

NATURAL HEALTH PRODUCT

RUTIN

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

July 31, 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)
		Common name(s)
<ul style="list-style-type: none"> ▶ 3,3',4',5,7-Pentahydroxyflavone-3-rutinoside ▶ 3-[[6-O-(6-Deoxy-alpha-L-mannopyranosyl)-beta-D-glucopyranosyl]oxy]-2-(3,4-dihydroxyphenyl)-5,7-dihydroxy-4H-1-benzopyran-4-one ▶ 3-(O-6-deoxy-alpha-l-mannopyranosyl-(1-6)-beta-d-glucopyranosyloxy)-2-(3,4-dihydroxyphenyl)-5,7-dihydroxy-4H-chromen-4-one 	<ul style="list-style-type: none"> ▶ Quercetin-3-rutinoside ▶ Rutin ▶ Rutoside 	<ul style="list-style-type: none"> ▶ Citrus bioflavonoids ▶ Rutin ▶ Rutoside trihydrate

References: Proper names: Ph.Eur. 2013, ChemID 2012, O'Neil et al. 2013; Common names: Ph.Eur. 2013, BP 2012, ChemID 2012, O'Neil et al. 2013; Source information: Ph.Eur. 2013, BP 2012, O'Neil 2013.



Route of administration

Oral

Dosage form(s)

This monograph excludes foods or food-like dosage forms as indicated in the Compendium of Monographs Guidance Document.

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)

- ▶ Source of/Provides antioxidant (Martindale 2011; Murray and Bongiorno 2006; Harborne et al. 1999).
- ▶ Used in Herbal Medicine as a capillary/blood vessel protectant (Martindale 2011; PDR 2008; Murray and Bongiorno 2006; Harborne et al. 1999; Leung and Foster 1996).

Dose(s)

Subpopulation(s)

Adults 18 years and older

Quantity(ies)

Antioxidant

Not to exceed 1000 milligrams of rutin per day and 500 milligrams per single dose (Boyle et al. 2000).

Capillary/ blood vessel protectant

400-1000 milligrams of rutin, per day. Not to exceed 500 milligrams per single dose (PDR 2008).

Direction(s) for use

No statement required.



Duration(s) of use

Products providing 250 mg or more of rutin, per day

Consult a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 6 weeks (Boyle et al. 2000).

Risk information

Caution(s) and warning(s)

Consult a health care practitioner/health care provider/health care professional/doctor/physician prior to use if pregnant or breastfeeding (PDR 2008).

Contraindication(s)

No statement required.

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

Store in a light-resistant container (Ph.Eur. 2013).

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.

References cited

- Boyle SP, Dobson VL, Duthie SJ, Hinselwood DC, Kyle JAM, Collins AR. Bioavailability and efficiency of rutin as an antioxidant: a human supplementation study. *European Journal of Clinical Nutrition* 2000;54(10):774-784.
- BP 2012: British Pharmacopoeia 2012. Volume I. London (GB): The Stationary Office on behalf of the Medicines and Healthcare products Regulatory Agency (MHRA); 2012.
- ChemID 2012: ChemIDplus advanced [Internet]. Bethesda (MD): United States National Library of Medicine; 2011. [Rutin: CAS # 153-18-4; Accessed 2018 June 6]. Available from: <http://chem.sis.nlm.nih.gov/chemidplus>
- Harborne JB, Baxter H, Moss GP, editors. *Phytochemical Dictionary: A Handbook of Bioactive Compounds from Plants*. Second edition. Philadelphia (PA): Taylor & Francis Ltd; 1999.
- Leung AY, Foster S. *Encyclopedia of Common Natural Ingredients: Used in Food, Drugs and Cosmetics*. 2nd edition. New York (NY): John Wiley & Sons; 1996.
- Martindale 2011: Sweetman SC, editor. *Martindale: The Complete Drug Reference* [Internet]. London (GB): Pharmaceutical Press; 2012. [Rutoside: synonym rutin, CAS: 153-18-4 (anhydrous rutoside), latest modification 05-Dec-2011; Accessed 2018 June 6]. Available from: <http://www.medicinescomplete.com>
- Murray MT, Bongiorno PB. Flavonoids—Quercetin, Citrus Flavonoids, and Hydroxyethylrutosides. In: Pizzorno JE, Murray MT, editors. *Textbook of Natural Medicine*, Third edition, volume 1. St. Louis (MI): Churchill Livingstone Elsevier; 2006. p. 967-973.
- O’Neil MJ, Smith A, Heckelman PE, Budavari S, editors. *The Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals*. 15th edition. Whitehouse Station (NJ): Merck & Co., Inc; 2013.
- PDR 2008: Hendler SS, Rorvik D. *PDR for Nutritional Supplements*. Second edition. Montvale (NJ): Thomson Healthcare; 2008.
- Ph.Eur. 2013: *European Pharmacopoeia*. 7th edition. Strasbourg (FR): Directorate for the Quality of Medicines and HealthCare of the Council of Europe (EDQM); 2012.

References reviewed

- Dietrych-Szostak D, Oleszek W. Effect of processing on the flavonoid content in buckwheat (*Fagopyrum esculentum* Möench) grain. *Journal of Agriculture and Food Chemistry* 1999;47(10):4383-4387.



Frankel EN, Waterhouse AL, Teissedre PI. Principal phenolic phytochemicals in selected California wines and their antioxidant activity in inhibiting oxidation of human low-density lipoproteins. *Journal of Agriculture and Food Chemistry* 1995;43(4):890-894.

United States Department of Agriculture, Agricultural Research Service, National Genetic Resources Program. Germplasm Resources Information Network (GRIN). [Internet]. National Germplasm Resources Laboratory, Beltsville (MD). [Accessed 2012 November 26]. Available from: http://www.ars-grin.gov/cgi-bin/npgs/html/tax_search.pl