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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

DRAFT ASSESSMENT REPORT ON *EUPHRASIA OFFICINALIS* L. AND *EUPHRASIA ROSTKOVIANA* HAYNE, HERBA

Note: This Assessment Report is published to support the release for public consultation of the draft Public statement on *Euphrasia officinalis* L. and *Euphrasia rostkoviana* Hayne, herba. It should be noted that this document is a working document, not yet fully edited, and which shall be further developed after the release for consultation of the Public statement. Interested parties are welcome to submit comments to the HMPC secretariat, which the Rapporteur and the MLWP will take into consideration but no 'overview of comments received during the public consultation' will be prepared in relation to the comments that will be received on this assessment report. The publication of this draft assessment report has been agreed, on an exceptional basis, to facilitate the understanding by Interested Parties of the assessment that has been carried out so far and led to the preparation of the draft Public statement.

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I. REGULATORY STATUS OVERVIEW[1]

MA: Marketing Authorisation
TRAD: Traditional Use Registration
Other TRAD: Other national Traditional systems of registration
Other: If known, it should be specified or otherwise add 'Not Known'

Member State	Regulatory Status				Comments
Austria	☐ MA	☐ TRAD	☒ Other TRAD	☐ Other Specify:	Only homeopathic products
Belgium	☐ MA	☐ TRAD	☒ Other TRAD	☐ Other Specify:	Homeopathic products* and non registered eye drops. A simplified registration procedure is allowed.
Bulgaria	☐ MA	☐ TRAD	X Other TRAD	☐ Other Specify:	Only in homoeopathic products
Cyprus	☐ MA	☐ TRAD	☐ Other TRAD	☐ Other Specify:	No information
Czech Republic	☐ MA	☐ TRAD	☐ Other TRAD	☐ Other Specify:	No authorized or registered preparations
Denmark	☐ MA	☐ TRAD	☐ Other TRAD	☐ Other Specify:	No aurhorized or registrered preparations
Estonia	☐ MA	☐ TRAD	☐ Other TRAD	☒ Other Specify:	Food supplements
Finland	☐ MA	☐ TRAD	☐ Other TRAD	☐ Other Specify:	No information
France	☐ MA	☐ TRAD	☐ Other TRAD	☐ Other Specify:	No information
Germany	☐ MA	☐ TRAD	☐ Other TRAD	☐ Other Specify:	No authorized or registered preparations
Greece	☐ MA	☐ TRAD	☐ Other TRAD	☐ Other Specify:	No information
Hungary	☐ MA	☐ TRAD	☐ Other TRAD	☐ Other Specify:	No information
Iceland	☐ MA	☐ TRAD	☐ Other TRAD	☐ Other Specify:	No authorized or registered preparations
Ireland	☐ MA	☐ TRAD	☐ Other TRAD	☐ Other Specify:	No authorized or registered preparations
Italy	☐ MA	☐ TRAD	☐ Other TRAD	☐ Other Specify:	No authorized or registered preparations
Latvia	☐ MA	☐ TRAD	☐ Other TRAD	☐ Other Specify:	No information

[1] This regulatory overview is not legally binding and does not necessarily reflect the legal status of the products in the MSs concerned.

Member State	Regulatory Status				Comments
Liechtenstein	☐ MA	☐ TRAD	☐ Other TRAD	☐ Other Specify:	No information
Lithuania	☐ MA	☐ TRAD	☒ Other TRAD	☐ Other Specify:	Multicompound homeopathic products
Luxemburg	☐ MA	☐ TRAD	☐ Other TRAD	☐ Other Specify:	No information
Malta	☐ MA	☐ TRAD	☐ Other TRAD	☐ Other Specify:	No authorized or registered preparations
The Netherlands	☐ MA	☐ TRAD	☐ Other TRAD	☐ Other Specify:	No authorized or registered preparations
Norway	☐ MA	☐ TRAD	☐ Other TRAD	☐ Other Specify:	No authorized or registered preparations
Poland	☐ MA	☐ TRAD	☐ Other TRAD	☐ Other Specify:	No information
Portugal	☐ MA	☐ TRAD	☐ Other TRAD	☐ Other Specify:	No authorized or registered preparations
Romania	☐ MA	☐ TRAD	☐ Other TRAD	☐ Other Specify:	No information
Slovak Republic	☐ MA	☐ TRAD	☐ Other TRAD	☐ Other Specify:	No authorized or registered preparations
Slovenia	☐ MA	☐ TRAD	☐ Other TRAD	☐ Other Specify:	No authorized or registered preparations
Spain	☐ MA	☐ TRAD	X Other TRAD	☐ Other Specify:	Only combined preparations used as an eye wash
Sweden	☐ MA	☐ TRAD	☐ Other TRAD	☐ Other Specify:	No authorized or registered preparations
United Kingdom	☐ MA	☐ TRAD	☐ Other TRAD	☐ Other Specify:	No authorized or registered preparations

