



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 September 2010
EMA/HMPC/149343/2010
Committee on Herbal Medicinal Products (HMPC)

Assessment report on *Achillea millefolium* L., flos

<Based on Article 10a of Directive 2001/83/EC as amended (well-established use)>

<Based on Article 16d(1), Article 16f and Article 16h of Directive 2001/83/EC as amended (traditional use)>

Draft

Herbal substance(s) (binomial scientific name of the plant, including plant part)	<i>Achillea millefolium</i> L., flos
Herbal preparation(s)	- Comminuted herbal substance - liquid extract (DER 1:5.8); extraction solvent: liquor vine: ethanol 96 (v/v) 91:9 (m/m)
Pharmaceutical forms	Herbal substance as herbal tea for oral and cutaneous use. Comminuted herbal substance as herbal tea or other herbal preparations in liquid dosage forms for oral use.

Note: This draft Assessment Report is published to support the release for public consultation of the draft Community herbal monograph on *Achillea millefolium* L., flos. 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 monograph. 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 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 monograph.



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1. Introduction

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

- Herbal substance(s)

Yarrow flower consist of the dried inflorescence of *Achillea millefolium* L. (Fam. Asteraceae)

Ph. Helv.VII: Millefolii flos.

Principal components of the herbal substance

Volatile oil, not less than 0.20% (*Ph. Helv.VII.*)

Essential oil contains numerous identified components including borneol, bornyl acetate (trace), camphor, 1.8-cineole, eucalyptol, limonene, sabine, terpin-4-ol, terpineol and α -thujone (monoterpenes), caryophyllene (a sesquiterpene) achillicin, achillin, milefin and millefolide (sesquiterpene lactones), azulene and chamazulene (sesquiterpene lactone derived), and isoartemisia ketone.

The relative composition of components varies greatly between *Achillea* species, especially the azulene content. Azulene has been reported as the major component. However, true yarrow (*A. millefolium*) is thought to be hexaploid and azulene-free, whereas closely related species, such as *Achillea lanulosa* Nutt. and *Achillea collina* Becker, are tetraploid and contain up to 50% azulene in their volatile oil. It is possible that the tetraploid species may be supplied for *A. millefolium*.

The azulenes are not present in the fresh herb: they are formed as artefacts during steam distillation of the oil, from unstable precursors called proazulenes (e.g. achillin and achillicin) via equally unstable azulene-carboxylic acid intermediates (Barnes J et al. 2007).

Candan F et al. (2003) performed GC-MS analysis of the essential oil which resulted in the identification of 36 compounds constituting 90.8% of the total oil. Eucalyptol, camphor, alpha-terpineol, beta-pinene, and borneol were the principal components comprising 60.7% of the oil.

- Herbal preparation(s)

Communitied herbal substance as infusion for tea preparation (Augustin B 1948, Rácz G et al. 1984, German Commission E monograph 1990, Blumethal M et al. 1998, 2000, Hänsel R et al. 1992).

- Combinations of herbal substance(s) and/or herbal preparation(s) including a description of vitamin(s) and/or mineral(s) as ingredients of traditional combination herbal medicinal products assessed, where applicable.

