of traditional medicine (e.g., Ground ivy is traditionally used in Herbal Medicine to help heal minor wounds such as cuts). When ALL of the medicinal ingredients (MIs) in the product are used within the SAME identified system of traditional medicine AND the product makes ONLY traditional claims, listing of MIs in the traditional claim(s) is not required Dose(s) Subpopulation(s) Adults 18 years and older Quantity(ies) Notes: On the PLA form, quantities can be expressed as percentage weight by weight (% w/w), percentage weight by volume (% w/v) or percentage volume by volume (% v/v), depending on the product formulation. On the product label, quantities can also be expressed in other equivalent concentration units (e.g., mg/mL). For wipes, the information in this section applies to the liquid with which wipes are saturated. Methods of preparation: Dry, Powdered, Fluid Extract 25 - 100% dried herb tops (Barnes et al. 2007; Grieve 1971). Notes: For fluid extracts, the extract ratio must be 1:1 and the solvent must be ethanol or a mix of ethanol and water. Products in a loose or powder dosage form must be prepared by the consumer prior to use (see directions for use). Methods of preparation: Non-Standardized Liquid Extracts (Decoction, Decoction concentrate, Infusion, Infusion concentrate, Tincture) 50 - 100% dried herb tops extract preparation in the finished product (Barnes et al. 2007; Grieve 1971). Note: The extract ratio must be between 1:2 and 1:4. The formulation must provide a quantity equivalent to a minimum of 250 milligrams crude dried herb tops per 1 gram of finished product. For example, for a tincture prepared with a 1:2 w/w ratio, the concentration of tincture in the finished product must be at least 50% (250 mg crude dried herb tops * 2 w/w (dilution) = 500 mg liquid extract in 1 g finished product = 50% w/w extract preparation in the finished product). Methods of preparation: Non-Standardized Dry Extracts (Extract dry) 5 - 50% dried herb top extract preparation in the finished product (Barnes et al. 2007; Grieve 1971). Notes: For dry extracts, the extract ratio must be between 2:1 and 5:1. The formulation must provide a quantity equivalent to a minimum of 250 milligrams crude dried herb tops per 1 gram of finished product. For example, for an extract prepared with a 4:1 w/w ratio, the concentration of extract in the finished product must be at least 6.25% (250 mg crude dried herb tops / 4 w/w (concentration) = 62.5 mg dry extract in 1 g finished product = 6.25% w/w extract preparation in the finished product). Solvents allowed for this method of preparation are ethanol and/or water. Direction(s) for use Loose/Powder dosage forms Prepare as a paste by mixing herb tops with a small amount of water until you achieve the desired consistency. Apply to affected area(s), up to 3 times per day (Barnes et al. 2007; Williamson 1988; Grieve 1971). Liquid dosage forms (Liquid, Topical liquid, Solution) Soak a small towel/pad/gauze/cotton in the product. Apply to affected area(s), up to 3 times per day (Barnes et al. 2007; Williamson 1988; Grieve 1971). Cream/Gel/Lotion/Ointment/Paste/Salve/Wipe dosage forms Apply to affected