*The following preparations could be identified in Belgium (they can be considered as homeopathic preparations without a tradition of at least 30 years):

- Optilan eye drops: 0.045g mother tincture per 100 mL.
- Optilan monodoses: 0.05g mother tincture per 100 mL.
- Oculoheel: D5 : solvent = aqua purificata.
- Euphrasia stillidoses Unda D2: solvent = aqua purificata

II. ASSESSMENT REPORT

BASED ON ARTICLE 16D(1), ARTICLE 16F AND ARTICLE 16H OF DIRECTIVE 2001/83/EC AS AMENDED

(TRADITIONAL USE)

Herbal substance(s) (binomial scientific name of the plant, including plant part)	*Euphrasia officinalis* L., and *Euphrasia rostkoviana* Hayne, herba
Herbal preparation(s)	Comminuted herbal substance Infusion (3% w/v; water) Tincture (ratio of herbal substance to extraction solvent 1:5; extraction solvent 45% v/v ethanol)
Pharmaceutical forms	Herbal preparation in liquid or semi-solid dosage forms for ocular or nasal use.
Rapporteurs	Gert Laekeman
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II.1 INTRODUCTION

This assessment report reviews the scientific data available for *Euphrasia officinalis* (L.) and *Euphrasia rostkoviana* Hayne, herba. The classification of the genus *Euprasia* differs greatly in the literature and is to some extent contradictory. Some authors consider *Euphrasia officinalis* the same as *Euphrasia rostkoviana* whereas others consider it as *E. rostkoviana* as a subspecies of *E. officinalis*[2]. According to some taxonomists, *E. officinalis* is also called *E. stricta* Wolff. (Heimans et al. 1983). However, other sources make a distinction between both species. *Euphrasia* or eyebright belongs to the botanical family of the *Scrophulariaceae*.

The herbal substance is mainly used in liquid form for external ocular application (i.e. conjunctivitis, blepharitis, styes,…). Secondly, the dried herb is used as an infusion for internal administration in case of common cold and eye problems. Thirdly, *Euphrasia* can be applied as an nasal ointment against a runny nose. There is only poor clinical evidence as the data available are scarce. Eyebright is listed by the Council of Europe as a natural source of food flavouring (category N3).

The following databases were assessed:

- PubMed, until February 2009;
- The Cochrane Library, December 2008;
- OvidMedline, December 2008;
- Embase, December 2008;

Search terms: Euphrasia, Eyebright, Euphrasia AND officinalis.
Apart from these sources standard books on phytotherapy were reviewed (see literature references).

II.1.1 Description of the herbal substance(s), herbal preparation(s) or combinations thereof

Herbal substance

The herbal substance described in the Hagers Handbuch der pharmazeutischen Praxis as the dried total herb of *Euphrasia officinalis* harvested before flowering and dried out under sunlight in a well-ventilated area (Blascheck et al. 1998). In the Deutsche Arzneimittel Codex (Anonymus 2003) 'Augentrostkraut' is described as: … *aus den zur Blütezeit gesammelten, getrockneten, ganzen oder geschnittenen oberirdischen Teilen verschiedener Euphrasia-Arten, besonders der Gruppen E. stricta D. Wolff ex F. J. Lehm., E. rostkoviana Hayne (E. officinalis L. p. p.) (Scrophulariaceae), deren Bastarde oder Mischungen davon ...*
According to the information in the DAC, the plant is collected in the flowering status.
The species used are confirmed.
Therefore, for the sake of the establishment of a Community herbal monograph, in the herbal substance definition, flowers are also included in the herb.