1.2. Information about products on the market in the Member States

Regulatory status overview

Member State	Regulatory Status				Comments (not mandatory field)
Austria	<input type="checkbox"/> MA	<input type="checkbox"/> TRAD	<input type="checkbox"/> Other TRAD	<input type="checkbox"/> Other Specify:	No products
Belgium	<input type="checkbox"/> MA	<input type="checkbox"/> TRAD	<input type="checkbox"/> Other TRAD	<input type="checkbox"/> Other Specify:	
Bulgaria	<input type="checkbox"/> MA	<input type="checkbox"/> TRAD	<input type="checkbox"/> Other TRAD	<input type="checkbox"/> Other Specify:	
Cyprus	<input type="checkbox"/> MA	<input type="checkbox"/> TRAD	<input type="checkbox"/> Other TRAD	<input type="checkbox"/> Other Specify:	
Czech Republic	<input type="checkbox"/> MA	<input type="checkbox"/> TRAD	<input type="checkbox"/> Other TRAD	<input type="checkbox"/> Other Specify:	No products
Denmark	<input type="checkbox"/> MA	<input type="checkbox"/> TRAD	<input type="checkbox"/> Other TRAD	<input type="checkbox"/> Other Specify:	No products
Estonia	<input type="checkbox"/> MA	<input type="checkbox"/> TRAD	<input type="checkbox"/> Other TRAD	<input type="checkbox"/> Other Specify:	No products
Finland	<input type="checkbox"/> MA	<input type="checkbox"/> TRAD	<input type="checkbox"/> Other TRAD	<input type="checkbox"/> Other Specify:	No products
France	<input type="checkbox"/> MA	<input type="checkbox"/> TRAD	<input type="checkbox"/> Other TRAD	<input type="checkbox"/> Other Specify:	
Germany	<input type="checkbox"/> MA	<input checked="" type="checkbox"/> TRAD	<input type="checkbox"/> Other TRAD	<input type="checkbox"/> Other Specify:	+ in combination
Greece	<input type="checkbox"/> MA	<input type="checkbox"/> TRAD	<input type="checkbox"/> Other TRAD	<input type="checkbox"/> Other Specify:	
Hungary	<input type="checkbox"/> MA	<input type="checkbox"/> TRAD	<input type="checkbox"/> Other TRAD	<input type="checkbox"/> Other Specify:	
Iceland	<input type="checkbox"/> MA	<input type="checkbox"/> TRAD	<input type="checkbox"/> Other TRAD	<input type="checkbox"/> Other Specify:	
Ireland	<input type="checkbox"/> MA	<input type="checkbox"/> TRAD	<input type="checkbox"/> Other TRAD	<input type="checkbox"/> Other Specify:	No products
Italy	<input type="checkbox"/> MA	<input type="checkbox"/> TRAD	<input type="checkbox"/> Other TRAD	<input type="checkbox"/> Other Specify:	
Latvia	<input type="checkbox"/> MA	<input type="checkbox"/> TRAD	<input type="checkbox"/> Other TRAD	<input type="checkbox"/> Other Specify:	
Liechtenstein	<input type="checkbox"/> MA	<input type="checkbox"/> TRAD	<input type="checkbox"/> Other TRAD	<input type="checkbox"/> Other Specify:	
Lithuania	<input type="checkbox"/> MA	<input type="checkbox"/> TRAD	<input type="checkbox"/> Other TRAD	<input type="checkbox"/> Other Specify:	
Luxemburg	<input type="checkbox"/> MA	<input type="checkbox"/> TRAD	<input type="checkbox"/> Other TRAD	<input type="checkbox"/> Other Specify:	
Malta	<input type="checkbox"/> MA	<input type="checkbox"/> TRAD	<input type="checkbox"/> Other TRAD	<input type="checkbox"/> Other Specify:	
The Netherlands	<input type="checkbox"/> MA	<input type="checkbox"/> TRAD	<input type="checkbox"/> Other TRAD	<input type="checkbox"/> Other Specify:	
Norway	<input type="checkbox"/> MA	<input type="checkbox"/> TRAD	<input type="checkbox"/> Other TRAD	<input type="checkbox"/> Other Specify:	
Poland	<input type="checkbox"/> MA	<input type="checkbox"/> TRAD	<input type="checkbox"/> Other TRAD	<input type="checkbox"/> Other Specify:	
Portugal	<input type="checkbox"/> MA	<input type="checkbox"/> TRAD	<input type="checkbox"/> Other TRAD	<input type="checkbox"/> Other Specify:	
Romania	<input type="checkbox"/> MA	<input type="checkbox"/> TRAD	<input type="checkbox"/> Other TRAD	<input type="checkbox"/> Other Specify:	
Slovak Republic	<input type="checkbox"/> MA	<input type="checkbox"/> TRAD	<input type="checkbox"/> Other TRAD	<input type="checkbox"/> Other Specify:	No products
Slovenia	<input type="checkbox"/> MA	<input type="checkbox"/> TRAD	<input type="checkbox"/> Other TRAD	<input type="checkbox"/> Other Specify:	No products
Spain	<input type="checkbox"/> MA	<input type="checkbox"/> TRAD	<input type="checkbox"/> Other TRAD	<input type="checkbox"/> Other Specify:	
Sweden	<input type="checkbox"/> MA	<input type="checkbox"/> TRAD	<input type="checkbox"/> Other TRAD	<input type="checkbox"/> Other Specify:	No products
United Kingdom	<input type="checkbox"/> MA	<input type="checkbox"/> TRAD	<input type="checkbox"/> Other TRAD	<input type="checkbox"/> Other Specify:	

