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Committee on Herbal Medicinal Products (HMPC)

Assessment report on *Fragaria vesca* L.; *Fragaria moschata* Weston; *Fragaria viridis* Weston; *Fragaria x ananassa* (Weston) Duchesne ex Rozier, folium

Draft - Revision 1

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

Herbal substance(s) (binomial scientific name of the plant, including plant part)	*Fragaria vesca* L.*; Fragaria moschata* Weston*; Fragaria viridis* Weston; *Fragaria x ananassa (*Weston) Duchesne ex Rozier, folium	
Herbal preparation(s)	Comminuted herbal substance	
Pharmaceutical forms	Comminuted herbal substance as herbal tea for oral use	
First assessment	Rapporteur	E. Widy-Tyszkiewicz
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Note: This draft assessment report is published to support the public consultation of the draft revised European Union herbal monograph on *Fragaria vesca* L.; *Fragaria moschata* West on, *Fragaria viridis* West on; *Fragaria x ananassa* (West on) Duchesne ex Rozier, folium. It is a working document, not yet edited, and shall be further developed after the release for consultation of the monograph. Interested parties are welcome to submit comments to the HMPC secretariat, which will be taken into consideration but no 'overview of comments received during the public consultation' will be prepared on 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)

Fragariae folium is defined in the Austrian Pharmacopoeia (Österreichisches Arzneibuch 2013) as "The collected, dried leaves of *Fragaria vesca* L., *Fragaria moschata* Weston, *Fragaria viridis* Weston, *Fragaria x ananassa* (Weston) Duchesne ex Rozier or a mixture of these species". Content: at least 3.0 percent of tannins, expressed as pyrogallol ($C_6H_6O_3$; Mr 126.1) and based on the dried drug.

Common wild strawberry (*Fragaria vesca* L.) is a perennial plant of the Rosaceae family which grows in meadows, woods and along roadsides (Mabberley 2002), native from the Ural Mountains across Northern Europe and North America. It is of about 5-20 cm height; leaves are complex, three-lobed, feathery, with serrated edges and hairy petioles. *Fragaria vesca* L., diploid (2x), have been cultivated since the Middle Ages in European gardens. The cultivated strawberry originated from a random hybridisation of two wild American octoploid (8x) species *Fragaria chiloensis* L. and *Fragaria virginiana* Duch in France in the next years gave various cultivars (Gündüz 2016). Another species of strawberries from which the leaves are collected are cultivated octoploid strawberry *Fragaria ananassa* (8x) (Sargent *et al*. 2009) and two wild species growing in European forests *F. moschata* L. (hexaploid) and *F. viridis* Duchesne (diploid). Chromosome number is used to differentiate *Fragaria* species by use of genetic barcoding (Lundberg *et al*. 2009; Rousseau-Gueutin *et al*. 2009). Comparative taxonomic morphological and anatomical studies of collected leaves of several *Fragaria* species in various parts of Austria were conducted by Scheller (2013).

In the European traditional medicine, wild strawberry leaves, collected during the flowering period, or cultivars which are mostly harvested of wild by rural populations in Albania, Bulgaria, Croatia, Kosovo, Serbia, North Macedonia and Ukraine are used (Medicinal Plants and Natural Ingredients, 2015).

Constituents of Fragariae folium relevant for this assessment report

Free and condensed tannins. Lamaison 1990, Scholz monograph in Hagers 5th edition (1993), Blaschek (HagerRom 2006), estimated 5-10% tannins. Oktyabrsky et al. (2009) reported Fragariae folium total tannin content of 8.2 mg/g (dry weight) in Fragaria vesca leaves ethanol extract. In a strawberry leaf decoction (15g in 150ml, 1.44 g of dry content), as minor peaks of phenolics (beside of soluble sugars) Mudnic et al. (2009) identified: epicatechin gallate, astringin, (+)-catechin and (-)-epicatchin. In the infusion (4 g in 200 ml) the main catechins were: (+)-catechin, sanguiin H10 isomer and procyanidin dimer, epicatechin hexoside and B type epicatechin trimer (Ivanov 2015, 2018).