Euphrasia herba is also known under the synonyms:
English: Eyebright
German: Augentrost
French: Euphraise, Casse-Lunettes
Dutch: Ogentroost

[2] Euphrasia officinalis is considered as an ambiguous name (De Langhe et al. Flora van België, het Groothertogdom Luxembrug, Noord-Frankrijk en de aangrenzende gebieden. Patrimonium van de Nationale Plantentuin van België)

Danish: Øjentrøst
Spanish: Ojo brillante
Lituanian: Akišveité
Norvegian: Augetrøst
Polish: Świetlik
Swedish: Ögontröstsläktet

Other species
Euphrasia stricta Host. is a well known European species (2 to 40 cm high), of which the aeral parts are harvested during flowering. *Euphrasia stricta* can be differentiated from *Euphrasia officinalis* by the presence of curved hairs on the tops of the leaves (Schulze & Diepenbrock, 1944).

- Constituents (Blazics 2008)
  - Flavonoids: 0.38%: apigenin, luteolin, kaempferol, rhamnetin, quercetin.
  - Polyphenols: 1.47%.
  - Phenolic acids: caffeic acid and its ester derivatives, chlorogenic acids and coumaric acids.
  - Hydroxycinnamic derivatives: 1.97%
  - Tannins: 0.56%
  - Iridoids: aucubin 0.05%

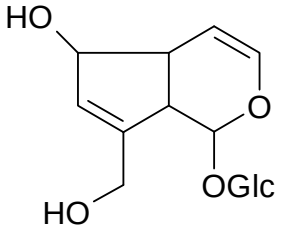

Figure 1: aucubine

From a phytopharmacological point of view *Euphrasia* has different effects: adstringent (due to the tannins) and anti-inflammatory (due to the iridoids).

Chudnicka et al (2005) showed that eyebright contains acidic phosphatases and naphtol-AS-BI-phosphohydrolase.

Herbal preparation(s):

- Comminuted herbal substance
- Infusion (2-3% w/v; water) (Delfosse et al, 1998; Weiss et al, 1999; Van Hellemont, 1985; Wichtl, 1994)
- Tincture (1:5 in 45% alcohol) (Barnes et al, 2007)

Combinations of herbal substance(s) and/or herbal preparation(s) (Delfosse et al, 1998)

- Infusion: 50% Camomille flower and 50% eyebright herb. Five soupspoons dried herb in 0.25 l freshly boiled water.

- Infusion: 60% eyebright herb, 20% melilot herb and 20% plantain herb. One soupspoon dried herb in a cup of freshly boiled water. After fifteen minutes the infusion is passed through a filtering tissue and applied as an ocular compress.
- Tincture: 50% eyebright tincture, 35% passionflower tincture and 15% belladonna tincture. Twenty drops in 15 ml of water can be taken orally up to four times a day.

II.2 HISTORICAL DATA ON MEDICINAL USE

II.2.1 Information on period of medicinal use in the Community

Euphrasia is used in a European tradition since the fourteenth century. It was supposed to cure 'all evils of the eye'. Paracelsus also recognised the structure of an eye in the plant. Many literature of different European countries from the late eighteenth and early nineteenth century refer to eyebright "as a solution for all the eye problems". *Euphrasia* is mentioned in standard works such as *The British flora medica* (Barton and Castle, 1837), *Reine Arzneimittellehre* (Hahnemann, 1826), *Flora parisiensis* (Bulliard, 1779), *Flora veneta* (Naccari, 1827), *Flora Scotica* (Lightfoot, 1777) and *Afbeeldingen der artsenygewassen met derselver nederduitsche en latynse beschryvingen* (Oskamp, 1796).

The use of *Herba Euphrasiae* in case of inflammations of the eye is confirmed by more recent sources. Indications for homoepathic use are common cold, headache, cough and also eye ailments (Anonymus 1953).