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'

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

According to the information provided by the National Competent Authorities¹

Active substance Pharmaceutical form	Indication	Posology	Legal status
Comminuted herbal substance for herbal tea	loss of appetite; dyspeptic disorders	2 g/250 ml; 1-2 times a day	since 1979 in Spain
Liquid extract (DER 1:5.8) from millefolii flos, extraction solvent: liquor vine : ethanol 96 (v/v) 91 : 9 (m/m) oral liquid	traditionally used to support gastro-intestinal function	oral use in adults and adolescents over 12 years several times daily 10-20 drops	at least since 1976 on the German market
Herbal substance as herbal tea	traditional herbal medicinal product for treatment loss of appetite and dyspeptic complaints (mild, spastic gastrointestinal discomfort). topical use: small superficial epidermal excoriation	oral use (infusion) 1.5 g herbal substance for ½ glass of boiling water. Use 2-3 times daily topical use: infusion should be prepared the in the same way as for oral use	more than thirty years in Poland
Tincture (1:5; ethanol 70% v/v) oral drops, solution	for functional bowel disorders	internal use: 20-30 drops in 50 ml water, twice a day (in the morning and in the evening, half hour before meal)	since 2006 in Romania
Comminuted herbal substance for preparing herbal tea	internal use: mild dyspeptic/gastrointestinal disorders, temporary loss of appetite external use: abscesses, skin wounds and burns, varicose ulcers, haemorrhoids	internal use: single dose: 2.5 g (in 250 ml water), 2-3 times daily external use: single dose: 8 g (in 200 ml water), topically	since 1996 in Romania

¹ Data are collected using the template entitled 'Document for information exchange for the preparation of the assessment report for the development of Community monographs and for inclusion of herbal substance(s), preparation(s) or combinations thereof in the list' (EMA/HMPC/137093/2006)

1.3. Search and assessment methodology

Articles and references retrieved from data bases (Pubmed, Toxnet) or internet sources (e.g. Google) until the end of April 2009. The term of *Achillea millefolium*, flower was searched.

2. Historical data on medicinal use

2.1. Information on period of medicinal use in the Community

According to Blumenthal M et al. (2000) yarrow has been used as medicine by many cultures for hundreds of years (Budavari 1996; Zeylstra 1997). Its English common name is a corruption of the Anglo-Saxon name *gearwe*; the Dutch, *yerw*. The genus name *Achillea* may have been derived from the Achilles of Greek mythology, which was fabled to have had his wounds treated by topical use of the herb. The species name *millefolium* is derived from the many segments of its foliage. The ancient Europeans called it *Herba Militaris*, the military herb – an ointment made from it was used as vulnerary drug on battle wounds. Yarrow flower was formerly official in United States Pharmacopoeia. Additionally, it is listed in the Indian Ayurvedic Pharmacopoeia for fevers and wound healing (Karnick, 1994).

A Polish product containing herbal substance for herbal tea has been on the market for more than 30 years.

Communitied herbal substance as infusion for tea preparation (Augustin B 1948).

A Spanish product containing comminuted herbal substance for herbal tea has been on the market for more than 30 years.

A German preparation, liquid extract (1:5.8) from *Millefolii flos*, extraction solvent: liquor vine: ethanol 96 (v/v) 91:9 (m/m) 2-3 times daily 10-20 drops has been on the market for more than 30 years.

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

Indication: Loss of appetite, dyspeptic ailments, such as mild, spastic discomforts of the gastrointestinal tract (German Commission E Monographs 1990, Blumethal M et al. 1999, 2000)

A Polish product containing herbal substance for herbal tea has been on the market for more than 30 years.