Phenolic acids. Phenolic acids were referred to be present in the leaves of *Fragaria vesca, Fragaria viridis, F. moschata* as 3.4% of phenolic acids (Blaschek et al. 2006). Najda and Dyduch (2009a) found 1.8% of phenolic acids in *Fragaria vesca* dry leaf weight and 1.3% in its cultivar 'Regina'. Dyduch and Najda (2009) found in dry *Fragaria vesca* cultivars 1.0-1.13% of phenolic acids in leaf blades and 0.13-0.20% in petioles. Ellagic acid was contained in 0.20-0.23%, gallic acid in 0.11-0.16% (Fecka, 2009). Methanolic extract of Fragaria vesca leaves contained gallic acid monohydrate, vanillic acid, caffeic acid and p-coumaric acid (Yildirim and Turker 2014). 2-pyrone-4.6-dicarboxylic acid was found in *Fragaria vesca* in 0.21% and in *Fragaria ananassa* 0.24%, Wilkes and Glasl (2001). Akšić et al. (2019b) found in acidified extract of strawberry leaf (methanol-water 7:3, V/V with 0.1% HCl) also small quantities of 5-O-caffeoylquinic acid.

Other constituents of strawberry leaf

Soluble sugars are dominating constituents of strawberry leaves hot water and and alcohol extracts. (Dias et al. 2015a) in hot water extract of the fresh freeze-dried leaves and stems estimated sum od soluble sugars 31.7%; sucrose 8.5%, glucose 7.4%, fructose 6.4%, xylose 5.8%, trehalose 3.6%. Akšić et al. 2019a found average content of 10.4 – 19.5% sugars in leaves of common cultivars.

The main characteristic group of strawberry leaf are oligomeric procyanidins derived from catechin, which were found in alcohol extracts by Stafford and Lester (1980). In methanol water extracts (1:1, w/v) of dry *Fragaria vesca* leaf were determined mainly 0.89-1.11% of agrimoniin and 0.40-0.68% of pedunculagin and 0.21-0.25% of catechin (Fecka, 2009). Yildirim and Turker (2014) found: pyrocatechol, (−) epigallocatechin, (+) catechin, procyanidin B1, B2, C1, (−) epicatechin, agrimoniin, pedunculagin, and other oligomeric (laevigatin isomers and sanguiin H-10 isomer, castalagin/vescalagin isomer, sanguiin H-2 isomer, casuarictin/potentillin isomer, sanguiin H-6/agrimoniin, lambertianin A isomer (Liberal et al. 2015) and monomeric ellagitannins (casuarictin, agrimonic acid A/B, isostrictinin/sanguiin H-4) with the total content of 5.2-8.9% ellagitannins in a hydro-methanolic crude extract (Moilanen et al. 2015). Maximum content of 12.4% procyanidins (B1, B2 and B5) from *Fragaria vesca* leaves was found in 56% acetone-water extract (Ivanov 2015). Last years Karlińska et al. (2021) studied content of elagitannins in the extract (70/29.9/0.1 (V/V/V) acetone/water/formic acid) of fresh leaves of six strawberry cultivars in Poland in four stages, leaf development stage (S1), flowering stage (S2), fruit development (S3) and fruit and achene maturation (S4). Maximum content 5.9-15.2% of elagitannines in the leaves of common cultivars in Poland was found in the leaf development stage.

Flavonoid glycosides. Najda and Dyduch (2009a), Dyduch and Najda (2009) reported that leaves from cultivated species (*Fragaria vesca* "Regina") contained more flavonoids (4%) as compared to the herb collected from natural habitats (3%). In the methanolic extract Yildirim and Turker (2014) shown the presence of luteolin-7-O-D-glucoside, rutin hydrate, myricetin, kaempferol-3-d-glucopyranoside, daidzein, quercetin, genistein and apigenin. The extracts from leaves with SO acidified water and 80% ethanol contained mainly quercetin-3-O-rutinoside and its -3-O-glucuronide (Oszmiański et al. 2011). Wild strawberry leaves contained 2.16mg/g (0.22%) quercetin and 0.34mg/g [0.34%] kaempferol (Haghi and Hatami, 2010). The flavonoid contents in the leaves Fragaria vesca was observed to decrease when growing in higher altitudinal zones of western Carpathian Mountains (Malinikova et al. 2013).

Terpenes. The air-dried leaves contained small amounts of essential oil, depending on the cultivar, from 0.46% (cv 'Baron von Solemacher') to 0.62% (cv 'Rugia') with dominated myrthenol, nonal, linalool and dibuthyl phtalide (Najda and Dyduch 2009b). Hampel et al. (2006) found in GC-MS of Fragaria vesca leaves (R)-linalool with a high enantiomeric purity (>90%). Gleńsk et al. (2021) isolated from strawberry leaves triterpenoid constituents with main glycoside nigaichigoside F1.