II.2.2 Information on traditional/current indications and specified substances/preparations

- Traditional herbal medicinal product for symptomatic treatment and prevention of conjunctivitis of any etiology (allergic, irritative, infectious). (Barnes et al, 2007; Blascheck, 1998; Delfosse, 1998; Van Hellemont, 1985; Weiss, 1999; Wichtl, 1994)
- Traditional herbal medicinal product for symptomatic treatment of minor ocular diseases; for example blepharitis, eye fatigue, purulent ocular inflammation and styes. (Barnes et al, 2007; Blascheck, 1998; Delfosse, 1998; Van Hellemont, 1985; Weiss, 1999; Wichtl, 1994)
- Traditional herbal medicinal product for symptomatic treatment of cold. (Delfosse, 1998)

II.2.3 Specified strength/posology/route of administration/duration of use for relevant preparations and indications

- Liquid preparations used for conjunctivitis and minor ocular affections.
  Application: oral and external use.
  Posology:

  Eye drops (D_3; a thousandfold dilution of *Euphrasia* M.T.): one drop 3 times daily. (Stoss et al, 2000)

  Eye rinse, ocular compress: tea is prepared by pouring freshly boiled water over two to three grams of the dried substance (2-3%). After five to ten minutes, the tea is passed through a filtering tissue and applied several times a day. (Wichtl et al, 1994)

  Oral use: an infusion of one teaspoon dried herb in 0.5 l freshly boiled water. (Weiss et al, 1999)

- Liquid preparations in case of common cold.
  Application: oral use.
  Posology:

  Tincture (1:5 in 45% alcohol): 50 drops 3 to 5 times a day. (Delfosse et al, 1998; Barnes et al, 2007; Van Hellemont, 1985)

- Nasal ointment for a runny nose (Van Hellemont, 1985)
  Application: external use.
  Posology:

R/	Euphrasia tincture	5 g
	Lanoline	5 g
	Vaseline	15 g
	Bergamot essence	2 drops

1 application 3 times a day in each nostril.

II.3 NON-CLINICAL DATA

II.3.1 Overview of available pharmacological data regarding the herbal substance(s), herbal preparation(s) and relevant constituents thereof

Porchezhian et al (2000) tested the anti-hyperglycemic effects of *Euphrasia officinalis* on wistar albino rats. Hyperglycemia was induced by an intraperitoneal injection of alloxan monohydrate. 100 grams of air-dried leaves from *Euphrasia officinalis* growing in Nilgiri district (India) were extracted with hot distilled water and dried using a vacuum rotating evaporator. The obtained extract was used in the experiment (600 mg extract per kg bodyweight).
In the first part of the experiment, there were three groups of rats (fasted overnight): control group (distilled water), test group (600 mg *Euphrasia* extract per kg, p.o.) and a reference group (phenformin, 600 mg/kg, p.o.). The control group received only the vehicle in which alloxan was dissolved, the other two groups received alloxan.
The administration of alloxan showed a rise in the blood glucose levels as compared to the control group. Three to six hours after oral administration of the aqueous extract of *Euphrasia* to diabetic rats, the blood glucose level had significantly dropped ($P<0.01$), while the control group showed no significant reduction of the blood glucose level.

The effect of oral administration of *E. officinale* aqueous extract on the blood glucose level in alloxan-diabetic rats[a]

Sampling time (h)	Blood glucose (mg/dl)		
	Control (distilled water, 10 ml/kg, p.o.)	Phenformin (600 mg/kg, p.o.)	*E. officinale* (600 mg/kg, p.o.)
0	303.0 ± 12.4	309.5 ± 15.4	302.1 ± 11.5
1	309.8 ± 12.7	245.0 ± 18.8*	262.4 ± 18.7
2	320.0 ± 11.2	191.3 ± 18.3*,**	198.9 ± 18.3*,**
3	328.3 ± 16.1	123.6 ± 19.2*,**	193.8 ± 9.8*,**
6	338.6 ± 14.4	127.7 ± 18.2*,**	184.2 ± 8.1*,**

[a]Values are expressed as mean ± S.E.M., $n = 8$; *$P < 0.001$ vs. control; **$P < 0.01$ vs. zero time, Student's t-test.

