



## NATURAL HEALTH PRODUCT

### ST. JOHN’S WORT- *HYPERICUM PERFORATUM*

#### Topical

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 PLA and product 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.

#### Date

December 18, 2018

#### Proper name(s), Common name(s), Source material(s)

Table 1. Proper name(s), Common name(s), Source material(s)

Proper name(s)	Common name(s)	Source material(s)		
		Proper name(s)	Part(s)	Preparation(s)
<i>Hypericum perforatum</i>	<ul style="list-style-type: none"> <li>▶ Goatweed</li> <li>▶ Hypericum</li> <li>▶ St. John’s wort</li> <li>▶ St. John’s-wort</li> </ul>	<i>Hypericum perforatum</i>	Flower	Fresh

References: Proper name: USDA 2018; Common names: Anghelescu et al. 2006, Gastpar et al. 2006, Szegedi et al. 2005, Wichtl 2004, McGuffin et al. 2000; Source material: Bradley 2006; Mills and Bone 2005, Hoffmann 2003, Blumenthal et al. 2000, Felter and Lloyd 1983, Wren 1907.

#### Route of administration

Topical

#### Dosage form(s)

Acceptable dosage forms for the age category listed in this monograph and specified route of administration are indicated in the Compendium of Monographs Guidance Document.



### **Use(s) or Purpose(s)**

(Traditionally) used in Herbal Medicine as an antiseptic and/or antimicrobial to assist in healing of minor skin wounds, cuts, burns and bruises (Bradley 2006; Mills and Bone 2005; Hoffmann 2003; Blumenthal et al. 2000; Felter and Lloyd 1983; Wren 1907).

### **Note**

Claims for traditional use must include the term “Herbal Medicine”, “Traditional Chinese Medicine”, or “Ayurveda”.

### **Dose(s)**

#### **Subpopulation(s)**

Infants 0-12 months, Children 1 to 11 years, Adolescents 12 to 17 years, and Adults 18 years and older (Bove 2001)

#### **Quantity(ies)**

Method of preparation: Oil, Medicated from fresh plant

20 - 25% of fresh flower (Isacchi et al. 2007; Sosa et al. 2007; Bradley 2006; Wichtl 2004; Hoffmann 2003; Blumenthal et al. 2000; Maisenbacher and Kovar 1992; Grieve 1971; DAB 1941; Wren 1907).

#### **Direction(s) for use**

Apply to affected area(s) as needed (Bove 2001; Blumenthal et al. 2000).

### **Duration(s) of use**

No statement is required

### **Risk information**

#### **Caution(s) and warning(s)**

Consult a health care practitioner/health care provider/health care professional/doctor/physician if symptoms persist or worsen.

#### **Contraindication(s)**

No statement is required

### Known adverse reaction(s)

No statement is 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

No statement required.

### 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.
- ▶ The preparations must meet at least one of the following conditions in order to prevent the growth of the bacterial spores associated with botulism:
  - i. Products are subjected to a validated treatment, such as heat treatment, with equivalent effect to the 12 D canning process (a thermal process designed to reduce the probability of survival of a single, heat-resistant spore of *Clostridium botulinum* by a factor of  $10^{12}$ ) to inactivate spores of *C. botulinum* (FAO 1985), or
  - ii. The water activity of the plant material is reduced to 0.94 or less before adding it to the oil, or
  - iii. Ensure that the pH of the plant material is adjusted to 4.6 or less before adding it to the oil.

### References cited

Angelescu IG, Kohnen R, Szegedi A, Klement S, Kieser M. 2006. Comparisons of Hypericum extract WS 5570 and paroxetine in ongoing treatment after recovery from an episode of moderate to severe depression: results from a randomized multicenter study. *Pharmacopsychiatry* 39(6):213-219.

Blumenthal M, Goldberg A, Brinkmann J, editors. 2000. *Herbal Medicine: Expanded Commission E Monographs*. Boston (MA): Integrative Medicine Communications.

Bove M. 2001. *An Encyclopedia of Natural Healing for Children & Infants*, 2nd edition. Toronto (ON): McGraw-Hill.