A Spanish product containing comminuted herbal substance for herbal tea has been on the market for more than 30 years.

A German liquid extract (1:5.8) from *Millefolii flos*, extraction solvent: liquor vine: ethanol 96 (v/v) 91:9 (m/m) has been on the market fore more than 30 years.

Indication: Traditional herbal medicinal product for treatment of small superficial wounds.

A Polish product containing herbal substance for herbal tea has been on the market for more than 30 years.

Proposed indication in the monograph:

1) Traditional herbal medicinal product used in temporary loss of appetite.

2) Traditional herbal medicinal product for symptomatic treatment of mild, spasmodic gastro-intestinal complaints including bloating, and flatulence.

3) Traditional herbal medicinal product for treatment of small superficial wounds.

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

3 g yarrow flower (German Commission E Monographs 1990)

- Herbal substance for oral use:

1.5 g herbal substance as infusion for ½ glass of boiling water; 2–3 times daily.

External use: Infusion should be prepared the in the same way as for oral use.
(product on the market for more than 30 years in Poland)

- Herbal preparation for oral use:

2 g comminuted herbal substance in 250 ml water as infusion; once or twice a day.
(product on the market more than 30 years in Spain)

liquid extract (1:5.8) from *Millefolii flos*, extraction solvent: liquor vine: ethanol 96 (v/v)
91:9 (m/m) 2-3 times daily 10-20 drops (product on the market for more than 30 years in Germany)

3. Non-Clinical Data

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

In vitro studies

- **Antibacterial activity**

A 50% ethanol extract of the flowers inhibited the growth of *Shigella dysenteriae*, but not that of *Escherchia coli* or *Salmonella enteritidis* at a concentration of 50 µl/agar plate (Caceres A et al. 1990).

The *in vitro* antimicrobial activity of the essential oil of *Achillea millefolium* subsp. *millefolium* Afan. (*Asteraceae*) was investigated. The oil exhibited moderate activity against *Streptococcus pneumoniae*, *Clostridium perfringens* and *Candida albicans*, and weak activity against *Mycobacterium smegmatis*, *Acinetobacter lwoffii* and *Candida krusei*. The growth inhibitions of test micro-organisms ranged from 4.5 mg/ml (w/v) to 72.00 mg/ml (w/v) with the lowest MIC value against *Streptococcus pneumoniae*, *Clostridium perfringens*, *Candida albicans* at 4.5 mg/ml (w/v) (Candan F et al. 2003).

- **Anti-oxidant effects**

Infusions (1:1; mg/ml) of dried pulverized flower heads of various *Achillea* (*Asteraceae*) species protected human erythrocytes and leucocytes against hydrogen peroxide-induced oxidative damage. This was shown by increased catalase, superoxid dismutate and glutation peroxidase activities, as well as by reduced glutathione content of the cells and decrease in lipid peroxidation. The human erythrocyte and leucocyte hemolysates served as control groups (Konyalioglu S and Karamenderes C 2005).

- **Haemostyptic activity**

A 5% m/V hot water infusium of yarrow (*Achillea millefolium*) significantly shortened recalcification time (a test of blood coagulation) in human plasma to 43% of that of the reference substance, 0.9%

sodium chloride ($p < 0.001$). The flowering herb had the highest haemostatic activity, whereas pressed juice significantly prolonged blood coagulation ($p < 0.05$ to $p < 0.001$) (Sellerberg U and Glasl H 2000).

In vivo studies

- **Anti-inflammatory effect**

An aqueous extract of the dry flower heads of *Achillea millefolium* L (yarrow) has been found to possess anti-inflammatory activity as measured by the yeast -induced mouse paw oedema test. Fractionation has resulted in the isolation of a material which reduces inflammation by 35% compared to 44% and 26% respectively for the same doses (40 mg/kg body weight) of indomethacin and phenylbutazone. This concentrate is water-soluble, non-steroidal and has a very low order of toxicity. Physical and chemical studies show this active fraction to be mixture of protein-carbo-hydrate complexes (Goldberg AS et al. 1969).