In the second part of the experiment, the effect of *Euphrasia* on normoglycemic rats was tested. Again there were three groups of rats (fasted overnight): control group (distilled water, test group (600 mg *Euphrasia* extract per kg, p.o.) and a reference group (phenformin, 600 mg/kg, p.o.). There was no alloxan administered.
Treatment with the extract showed no significant decrease in blood glucose levels in normoglycemic rats ($P<0.01$).

The effect of oral administration of *E. officinale* aqueous extract on the blood glucose level in normoglycemic rats[a]

Sampling time (h)	Blood glucose (mg/dl)		
	Control (distilled water, 10 ml/kg, p.o.)	Phenformin (600 mg/kg, p.o.)	*E. officinale* (600 mg/kg, p.o.)
0	99.0 ± 6.23	102.3 ± 7.6	96.7 ± 5.48
1	92.3 ± 5.92	98.3 ± 3.18	91.3 ± 5.44[c]
2	88.8 ± 14.4	83.9 ± 3.66[c]	97.8 ± 8.28[b]
3	96.1 ± 7.22	92.0 ± 3.42[c]	98.9 ± 8.80
6	96.4 ± 3.21	94.0 ± 6.02[c]	97.2 ± 6.24

[a]Values are expressed as mean ± S.E.M., $n = 8$; [b]$P < 0.001$ vs. control; [c]$P < 0.01$ vs. zero time, Student's t-test.

II.3.2 Overview of available pharmacokinetic data regarding the herbal substance(s), herbal preparation(s) and relevant constituents thereof

No data available.

II.3.3 Overview of available toxicological data regarding the herbal substance(s)/herbal preparation(s) and constituents thereof

Porchezhian et al (2000) investigated the acute toxicity of aqueous eyebright extract on wistar albino rats. 100 grams of air-dried leaves from *Euphrasia officinalis* growing in Nilgiri district (India) were extracted with hot distilled water and dried using a vacuum rotating evaporator (DER = 4:1). The obtained extract was used in the experiment (600 mg extract per kg bodyweight). Graded doses ranging from 0.1 to 6 g/kg were orally administered to groups of six rats and observed for 72 h. There were no symptoms of toxicity seen.
Tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed.

II.3.4 Overall conclusions on non-clinical data

In general there is a discrepancy between the traditional use and the non-clinical data, as these data are not related to ocular use. Safety data on ocular use are not available either.

II.4 CLINICAL DATA

II.4.1 Clinical Pharmacology

No data available.

II.4.1.1 Overview of pharmacodynamic data regarding the herbal substance(s)/preparation(s) including data on relevant constituents

No data available.

II.4.1.2 Overview of pharmacokinetic data regarding the herbal substance(s)/preparation(s) including data on relevant constituents

No data available.

II.4.2 Clinical Efficacy

II.4.2.1 Dose response studies

No data available.

II.4.2.2 Clinical studies (case studies and clinical trials)

Stoss et al (2000) performed an open prospective cohort trial of *Euphrasia* single-dose eye drops (WALA Heilmittel GmbH, Eckwälden/Bad Boll, Deutschland) in conjunctivitis. Eighty patients were enrolled. The eye drops contained 10 g *Euphrasia* 33c D3 and 10 g *Rosae* aetheroleum D7.
The recommended dose was one drop 1-3 (up to 5) times a day during fourteen days. As efficacy parameters the variables "reddening", "swelling", "secretion", "burning of the conjunctiva" and "foreign body sensation" were investigated as therapeutic outcomes. Undesirable effects were also observed and documented.
In 81% of the patients, there was complete recovery. Only one case showed a slight worsening of the symptoms. The tolerability of the medication was very good. No undesirable serious adverse events occurred due to the medication during the entire prospective cohort trial.