Constituents of Fragariae folium infusions and decoctions

Mudnic et al. (2009) in a strawberry leaf decoction (15 g in 150 ml, 1.44 g of dry content after evaporation) identified as minor peaks in phenolics: epicatechin gallate, astringin, (+)-catechin, (-)-epicatchin and smaller amounts of quercetin-4'-glucoside and procyanidin B1 (HPLC-RP-DAD, 330nm, RP18 column). Liberal et al. (2014) analysed phenolic profile of the the strawberry leaf infusion (4g in 150 ml, w/v) by HPLC-PDA-ESI/MSn method with mass analyses in negative ion mode. The infusion show presence of kaempferol glucuronyl-rhamnoside and quercetin glucuronide, quercetin glucuronyl-rhamnoside, methyl elagic acid rhamnoside, sanguine H-6/agrimoniin, epiafzelechin-epicatechin, quercetin hexosyl-glucuronide, unidentified elagic acid derivative and smaller quantities

casuarictin/potentilin, castalagin/vescalagin and epicatechin-epicatechin. Dias et al. (2015a, 2015b) found in the herbal teas of Fragaria vesca leaves and stems (2 g in 200 mL), beside amount of soluble sugars (mainly glucose and fructose) citric and malic acids and manganese. Main flavonoid compounds in the infusions were: quercetin 0-glucuronide, quercetin 3-O-rutinoside, methylquercetin deoxyhexose glucuronide, quercetin deoxyhexose glucuronide, kaempferol deoxyhexose glucuronide, quercetin hexose glucuronide. Main catechin compounds in the infusions: (+)-catechin, sanguiin H10 isomer and procyanidin dimer, epicatechin hexoside and B type epicatechin trimer. Ivanov (2015, 2018) determined in Fragariae folium infusions and decoctions (4 g in 200 ml). Total phenolics with the use of Folin-Ciocalteau method counted as gallic acid equivalent were 107 and 129 GAE/g. Tannin contents (spectrophotometric method) were 46 and 53 mg/g. Procyanidin contents with spectrophotometric method (ferrum ammonium sulfate) counted as leucocyanidin equivalent were 116 and 134 mg LE/g.

- Herbal preparations described in pharmacopoeias and national codexes

There are no preparations of strawberry leaf in the European Pharmacopoeia and national codexes.

The only used in the EU countries is herbal tea, infusion (see above).

- 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.

Not applicable

1.2. Search and assessment methodology

Scientific databases

☒ Scientific/Medical/Toxicological databases

Search terms: Fragaria; Fragaria vesca, Fragaria moschata, Fragaria viridis, Fragaria x ananassa strawberry leaves. Databases: PubMed, Embase, Medline, Scopus, Toxnet. The search was performed between June 2015 and May 2017 and between June and December 2023. Libraries: Library of Warsaw Medical University, Department of Pharmacognosy and Pharmacology, Faculty of Pharmacy of the University Complutense of Madrid, Spain

☒ Pharmacovigilance databases

☒ data from EudraVigilance

☒ from other sources (e.g. data from VigiBase)

☒ Other National database. Poland

Books

☒ New editions of old manuals were searched for

Regulatory practice

☒ Old market overview in AR (i.e. check products fulfilling 30/15 years of TU or 10 years of WEU on the market).

☒ Market overview (including pharmacovigilance actions taken in member states)

☒ PSUSA. Not applicable, no medicinal products are available

☒ Feedback from experiences with the monograph during MRP/DCP procedures. Not applicable, no medicinal products are available

☒ Ph. Eur. Monograph. No monograph is available in the European Pharmacopoeia

☒ Other: There is a monograph for strawberry leaf in Austrian Pharmacopoeia (Österreichisches Arzneibuch 2013)

Consistency (e.g. scientific decisions taken by HMPC)

☒ Public statements or other decisions taken by HMPC

☒ Consistency with other monographs within the therapeutic area

☐ Other

1.3. Main changes introduced in the 1st revision

1. Chapter 1.1 on herbal substance is shortened and part on herbal preparations (herbal tea, infusion) is updated.
2. Chapter 2.2 was updated on a base of verified data.
3. Chapter 3.1.1 on primary pharmacodynamics is restructured in line with a new template.
4. Chapter 3.1.2 on secondary pharmacodynamics is shortened in line with a new template and updated.
5. Chapter 4.2.2 'Clinical studies' was updated.

2. Data on medicinal use

2.1. Information about products on the market

2.1.1. Information about products on the market in the EU/EEA Member States

Information on medicinal products marketed in the EU/EEA

There are no registered or authorised medicinal products in the EU/EEA Member States according to information provided by the national competent authorities upon inquiry in preparation of this Assessment Report.

The overview is not exhaustive. It is provided for information only and reflects the situation at the time when it was established.

Overview of data obtained from non-marketed medicinal products

No data available.

Information on relevant combination medicinal products marketed in the EU/EEA

No data available.