- Bradley PR, editor. 2006. *British Herbal Compendium, Volume 1*. Bournemouth (GB): British Herbal Medicine Association.
- DAB 6: *Deutsches Arzneibuch*. 1941. *Pharmacopoea Germanica*. Berlin (DE): Decker.
- FAO 1985. Food and Agriculture Organization of the United Nations. Planning and engineering data 2: Fish canning [online]. Myrseth A, editor. Fisheries Circular - C784; 1985. Rome (I): Food and Agriculture Organization of the United Nations Document Repository. [Accessed 2018 October 1]. Available from: <http://www.fao.org/DOCREP/003/R6918E/R6918E02.HTM>
- Felter HW, Lloyd JU. 1983. *King's American Dispensatory, Volume 1*, 18<sup>th</sup> edition. Sandy (OR): Eclectic Medical Publications; [Reprint of 1898 original].
- Gastpar M, Singer A, Zeller K. 2006. Comparative efficacy and safety of a once-daily dosage of hypericum extract STW3-VI and citalopram in patients with moderate depression: a doubleblind, randomised, multicentre, placebo-controlled study. *Pharmacopsychiatry* 39(2):66-75.
- Grieve M. 1971. *A Modern Herbal, Volume 2*. New York (NY): Dover Publications [Reprint of 1931 Harcourt, Brace & Company publication].
- Hoffmann D. 2003. *Medical Herbalism: The Science and Practice of Herbal Medicine*. Rochester (VT): Healing Arts Press.
- Isacchi B, Bergonzi MC, Carnevali F, van der Esch SA, Vincieri FF, Bilia AR. 2007. Analysis and stability of the constituents of St. John's wort oils prepared with different methods. *Journal of Pharmaceutical and Biomedical Analysis* September 7. doi:10.1016/j.jpba.2007.08.025.
- Maisenbacher P, Kovar KA. 1992. Analysis and stability of *Hyperici oleum*. *Planta Medica* 58(4):351-354.
- McGuffin M, Kartesz JT, Leung AY, Tucker AO, editors. 2000. *Herbs of Commerce*, 2<sup>nd</sup> edition. Silver Spring (MD): American Herbal Products Association.
- Mills S, Bone K. 2005. *The Essential Guide to Herbal Safety*. St. Louis (MO): Elsevier Churchill Livingstone.
- Sosa S, Pace R, Bornancin A, Morazzoni P, Riva A, Tubaro A, Della Loggia R. 2007. Topical anti-inflammatory activity of extracts and compounds from *Hypericum perforatum* L. *The Journal of Pharmacy and Pharmacology* 59(5):703-709.
- Szegedi A, Kohnen R, Dienel A, Kieser M. 2005. Acute treatment of moderate to severe depression with hypericum extract WS 5570 (St John's wort): randomised controlled double blind non-inferiority trial versus paroxetine. *British Medical Journal* 330(7490):503.



USDA 2018: United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN) [online database]. *Hypericum perforatum* L. Beltsville (MD): National Germplasm Resources Laboratory. [Accessed 2018 October 1]. Available from: <https://npgsweb.ars-grin.gov/gringlobal/taxonomydetail.aspx?id=19600>

Wichtl M, editor. 2004. Herbal Drugs and Phytopharmaceuticals: A Handbook for Practice on a Scientific Basis, 3<sup>rd</sup> edition. Stuttgart (D): Medpharm GmbH Scientific Publishers.

Wren RC. 1907. Potter's Cyclopaedia of Botanical Drugs and Preparations. London (GB): Potter and Clark.

### References reviewed

Cosmetic Ingredient Review Expert Panel. 2001. Final report on the safety assessment of *Hypericum Perforatum* extract and *Hypericum perforatum* oil. International Journal of Toxicology 20 (Suppl 2):31-39.

Schempp CM, Hezel S, Simon JC. 2003. Topical treatment of atopic dermatitis with *Hypericum* cream. A randomised, placebo-controlled, double-blind half-side comparison study. Der Hautarzt; Zeitschrift für Dermatologie, Venerologie, und Verwandte Gebiete 54(3):248-253.

Schempp CM, Ludtke R, Winghofer B, Simon JC. 2000. Effect of topical application of *hypericum perforatum* extract (St. John's wort) on skin sensitivity to solar simulated radiation. Photodermatology, Photoimmunology and Photomedicine 16(3):125-128.