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

There are no pharmacokinetic data.

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

Single dose study:

According to a safety assessment for its use in cosmetics, the oral and subcutaneous LD₅₀ values in mice of yarrow, *Achillea millefolium* L. extract (2% **flowers** in propylene glycol and water) were both 1g/kg (Anonymous 2001).

Reproductive toxicity:

The effect of hydro-alcoholic extract (200, 400, 800 mg/kg) of *Achillea millefolium* L. yarrow **flowers** on spermatogenesis of 50 Wistar rats by intra-peritoneal administration. The animals were divided into 3 experimental groups (10 rats in each group) and control group (10 rat received distilled water) and 1 sham group (10 rats received nothing). At the dose of 200 mg/kg, there was no effect on spermatogenesis and all of cells had normal arrangement and account. At dose of 400 mg/kg, a significant difference in cell arrangement and cell count, but after 22 days, on which 5 number of this group was kept without any extract administration, there was no significant difference between them and control group, so this dose was reversible. At dose of 800 mg/kg a significant effect was observed as well, but after 22 days it was not reversible (Takzaree N et al. 2008).

Sensitization potential

Sensitization potential was assessed in groups of guinea pigs (Hausen BM et al. 1991) in a modified Freund's complete adjuvant method, by 0.1% and 1% crude extract of the flowers. The sensitization potential of the sesquiterpene lactone alpha-peroxyachifolid was also tested at 0.01% and 0.1% using groups of 10 guinea pigs and at 1% using a group of 3 guinea pigs. All animals tested with flower extract were sensitized. Sesquiterpene lactone alpha-peroxyachifolid was identified as a strong sensitizer. Other known yarrow constituents like dehydromatricaria ester and pontica epoxide appear to play no role.

From the ether extract of the blossoms of yarrow, *Achillea millefolium* L., two guaianolides (1, 2) with a peroxide bridged cyclopentane ring and an alpha-methylene-gamma-butyrolactone structure have

been isolated. For these compounds the names alpha-peroxyachifolid (1) and beta-peroxyisoachifolid (2) are proposed. Alpha-peroxyachifolid is responsible for the allergic contact dermatitis caused by yarrow (Rücker G et al. 1991).

3.4. Overall conclusions on non-clinical data

There are only very few data on the pharmacological effects of yarrow flower.

Some in vitro experiments on antibacterial and anti-oxidant activity and the in vivo yeast-induced mouse paw oedema test may contribute the long-standing use of yarrow in the indication of gastrointestinal complaints and of treatment of small superficial wounds.

Adequate tests on reproductive toxicity, genotoxicity and carcinogenicity have not been performed. Guinea pig sensitization tests indicated some sensitization potential for yarrow extracts and for one sesquiterpene lactone component.

4. Clinical Data

4.1. Clinical Pharmacology

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

Oral administration of a 70% ethanol extract of the flowers (dose not stated) increased the secretion of gastric juice in healthy volunteers by 178% (Mahler P 1926). No further information on this study was available.

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

4.2. Clinical Efficacy

4.2.1. Dose response studies

No studies available.

4.2.2. Clinical studies (case studies and clinical trials)

No studies available.

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

No studies available.

4.3. Overall conclusions on clinical pharmacology and efficacy

The promotion of gastric juice secretion in a clinical study by an ethanol extract of the flowers in healthy volunteers may contribute the long-standing use of yarrow flower in the indication of loss of appetite.

5. Clinical Safety/Pharmacovigilance

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

In clinical testing, cosmetic product formulations containing 0.1% to 0.5% of ingredient that actually contained 2% of yarrow flower extract were generally not irritating. In provoking testing, patients reacted to a *Compositae* mix that contained yarrow, as well as to yarrow itself. Also in clinical testing, a formulation containing 0.1% yarrow (*Achillea millefolium*) extract (2% yarrow flower in propylen glycol (75%) and water) was not a sensitizer in a maximization test and alcoholic extracts of dried leaves and stalks of *Achillea millefolium* did not produce a phototoxic response (Anonymus 2001).

5.2. Patient exposure

No data available.