Information on other products marketed in the EU/EEA (where relevant)

Strawberry leaves are included as part of several multi-component preparations marketed as food supplements in the EU, intended 'to improve metabolism' or for improving taste of traditional tinctures (in Poland).

2.1.2. Information on products on the market outside the EU/EEA

Wild strawberry leaves are widely used especially in Serbia, as herbal tea (infusion), to treat diarrhea (Šavikin et al. 2013); to treat cough (Zlatković et al. 2014a); as antidiarrheal, antihelmintic, diuretic, blood purifier, for relieve pain from kidney stone and in liver and bladder area; as antigout (Jarić et al. 2007); laxative or in diarrhea and haemorrhoids (Zlatković and Bogoslavljević 2014a,b). The tea from young leaves is used as antitussive, to 'heal' asthma, catarrh and cough; a tea from 'herbal parts' is used as nerve relaxant (Popović et al. 2014).

2.2. Information on documented medicinal use and historical data from literature

In the old European tradition wild strawberry leaf was used as an astringent for diarrhoeas (especially *summer diarrhea*), jaundice, abdominal congestion, as an intestinal tonic, and as a mild diuretic (Kosch 1939). *Summer diarrhoea* was named paediatric diarrhoeas occurring in Europe, America and Southern Africa during the summer in infants and children (Ebbs 1957, Robins-Browne et al. 1980) although since the 1950s this disease in Europe and America becomes less frequent (Anderson et al. 2020, Mallier et al. 2023). For diarrhoea in children and adolescents a decoction made of 1-2 tablespoons in a glass of water or the infusion of 4.0 g in 150 ml of water cup, used as a single dose, were referred by Ożarowski (1978) and Blaschek (HagerRom 2006).

As a mild diuretic was reported use, of hot infusion prepared of one tablespoon of the herbal substance in 1 cup of boiling water, taken twice daily (Kosch 1939) or the infusion of one tablespoon in one glass of water, taken in a quantity of ¼ of glass twice daily.

Beside of the use of wild strawberry leaves as infusion or decoction in the treatment of diarrhoea, especially for children, it has been mentioned the use for the inflammation of oral mucosa and throat (as gargles) and in urinary-tract diseases (Dragendorff 1898, Schneider 1974, van Wyk and Wink 2004, Wren 1975) and in rheumatism and gout. Blaschek *et al*. (HagerRom 2006) referred mainly internal use of folk medicines prepared as follows: Boil a handful of young leaves in 500 ml of water for diarrhoea. The decoction of 375 g of fresh green leaves in 1.15 l boiled until the volume reduces to 550 ml and condensed preparation was dosed with a teaspoon every 3-4 hours. 20 g of fresh leaves in 500 ml of water boiled until its volume reduces to half of the initial volume and it is used one teaspoon before and one after a sleep. Although in the folk medicine mainly fresh leaves were used to prepare a decoction for gargles and the treatment of oral mucosa inflammation, in this assessment are included only data on dried strawberry leaf, as defined in Chapter 1.1.

Also in South European folk medicine of Bulgaria, Italy, Spain and Portugal the *Fragaria vesca, Fragaria viridis* and *Fragaria moschata* leaves, leaves were used as a herbal teas as diuretic and in gout (Akerreta et al. 2007, Nedelcheva et al. 2010, Leporatti and Ivancheva 2003, Camejo-Rodrigues et al. 2003, Neves et al. 2009); as astringent in diarrhea and stomatic diseases; throat and mouth diseases as anti-inflammatory and topically on the skin in wound treatment (Tuttolomondo et al., 2014, Nedelcheva *et al*. 2010, Leporatti and Ivancheva 2003, Akerreta et al. 2007).

Table 1 shows a summary of the traditional uses of strawberry leaves.