area(s), up to 3 times per day (Barnes et al. 2007; Grieve 1971). Duration(s) of Use No statement required. Risk Information Caution(s) and warning(s) For external use only. Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding (Barnes et al. 2007). When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water. Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms worsen or last (for) more than 7 days. Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away. Contraindication(s) Do not use on deep or puncture wounds, animal bites or serious burns. Known adverse reaction(s) No statement required. Non-medicinal ingredients Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database. Storage conditions Must be established in accordance with the requirements described in the Natural Health Product Regulations . Specifications The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide. The medicinal ingredient must comply with the requirements outlined in the NHPID. EXAMPLE OF PRODUCT FACTS: Consult the Guidance Document, Labelling of Natural Health Products for more details. References Cited Barnes J, Anderson LA, Philipson JD. Herbal Medicines, 3 rd edition. London (UK): The Pharmaceutical Press; 2007. Bradley PR, editor. British Herbal Compendium: A Handbook of Scientific Information on Widely Used Plant Drugs, Volume 1. Bournemouth (UK): British Herbal Medicine Association; 1992. Grieve M. A Modern Herbal, Volume 1. New York (NY): Dover Publications; 1971 [Reprint of 1931 Harcourt, Brace & Company publication]. Gardner Z, McGuffin M, editors. American Herbal Products Association's Botanical Safety Handbook. 2nd edition. Boca Ration (FL): Taylor and Francis Group; 2013. USDA 2024: United States Department of Agriculture, Agricultural Research Service (USDA ARS), Germplasm Resources Information Network (GRIN) - Global. U.S. National Plant Germplasm System. [Accessed 2024 May 13]. Available from: https://npgsweb.ars-grin.gov/gringlobal/taxon/taxonomysearch Williamson EM, Evans FJ, Wren RC. Potter's New Cyclopaedia of Botanical Drugs and Preparations. Saffron Walden (UK): C.W. Daniel Company Limited; 1988. References Reviewed Bartram T. Bartram's Encyclopedia of Herbal Medicine. New York (NY): Marlowe and Company; 1998. Berardi RR, DeSimone EM, Newton GD, Oszko MA, Popovich NG, Rollins CJ, Shimp LA, Tietze KJ, editors. Handbook of Nonprescription Drugs: An Interactive Approach to Self- Care, 13th edition. Washington (DC): American Pharmaceutical Association; 2002. BHP 1996: British Herbal Pharmacopoeia. Bournemouth (UK): British Herbal Medicine Association; 1996. Brinker F. Herb Contraindications and Drug Interactions, 3 rd edition. Sandy (OR): Eclectic Medical Publications; 2001. Cook, WH. The Physio-medical Dispensatory. Cincinnati (OH): WH Cook; 1869. [Accessed 2024 May 30]. Available from: http://medherb.com/cook/home.htm Felter HW, Lloyd JU. King's American Dispensatory, Volume 2, 18 th edition. Sandy (OR): Eclectic Medical Publications; 1983 [Reprint of 1898 original]. Gruenwald J, Brendler T, Jaenicke C, editors. PDR for Herbal Medicines, 2 nd edition. Montvale (NJ): Medical Economics Co.; 1998. Hoffmann D. The Complete Illustrated Holistic Herbal. Rockport (MA): Element Books Inc.; 1996. Lontos S, Jones RM, Angus PW, Gow PJ. Acute liver failure associated with the use of herbal preparations containing black cohosh. The Medical journal of Australia 2003;179(7):390-391. Moerman DE. Native American Ethnobotany. Portland (OR): Timber Press; 1998. Remington JP and Woods HC, editors. The Dispensatory of the United States of America, 20th edition. 1918. Scanned by Southwest School of Botanical Medicine as Abridged - botanicals only; 2008 [Accessed 2024 May 30]. Available from: https://www.swsbm.com/Dispensatory/USD-1918-complete.pdf Sayre LE. A Manuel of Organic Materia Medica and Pharmacognosy, 4 th edition. Philadelphia (PA): P. Blakiston's Son & Co; 1917. [Accessed 2008 February14]. Available from: http://www.swsbm.com/SayreMM/SayreMM.html Thomsen M, Vitetta L, Sali A, Schmidt M. Acute liver failure associated with the use of herbal preparations containing black cohosh. The Medical journal of Australia 2004; 180(11):598-599. Wiersema J, Léon B. World Economic Plants: A Standard Reference. Boca Raton (FL): CRC Press LLC; 1999. Report a problem on this page Date modified: 2019-03-01

RISK INFORMATION

Caution(s) and warning(s) For external use only.Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding (Barnes et al. 2007).When using this product avoid contact with eyes. If contact occurs, rinse thoroughly with water.Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if symptoms worsen or last (for) more than 7 days.Keep out of reach of children. If swallowed, call a poison control centre or get medical help right away. Contraindication(s) Do not use on deep or puncture wounds, animal bites or serious burns. Known

adverse reaction(s) No statement required.

NON-MEDICINAL INGREDIENTS

Must be chosen from the current Natural Health Products Ingredients Database (NHPID) and must meet the limitations outlined in the database. Storage conditions Must be established in accordance with the requirements described in theNatural Health Product Regulations.

STORAGE CONDITION(S)

Must be established in accordance with the requirements described in theNatural Health Product Regulations.

SPECIFICATIONS

The finished product specifications must be established in accordance with the requirements described in the Natural and Non-prescription Health Products Directorate (NNHPD) Quality of Natural Health Products Guide.The medicinal ingredient must comply with the requirements outlined in the NHPID. EXAMPLE OF PRODUCT FACTS:Consult the Guidance Document,Labelling of Natural Health Productsfor more details.

REFERENCES

Route of Administration Topical

Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation(s)		
Glechoma hederacea	Ground ivy	Glechoma hederacea	Herb top	Dry