5.3. Adverse events and serious adverse events and deaths

None known (German Commission Monograph 1990, Blumenthal M et al. 1998, 2000).

If the skin comes into contact with the flowers, in rare cases hypersensitivity (allergy) may occur, with reddening of the skin and formation of small blisters (Bisset NG 1994).

Since 5 months after her first contact with dried flowers of yarrow a 44-year-old woman began to experience rhinitis, asthma and urticaria symptoms in the workplace when she handled these dried flowers as an instructor of personnel making dried flower arrangements. She had a clinical history of spring seasonal rhino-conjunctivitis and asthma but no family history of atopy. The physical examination was normal. Basal spirometry and chest X-ray was normal. Methacholine inhalation test was positive with a PC20 of 2.5 mg/ml. Total serum IgE was 7.94 kU/l. Skin prick test with aqueous extracts from dried flowers were positive to yarrow (10-7 mm). Specific Inhalation Bronchial Challenge with aqueous extract of yarrow (1.25 mg/ml) elicited an asthmatic response with a fall in FEV1 of 31%. Specific IgE (EAST) with yarrow flowers was 0.9 kU/l respectively. Immunoblotting with yarrow flowers revealed several IgE binding bands of 51, 21 and 18 kDa. Occupational respiratory symptoms caused by decorative flowers are seldom reported in the literature (Compes E et al. 2006).

Proposed wording in the monograph:

Hypersensitivity reactions of the skin have been reported. The frequency is not known.

If the skin comes into contact with the flowers, in rare cases hypersensitivity (allergy) may occur, with reddening of the skin and formation of small blisters.

5.4. Laboratory findings

No data available.

5.5. Safety in special populations and situations

Contra indications (hypersensitivity and allergic potential to be both covered)

Allergy to yarrow and other *Compositae* (Blumenthal M et al. 1998, 2000, Hänsel R et al. 1992).

Known hypersensitivity (allergy) to *Asteraceae* such as: yarrow, arnica, matricaria flowers or marigold flowers, for example (Bisset NG 1994).

Warnings and precautions for use

The use in children and adolescents under 18 years of age has not been established due to lack of adequate data.

If the symptoms worsen during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

If signs of skin infection are observed, a doctor or a qualified health care practitioner should be consulted.

For tinctures, extracts containing ethanol the appropriate labelling for ethanol, taken from the 'Guideline on excipients in the label and package leaflet of medicinal products for human use', must be included.

Drug interactions

None documented.

Use in pregnancy and lactation

It is frequently considered that yarrow should not be taken during pregnancy. It is reputed to be an abortifacient and to affect the menstrual cycle, and the volatile oil contains trace amounts (0.3%) of the abortifacient principle thujone. Excessive use should be avoided during lactation (Newal CA et al. 1996, Barnes J et al. 2007).

Assessor's comment: Due to lack of adequate data a specific warning is not included in the monograph. Preparations of yarrow contain only trace amounts of thujone.

Proposed text in the monograph:

Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended.

Overdose

No case of overdose has been reported.

Effects on ability to drive or operate machinery or impairment of mental ability

No studies on the effect on the ability to drive and use machines have been performed.

5.6. Overall conclusions on clinical safety

The medicinal use of yarrow preparation can be considered safe. Only the reported hypersensitivity reactions may present a risk but the contra-indication paragraph of the monograph will draw the attention to it.

The known toxic principle thujone has been documented as a minor component of yarrow oil, but the concentrations are too low to present a risk to human health.

Since there are insufficient data, the use during pregnancy and lactation is not recommended.

6. Overall conclusions

Yarrow flowers have been in medicinal use for a period of at least 30 years as requested by Directive 2004/24/EC, thus the requirement for the qualification as a traditional herbal medicinal product is fulfilled (long-standing use dating back to ancient time).

It is possible that the anti-inflammatory effect is due to its sesquiterpene lactones content and this property may support the traditional indications.

The medicinal use of yarrow preparation can be considered safe. Only the reported hypersensitivity reactions may present a risk but the contra-indication paragraph of the monograph will draw the attention to it.

Since there are insufficient data, the use during pregnancy and lactation is not recommended.

Annex