Table 1: Overview of historical data

Herbal preparations	**Documented use/Traditional use**	**Posology and method of administration**	**Reference and date of reference**
Fragariae folium	As an astringent for diarrhea (*summer diarrhea*), jaundice, abdominal congestion, as an intestinal tonic, and as a mild "opening" diuretic.	Oral hot infusion. 1 tablespoon in 1 cup, 2 cups daily	Kosch 1939
Fragariae folium	Oral use as diuretic	Oral use. 1 tablespoon[1] of the leaves in a glass of water as decoction. Drink ¼ of glass[2] of the prepared decoction 2 times daily	Bobowska *et al*. 1977
Fragariae folium	Oral use as weak diuretic in gout and urinary tract calculitis. For children in mild diarrhoeas as adstringent. Used especially in herbal tea combinations.	Decoction. 1-2 tablespoons for 1.5-2 glasses of water. Drink a half of glass ml 2-3 times daily; in children 1/4 - 1/3 of a glass.	Ożarowski 1976, Ożarowski *et al*. 1978
Fragaria vesca L., leaf	In mild diarrhoeas in children. Also declared to possess diuretic and antispasmodic properties.	Infusion for oral use. Strength: 1 – 2 tablespoons pour with 1.5-2 glasses of boiling water for 15 min. The prepared infusion is kept in a thermos and given to children in dose of half of glass.	Olechnowicz-Stępień, Lamer-Zarawska 1986
Fragaria vesca L., leaf	Adstringent. Folk use for for mild diarrhea in children	Infusion with 4 g of drug per 150 ml as a single dose for children's diarrhea	Hänsel et al. (red.) Hagers Handbuch Vol. V, 1993
Fragaria vesca L., dried leaf	Folk use for mild diarrhea especially in children	Oral use: Infusion of 4 g of drug in 150 ml as a single dose for children's diarrhea.	Blaschek et al. HagerROM 2006
Fragaria vesca L. as herbal tea	1. Topical use in mouth and throat infection. 2. Internal oral use as diuretic and in diarrhea	Decoction: 5 g of the leaves in 100 ml of water. Gargle the mouth and throat several times per day.	Wurzer 1994

[1] Average spoons used in Poland over the last 30 years have contained 4.4±0.5g - 5.5±0.6g of Fragariae folium dried herbal substance, (Dymowski & Jackiewicz, 2020)

[2] Average glass used in Poland over the last 30 years have contained about 200 ml

		Infusion: 4 g in 100 ml of water. Drink 3-4 times per day a small cup	

2.3. Overall conclusions on medicinal use

The evidence on the period of medicinal use for *Fragaria* leaves is limited to those references including all the species, with a traditional indication and posology (Table 2).

In the monograph, the posology of *Fragaria vesca* leaves as a diuretic in patients with mild urinary symptoms was calculated based on the publications of Ożarowski *et al*. 1978 and Bobowska *et al*. 1977.

Table 2. Overview of evidence on period of medicinal use.

Herbal substance/ preparation	**Indication**	**Posology and method of administration**	**Period of medicinal use**
Fragariae folium. Herbal tea, infusion	As astringent in mild diarrhoea in children, and as mild diuretic	Oral use. Hot infusion made of 1 tablespoon in 1 cup, 2 times daily	Kosch 1939
Fragariae folium. Herbal tea, decoction	Oral use as diuretic	Oral use. 1 tablespoon (5g) of the leaves as a decoction for 200 ml of water. Posology: Drink 50 ml 2 times daily	Bobowska *et al*. 1977
Fragariae folium. Herbal tea, decoction	Oral use as weak diuretic (gout, urinary ways calculitis) and astringent mainly for diarrhoeas in children	Oral use. 1-2 tablespoons (5-10 g) for 1.5-2 glasses of water (300-400 ml) as decoction. Posology: Drink ½ of glass (100 ml) 2-3 times daily; for children: 1/4 -1/3 of a glass (50-60 ml)	Ożarowski 1976, Ożarowski *et al*. 1978
Fragaria vesca L., leaf	Adstringent. Folk use for for mild diarrhea in children	Infusion with 4 g of drug per 150 ml as a single dose for children's diarrhea	Hänsel et al. (red.) Hagers Handbuch Vol. V, 1993

Historical data in the EU support the evidence of traditional use of comminuted Fragaria leaves:

In adults and elderly in Indication 1): Traditional herbal medicinal product used for the relief of symptoms associated with minor urinary tract complaints in addition to the general recommendation of a sufficient fluid intake to increase the amount of urine;

In children and adolescents in Indication 2) Traditional herbal medicinal product for symptomatic treatment of mild diarrhoea.

The historical and bibliographic data are consistent in the use as mild adstringent in diarrhoeas in children, although the traditional data are not adjusted to the contemporary pediatric age groups.

However, the use of the infusions/decoctions is less documented in adults but by some of experts is estimated as plausible.

3. Non-Clinical Data

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

Although wild strawberry leaves are traditionally used to promote urine flow, the studies conducted to evaluate the diurectic activity are scarce and results are not conclusive. In rats, the decoction of the leaves (10 g in 100 ml) in doses corresponding to 1 g drug/kg b.w. did not have any significant influence on diuresis following oral administration while positive control of probenecid 25 mg/kg b.w. and other substances used traditionally, like barley grain, coriander and parsley fruits gave important increase of urine excretion (Caceres et al. 1987). The extract made from 0.5 g dried leaves with 20 ml ethanol 50% at a concentration of 100 µl/2.5 ml medium inhibited the proteolytic activity of the enzyme elastase by 85%; however, no data on the effect of a positive control are available (Blaschek et al. 2006).

