

Heal-all - Prunella Vulgaris - Topical

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HEAL-ALL - PRUNELLA VULGARIS - 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 - 299 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) Prunella vulgaris Common selfheal Heal-all Prunella Self-heal Woundwort Xiakucuo Prunella vulgaris Leaf Shoot Shoot and leaf Dry References: Proper name: USDA 2024; Common names: USDA 2024; Gardner and McGuffin 2013; Meyer 1993; Lust 1987; Source information: Bartram 1998; Hoffmann 1996. 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; Powder; 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) (Williamson 2003; Hoffmann 1996; Culpeper 1995). (Traditionally) used in Herbal Medicine (as an astringent) to help relieve hemorrhoids (Hoffmann 1996; Grieve 1971). Notes The above uses can be combined on the product label if from the same traditional or non-traditional system of medicine (e.g., Traditionally used in Herbal Medicine to help heal minor wounds and to help relieve hemorrhoids). 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., Heal-all 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. Loose/Powder dosage forms Methods of preparation: Dry, Powdered 100% of dried shoots and/or leaves (Grieve 1971; Wren 1907). Note: Products in loose or powder dosage forms must be prepared as an infusion by the consumer prior to use (see direction for use). Cream/Gel/Liquid/Lotion/Ointment/Solution/Topical liquid/Wipe dosage forms Methods of preparation: Non-Standardized Liquid Aqueous Extracts (Decoction, Decoction concentrate, Infusion, Infusion concentrate) 10 - 100% dried shoots and/or leaves extract preparation in the finished product (Grieve 1971; Wren 1907). Note: The extract ratio must be between 1:2 and 1:20. The formulation must be prepared in a way which is equivalent to a quantity of 50 to 80 milligrams crude dried shoots/leaves for 1 milliliter or 1 gram of finished product. For example, for a decoction prepared with a 1:10 w/v ratio, the concentration of decoction in the final formulation must be 50 to 80% (50 - 80 mg crude dried shoots/leaves * 10 w/v (dilution) = 0.5 - 0.8 mL liquid extract in 1 mL finished product = 50 - 80% v/v extract preparation in the finished product). Methods of preparation: Non-Standardized Dry Aqueous Extracts (Extract dry) 0.5 - 5.3% dried shoots and/or leaves extract preparation in the finished product (Grieve 1971; Wren 1907). Notes The extract ratio must be between 2:1 and 16:1. The formulation must be prepared in a way which is equivalent to a quantity of 50 to 80 milligrams crude dried shoots/leaves for 1 gram of finished product. For example, for a dry extract prepared with a 5:1 w/w ratio, the concentration of dry extract in the finished product must be 1 to 1.6% (50 - 80 mg crude dried shoots/leaves / 5 w/w (concentration) = 10 - 16 mg dry extract in 1 g finished product = 1 - 1.6% w/w extract preparation in the finished product). The minimum quantity of 0.5% still applies for more concentrated extracts,