II.4.2.3 Clinical studies in special populations (e.g. elderly and children)

Stoffel et al (2007) performed a pilot project to investigate the effect of local application of *Euphrasia* eye drops (in Switzerland 'Euphrasia Augentropfen': exact composition not given) on antibiotic consumption by 44 neonates. They selected neonates with redness and lacrymation of the eyes. Before the treatment, they performed a culture of the eyefluid.
There were 2 groups: in the control group (20 neonates) the eyes of the neonates were washed every six hours with NaCl 0.9% and in the test group (24 neonates) the eyes were washed every six hours with NaCl 0.9% and additionally one drop of *Euphrasia* was administered. If the doctors considered the treatment after 48 hours as "successfull", it was not changed. If they considered the treatment as "not successfull", the treatment changed to Neosporin-Augentrophen®. The criteria for this decision was a worsening of the symptoms or a positive culture. Seven neonates of the test group and 3 of the control group had to change to Neosporin-Augentrophen®. Cultures of 11 neonates were positive for *Staphylococcus aureus,* but there was no need to change the treatment because the symptoms had ameliorated.
The authors concluded that there was no difference between the control group and the test group and so immediate antibiotic treatment is not always necessary. There were no side effects reported.

II.4.3 Overall conclusions on clinical pharmacology and efficacy

The two published studies are of limited value. The open design of the first one is not reliable to confirm whether the therapeutic effect is due to the preparation or to spontaneous healing. The second study with the neonates is not conclusive due to the limited number of patients and divergent outcomes. No adverse effects were reported, but this finding is also not conclusive because of the small-scale of the trials. As a consequence of these results, only a traditional use could be considered.

II.5 CLINICAL SAFETY/PHARMACOVIGILANCE

II.5.1 Overview of toxicological/safety data from clinical trials in humans

In the study performed by Stoss et al (2000) no serious adverse events were reported.

II.5.2 Patient exposure

No data available.

II.5.3 Adverse events and serious adverse events and deaths

No data available.

II.5.4 Laboratory findings

No data available.

II.5.5 Safety in special populations and situations

No data available.

II.5.6 Overall conclusions on clinical safety

The clinical studies reported above involved 124 patients. The number is too few to draw any conclusions on clinical safety. As up to now no authorized or registered medicinal preparations are on the market in Europe, no periodic safety update reporting has been established.

II.6 OVERALL CONCLUSIONS

Traditional herbal preparations from *Euphrasiae herba* are mainly liquid water extracts which are *ex tempore* made as infusions for application as an ocular impregnated dressing for symptomatic treatment of minor irritation of the eye". A nasal ointment containing an *Euphrasia* tincture[3] 20% as a traditional herbal medicinal product for the relief of local nasal irritation in common cold has also been described.

No adequate data are however available for these preparations concerning their safe use and the plausibility of their pharmacological effects.

[3] Specifications of the tincture not available.

STRUCTURAL RISK – BENEFIT ANALYSIS

Quality

A monograph on *Euphrasia rostkoviana* does not yet exist in the actual European Pharmacopoeia. There is no major concern about adulteration with related species as *Euphrasia stricta* can be differentiated from *Euphrasia officinalis* by the presence of curved hairs on the tops of the leaves.

Safety

There are no concerns about serious adverse events or drug-drug interactions with *Euphrasia* preparations. Also from non-clinical experiments, no toxic effects were reported. However, in order to avoid deterioration of ocular conditions, medical supervision is necessary when the symptoms do not improve within 2 days. There is only one study with a limited amount of paediatric patients, not resulting in serious adverse events.

Efficacy

From the presence of secondary metabolites, an adstringent and anti-inflammatory activity can be hypothesized for Euphrasia preparations. On one hand ocular use of Euphrasia is based upon a long-standing tradition. On the other hand, there is no clinical proof for such an indication. An ointment made with Euphrasia tincture has been documented as a traditional herbal medicinal product for the relief of local nasal irritation in common cold.

Conclusion

Based on the above-mentioned concerns, no Community herbal monograph on *Euphrasia officinalis* L. and *Euphrasia rostkoviana* Hayne, herba can be established.

III. ANNEXES

III.1 PUBLIC STATEMENT ON *EUPHRASIA OFFICINALIS* L. AND *EUPHRASIA ROSTKOVIANA* HAYNE, HERBA

III.2 LITERATURE REFERENCES