Antidiarrheal effect

Fragaria leaves due to their tannin content may have plausible astringent effects (Hänsel et al. 1993, HagerROM 2006) and have been used for mild diarrhoeas, especially in children (Kosch 1939, Olechnowicz-Stępień & Lamer-Zarawska 1986, Ożarowski et al. 1978) although there are no experimental studies available to support this indication.

Table 3. Overview of the main non-clinical data.

Herbal preparation tested	Concentration/ Dosage	Experimental model	Reference	Main outcome(s) according to the authors
Data on diuretic effect of herbal tea, decoction				
Strawberry leaf decoction of 10g in 100ml	Dose of the decoction corresponded to 1g/kg b.w.	In vivo test. 6 inbread albino rats, weight 220-289g, of the same sex and age, kept controlled animal colony conditions. The decoction was administered at by the catheter. Urine was collected at 2, 4 and 6h. The urinary growth output was expressed percent of the control	Caceres et al. 1987	The urinary output was below 90% of growth what authors classified as weak or no effect (medium effects 90%-180%). Hydrochlorothiazide control gave 286% of growth

		output. Positive control hydrochlorothiazide 25mg/kg b.w.		
Data on of other preparations (ethanol extract, tincture)				
Strawberry leaf fluid extract (DER 1:2) extraction solvent ethanol 70% (V/V) with added 10% of propylene glycol; dried and dissolved in water. Tincture (1:2) with 90% (V/V) ethanol	The dried fluid extract was administered to two rats in a dose of 15 mg/100g and to two rats in a dose 150mg/100g, orally in water solution; one administered with furosemide injection 20mg/100g as a positive control and one with water as a negative control	In vivo. Diuretic effect was observed on group of 7 Wistar rats (average 200g) administered by oral gavage with a dose 15 mg/100g of the dried extract (what correspond 10 g in 70kg human) or the dose 10x higher 150 mg/100g, in compared to furosemide injection 20 mg/100g as a positive control and one with water as a negative control and water.	Vicas et al., 2015	In two rats with an oral dose of 15 mg/100 g of extract urine output over 10 h was observed 3.5 and 7 ml; in two rats with 150 mg/100 g 5 and 4 ml; in the injected with furosemide 4 ml. The analysis of sodium and potassium in the urine indicated stimulation of sodium elimination.

Assessor's comment:

Antidiarrheal effect.
There are no experimental studies available for supporting antidiarrhoeic effect. Antiinflammatory activity in the in vitro test was moderate and shown only in less polar extracts.
Diuretic effect.
There are no data on diuretic activity of infusions or decoctions. Preliminary data on possible diuretic activity of strawberry leaf ethanol-water extract or tincture in animals are not conclusive for herbal teas.

3.1.2. Secondary Pharmacodynamics*Anti-inflammatory activity - in vitro*

Havlik et al (2010) searched for the xanthine oxidase inhibitory properties in vitro among 27 extracts of plants, which were traditionally used in Central-Eastern Europe for gout, arthritis or rheumatism treatment. Three extracts of 5 g powdered Fragaria vesca leaves were prepared with 20% aqueous ethanolic, 80% aqueous ethanolic and methylene chloride–methanolic extracts (50/50 CH_2Cl_2/ MeOH) tested at the starting concentration 200 µg/ml did not show any evident effects.

Liberal et al. (2014) studied the antinflammatory activity of extracts from Fragaria vesca leaves extract with dichloromethane (1:10, w/v-2 times) and 50% aqueous ethanol (3 times) (1:10, w/v) at room temperature, filtrated and lyophilized (yield 30%). The extract (dissolved in phosphate buffered saline, PBS) was tested at non-toxic concentrations of 80 µg/ml and 160 µg/ml for NO production in the cultured mouse leukemic monocyte macrophage cell line Raw 264.7. Control cells produced very low NO levels (0.35±0.23 µM), the cells treated with LPS (for 24 hours) increase of NO content (28.64±2.10 µM); the cells pretreated with the tested plant extract (160 µg/ml and 80 µg/ml), gave significant decreases (40% and 31% respectively) of nitrite production. The extract tested at 160 µg/ml) in experiment, where S-nitroso-N-acetylpenicillamine (SNAP) was used as NO donor in the culture medium, promoted significant decrease (23% of inhibition) of nitrite content. The extract tested on iNOS and COX-2 protein expression (Western blot method), shown no difference LPS-induced COX-2 protein levels compared with LPS alone (1480±499% of control) and not influenced the activity of LPS on mRNA levels of iNOS and IL-1β in mouse macrophages. The authors indicated that inhibition of the nitrite production by the extract is probably.

