



## NATURAL HEALTH PRODUCT

### HAEMATOCOCCUS PLUVIALIS EXTRACT

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

January 10, 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)
<i>Haematococcus pluvialis</i>	<i>Haematococcus pluvialis</i>	<i>Haematococcus pluvialis</i>	Broken cell	Dry

References: Proper name: NHPID 2024; Common name: NHPID 2024; Source information: NHPID 2024.

#### 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 oral use are indicated in the dosage form drop-down list of the web-based Product Licence Application form for Compendial applications.



## Use(s) or Purpose(s)

- Source of antioxidants/Provides antioxidants (Karppi et al. 2007; Kim and Chyun 2004).
- Source of antioxidants/Provides antioxidants that help fight/protect (cell) against/reduce (the oxidative effect of/the oxidative damage caused by/cell damage caused by) free radicals (Karppi et al. 2007; Kim and Chyun 2004).
- Helps to maintain/support skin health (Tominaga et al. 2012; Yamashita 2006).
- Helps to improve/maintain/support skin moisture/hydration (Ito et al. 2018; Tsukahara et al. 2016; Phetcharat et al. 2015; Yamashita 2006).
- Helps to improve/maintain/support skin elasticity (Tsukahara et al. 2016; Phetcharat et al. 2015; Tominaga et al. 2012; Yamashita 2006).
- Helps to maintain/support skin texture (Ito et al 2018).
- Helps to reduce the appearance of fine lines/wrinkles (Phetcharat et al. 2015; Tominaga et al. 2012; Yamashita 2006).
- Helps to maintain/support eye/ocular health (Hashimoto et al. 2016; Hashimoto et al. 2013; Nakamura et al. 2004).
- Helps to reduce eye strain/eye fatigue (Nagaki et al. 2006; Nitta et al. 2005; Nakamura et al. 2004).

### Notes:

- The above uses can be combined on the product label (e.g., Helps to maintain skin texture and elasticity).
- The terms 'Helps' or 'Helps to' can be used interchangeably on the label.

## Dose(s)

### Subpopulation(s)

Adults 18 years and older.

### Quantity(ies)

**Methods of preparation:** Powdered, standardized; Standardized Extracts (Dry extract); Supercritical fluid extraction, standardized.

### *Antioxidant*

Preparation/extract providing up to 40 milligrams of astaxanthin, per day; Not to exceed 1 gram of dried broken cells (Ito et al 2018; Hashimoto et al. 2016; Tsukahara et al 2016; Phetcharat and al 2015; EFSA 2014; Hashimoto et al. 2013; Tominaga et al 2012; Earnest et al. 2011; Malmstein and Lignell 2008; Karppi et al. 2007; Iwasaki and Tawara 2006; Nagaki et al. 2006; Yamashita 2006; Nitta et al. 2005; Kim and Chyun 2004; Nakamura et al. 2004).



**Methods of preparation:** Standardized Extracts (Dry extract); Supercritical fluid extraction, standardized.

*Eye strain, Eye fatigue*

Extract providing 6 – 40 milligrams of astaxanthin, per day; Not to exceed 1 gram of dried broken cells, per day (Earnest et al. 2011; Malmstein and Lignell 2008; Iwasaki and Tawara 2006; Nagaki et al. 2006; Nitta et al. 2005; Nakamura et al. 2004).

*Skin health, Skin elasticity, Skin moisture/hydration, Skin texture, Skin appearance of lines/wrinkles, Eye/ocular health*

Extract providing 4 – 40 milligrams of astaxanthin, per day; Not to exceed 1 gram of dried broken cells, per day (Ito et al 2018; Hashimoto et al. 2016; Phetcharat et al 2015; Hashimoto et al. 2013; Tominaga et al 2012; Tsukahara et al 2016; Yamashita 2006; Nakamura et al. 2004).

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

No statement required

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

*Products providing more than 4 milligrams of astaxanthin, per day*

Ask a health care practitioner/health care provider/health care professional/doctor/physician for use beyond 3 months (EFSA 2014; Parisi et al. 2008).

### **Risk information**

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

*All products*

**Ask a health care practitioner/health care provider/health care professional/doctor/physician before use if you are pregnant or breastfeeding.**

*Eye strain, Eye fatigue*

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

#### **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**

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.

<b>Product Facts</b>	
<b>Medicinal ingredient</b> in each capsule <i>Haematococcus pluvialis</i> broken cell extract Providing YY mg of astaxanthin Equivalent to ZZ mg of dried broken cells <sup>1</sup>	XX mg
<b>Uses</b>	
<ul style="list-style-type: none"> <li>• Source of antioxidants.</li> <li>• Source of antioxidants that help protect cell against free radicals.</li> <li>• Helps maintain skin health.</li> <li>• Helps improve skin hydration.</li> <li>• Helps support skin elasticity.</li> <li>• Helps maintain skin texture.</li> <li>• Helps reduce the appearance of fine lines.</li> <li>• Helps maintain ocular health.</li> <li>• Helps reduce eye strain.</li> </ul>	
<b>Warnings</b>	
<b>If applicable<sup>2</sup>:</b>	
<b>Allergens: food allergen, gluten (gluten source), sulphites</b>	
<b>Contains aspartame</b>	
<b>Ask a health care practitioner before use if</b> you are pregnant or breastfeeding.	
<b>Ask a health care practitioner if</b> symptoms persist or worsen <sup>3</sup> .	
<b>Directions</b>	
Adults 18 years and older: • Take X capsule(s), X time(s) a day • Ask a health care practitioner for use beyond 3 months <sup>4</sup> .	
<b>Other information</b>	
(Add storage information)	
<b>Non-medicinal ingredients</b>	
List all NMIs	
<b>Questions?</b> (Call) 1-XXX-XXX-XXXX	

<sup>1</sup>For standardized extracts of *Haematococcus pluvialis*, the quantity crude equivalent information is required on the PLA form but optional on the label.

<sup>2</sup>This section can be removed from the table if the product contains no allergen or aspartame.

<sup>3</sup>The qualifier ‘For eye strain/eye fatigue:’ may be included on the label to inform consumers.

<sup>4</sup>Products providing more than 4 mg of astaxanthin, per day.



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