(e.g., a product containing 0.5% of a dry extract contains 5 mg dry extract in 1 gram finished product; 5 mg of a 15:1 w/w dry extract is equivalent to 75 mg crude dried shoots and/or leaves). Direction(s) for use Loose/Powder dosage forms Place [insert volume to be measured by consumer in order to obtain 4 to 6 grams dried leaves and/or shoots, e.g., 1 teaspoon] of product in 1/3 cup (80 ml) of boiling water, infuse for 10 minutes and strain. Let cool. Soak a small towel/pad/gauze/cotton in the product (Chevalier 1996; Grieve 1971; Wren 1907). Products for use on hemorrhoids Cleanse the affected area with mild soap and warm water, rinse and dry. Apply to the affected area by patting gently (using a cleansing pad), up to 3 times daily (or after each bowel movement) (Hoffman 1996; Grieve 1971). Do not put this product into the rectum. Products for use on minor wounds Apply to affected area(s), up to 3 times per day (Hoffman 1996; Grieve 1971). Duration(s) of use No statement required. Risk information Caution(s) and warning(s) For external use only. 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) Products for use on minor skin wounds/irritations Do not use on deep or puncture wounds, animal bites or serious burns. Known adverse reaction(s) Products for use on hemorrhoids Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if you experience bleeding. 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 Products 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 Bartram T. Bartram's Encyclopedia of Herbal Medicine. New York (NY): Marlowe and Company; 1998. Chevallier A. The Encyclopedia of Medicinal Plants. London (UK): Dorling Kindersley Limited. Culpeper N. 1995. Complete Herbal. Ware (UK): Wordsworth Editions Limited; [Reprint of 1653 original]; 1996. Felter HW, Lloyd JU. King's American Dispensatory, Volume 1, 18th edition. 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Saffron Walden (UK): C.W. Daniel Company Limited; 2003. Wren RC. Potter's Cyclopaedia of Botanical Drugs and Preparations. London (UK): Potter and Clark; 1907. References reviewed Bensky D and Gamble A. Chinese Herbal Medicine Materia Medica. Revised edition. Seattle (WA): Eastland Press, Incorporated; 1993. Duke JA, Bogenschutz-Godwin MJ, du Cellier J, Duke PK. Handbook of Medicinal Herbs, 2nd edition. Boca Raton (FL): CRC Press; 2002. Fauci AS, Braunwald E, Isselbacher KJ, Wilson JD, Martin JB, Kasper DL, Hauser SL and Longo DL, editors. Harrison's Principles of Internal Medicine, 14th edition. Toronto (ON): McGraw-Hill Health Professions Division; 1998. Fetrow CW, Avila JR. Professional's Handbook of Complementary and Alternative Medicines, 3rd edition. Philadelphia (PA): Lippincott Williams and Wilkins; 2004. Gerard J. The Herbal or General History of Plants. The Complete 1633 Edition as Revised and Enlarged by Thomas Johnson. NY (NY): Dover Publications; 1975. Hoffmann D. Medical Herbalism. Rochester (VT): Healing Arts Press; 2003. Meyrick W. The New Family Herbal; or, Domestic Physician: enumerating, with accurate descriptions, all the known vegetables which are any way remarkable for medical efficacy; with an account of their virtues in the several diseases incident to the human frame. Birmingham (UK): Knott and Lloyd; 1790. Sherman JA. The Complete Botanical Prescriber, 3rd edition. Corvallis (OR): self-published; 1993. Shou-zhong Y, translator. The Divine Farmer's Materia Medica - A translation of the Shen Nong Ben Cao Jing. Boulder (CO): Blue Poppy Press; 2004. Wiersema J, León B. World Economic Plants: A Standard Reference. Boca Raton (FL): CRC Press LLC; 1999. Williamson EM, Evans FJ, Wren RC. Potter's New Cyclopaedia of Botanical Drugs and Preparations. Saffron Walden (UK): C.W. Daniel Company Limited; 1988. Wiseman N and Ye F. A Practical Dictionary of Chinese Medicine. 2nd edition. Brookline (MA): Paradigm Publications; 1999. Yeung H. Handbook of Chinese Herbal Formulas. Rosemeade (CA): Institute of Chinese Medicine; 1998. Report a problem on this page Date modified: 2019-03-01

RISK INFORMATION

Caution(s) and warning(s) For external use only.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) Products for use on minor skin wounds/irritations Do not use on deep or puncture wounds, animal bites or serious burns. Known adverse reaction(s) Products for use on hemorrhoids Stop use and ask a health care practitioner/health care provider/health care professional/doctor/physician if you experience bleeding.

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 Products Regulations

STORAGE CONDITION(S)

Must be established in accordance with the requirements described in theNatural Health Products 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:

REFERENCES

Route of administration Topical

Proper name(s)	Common name(s)	Source information		
Source material(s)	Part(s)	Preparation(s)		
Prunella vulgaris	Common selfhealHeal-allPrunellaSelf-healWormwood	Prunella vulgaris	LeafShootShoot and leaf	Dr