Assessor's comments:

Pharmacological experiments on possible antiinflammatory and antimicrobial activities are generally in line with a traditional use, however observed only in substances from less polar extracts than water infusion (dichloromethane and/or alcohol extracts).

3.1.2.2. Antithrombin and anticoagulant activity - in vitro

Goun et al. (2002) determined the antithrombin activity of dry wild strawberry leaf extract (200 g extracted with methylene chloride for 24 hours, methanol 24 hours in a Soxhlet apparatus and the solvents were removed in vacuum). In parallel, the cytotoxic activity of extracts was tested on mouse leukemia cells (L1210). The idea of the test was that the lower the activity of thrombin, the lower the coagulability, and therefore, the lower the possibility of tumor cells to adhere to any tissue or to spread. Both fragaria extracts showed no antithrombin activity. The cytotoxicity tested at only one concentration (10 µg per well) was given with 77 % for the methylene chloride extract and 11% for the methanol extract.

Pawlaczyk et al. (2009; 2013) in extracts of strawberry leaves with methanol and acetone obtained 5 glycoconjugates (Fv I–FvV) composed of carbohydrates and phenolic and protein constituents with sugar component 21.1-31.7%, phenolic component 0.8-3.5% and protein components 0.5-1.8%. The main carbohydrate was hexuronic acid (31-61% of the carbohydrates) with other monosaccacharides (Rh, Fu, Ar, Xyl, Ma, Gl, Glc) comparable to polysaccharide anticoagulants like glycosaminoglycans, i.e. heparin. Fractions Fv I–V were tested in vitro for their anticoagulant activity on human plasma by activated partial thromboplastin time test (aPTT), prothrombin time test (PT), and thrombin time test (TT) in the concentration range from 4000 µg/ml to 7.81µg/ml and showed that only two glycoconjugates, i.e. Fv III and Fv I have a significant activity, but lower than that of unfractionated heparin. The most active conjugates contained similar amounts of galacturonic acid, and the highest amounts of phenolics.

3.1.2.3. Vasoactive effects – ex vivo

Vasodilatory activity of wild strawberry leaves decoction (15 g in 150 ml) dried with a yield of 1.44g and redissolved to a final concentration of 6 g/100 ml.) was studied on aortic rat rings endothelium-model ex vivo, exposed to nitric oxide (NO) synthase inhibitor L-NAME or to the cyclooxygenase inhibitor indomethacin (Mudnic et al. 2009). Isolated rat aortic rings (endothelium denuded and intact) were exposed to the extract concentrations: 0.06, 0.6, 6 and 60 mg/100 ml. The model rings were

pretested by contraction induced with a test dose of noradrenaline (10^{-7} mol/l) and with subsequent relaxation acetylcholine (10^{-6} mol/l, 70% of relaxation). The relaxation of the rat aortic rings was expressed as the percentage decrease of NA-induced vasoconstriction. The maximum relaxation induced by the strawberry extract was 72.2±4.45. Removal of the endothelium caused a loss of vasodilatory response to the strawberry extract. The strawberry extract at only at higher dose (60.0 mg/100 ml) antagonised the inhibitory activity of indomethacin. Malheiros et al. (2022), studied the possible vascular effects of the Fragariae folium extract (preextraction with dichloromethane, extraction with 50% aqueous ethanol (3 x, 1:10, w/v) and the infusion (4g in 150 mL), freeze-dried (yield 23%) on human artery rings ex vivo. Both extract and infusion lyophilisate elicited no effect on vascular tone in the experiment.

3.1.2.4. Cardiac effects - ex vivo

The wild strawberry leaf dry decoction (as described in 3.1.2.3) was tested in guinea pig isolated hearts (Mudnic et al. 2009) at concentrations of 0.06, 0.18, 0.6, and 1.8 mg/100 ml. Each concentration was perfused for 3.5 minutes with 15 minutes of washout periods. Heart contractility, electrophysiological activity, coronary flow and oxygen consumption were continuously monitored. The heart rate was not influenced by application in all doses. The initial control values for heart rate, AV conduction time and LVP were 224±6 beats per minute, 63±2 ms and 92±2 mm Hg, respectively. The initial control value of coronary flow was 13.1±0.5 ml per minute. The extract at concentrations of 0.06, 0.18, 0.6, and 1.8 mg/100 ml increased coronary flow by 3.6±1.2, 8.4±1.6, 32.7±5.0 and 44.5±4.5% over the control value, respectively. Oxygen extraction in the guinea pig hearts was significantly reduced by the consecutive doses of the extract as follows: by 3±1, 11±2, 27±2 and 34±4% from the control value of 78±2%; as a result of direct vasodilation.

3.1.2.5. Antimicrobial activity - in vitro experiments

Borah et al. (2012) evaluated the antimicrobial activity of water solutions of dry ethanolic extracts (percolation with ethanol 90%) of four medicinal plants, including Fragaria vesca leaves. An aqueous solution was used to determine the diameter of the inhibition zones in the agar cultures discs of bacteria. Standard commercial discs of ciprofloxacin (5 µg/ml) were used as a reference standard and ethanol (90%) impregnated discs were used as negative controls. The plates were incubated (37°C for 24 h) to estimate the antibacterial activity against selected bacterial strains of Staphylococcus aureus, Escherichia coli, Pseudomonas aeruginosa. Marked antibacterial effect has been found for the Fragaria leaves ethanolic extract (0.5 mg and 1 mg samples) against Staphylococcus aureus (16.5 and 13.7 mm) and Escherichia coli strains (14.8 and 17.3 mm); ciprofloxacin zones (21.5-22.0mm). The Pseudomonas aeruginosa showed less growth inhibition to the Fragaria extract compared to the other bacterial strains.

Pereira et al. (2012) investigated strawberry leaf ethanol extract fractions (eluted with 50% aqueous methanol [Fa], 75% aqueous methanol [Fb], and 70% aqueous acetone [Fc]) on metallo-beta-lactamase, MBL Pseudomonas aeruginosa clinical strain isolates (VIM-2 producers). For the determination of MICs against MBL VIM-2 producers Pseudomonas aeruginosa standard microplate assays were used. The tested extracts gave MICs as follows: crude extract (MIC_{50}=10.35 mg/ml, MIC_{90}=20.7 mg/ml); fraction Fa (MIC_{50} and MIC_{90}=25 mg/ml); fraction Fb (MIC_{50}=6.25 mg/ml, MIC_{90}=12.5 mg/ml); fraction Fc (MIC_{50} and MIC_{90}=12.5 mg/ml). The most active antibacterial fraction was the Fb (MeOH 75%) fraction consisting essentially of tannins: proanthocyanidins and ellagitannins.

Weak antimycobacterial activity of higher concentration of the methanol extract of Fragaria vesca leaves was detected studied by Mc Cutcheon et al. (1997) and cited after in Newton et al. (2000). It

was found that methanol extract induced of small zone of clearing of Mycobacterium tuberculosis at 50 µg extract per disc. No activity of the extract against Mycobacterium avium at 50 µg extract per disc has been found.

3.1.2.6. Antidiabetic activity – in vivo

Czapska-Pietrzak et al. 2019 found the extract of Fragariae folium rich in gallic acid and claimed it to be potentially antidiabetic. Shikov AN et al. (2021) mentioned Fragariae folium among herbal substances most frequently used in antidiabetic products in Russia. Ibrahim DZ & Abd El-Maksoud (2015) tested strawberry leaf extract (DER 2:1, extract solvent water) in doses: 50, 100, 200 mg/kg to diabetic (streptozotocin induced) rats. The extract at the tested doses significantly decreased levels of blood glucose, urea nitrogen, plasma kreatinine, renal malondialdehyde, TNF-alpha and IL-6 in the diabetic rats. LD50 was found to be over 800mg/kg. Takacs J et al. (2020) studied the inhibition of alpha-glucosidase effect of the lyophilized decoction (3g in 300ml) of the Fragariae folium administered to normal mice, obese mice, prediabetic and diabetic (STZ) and in model of starch-induced rise in blood glucose level. The wild strawberry leaf extract alleviated starch induced hyperglycaemia in prediabetic and diabetic mice. Zhang L et al. (2020) administered water strawberry extract (100g of powdered material in 100ml of water, dried, 55% of dry residue) to Spraque-Dawley rats with STZ induced diabetes, where blood glucose raise over 200mg/dL. The authors observed alleviation of cognitive impairment, decrease of malonyldialdehyde, decreased tmRNA expression of IL-6 and TNF alpha after 4 months of treatment.

3.1.2.7. Antioxidant activity - in vitro

Fragaria vesca water extract

Katalinic et al (2006) determined antioxidant capacity of Fragaria vesca infusions (3g of leaves or herb, in 200 ml) using the Ferric Reducing/Antioxidant Power (FRAP) at values of 0.06 to 25 mM/l finding an overall linear correlation between total phenolic content and FRAP (841 mg catechin equivalent/l and 11022 FRAP (µM/l). Fragaria vesca infusions were found as a rich source of antioxidants. (Buricova & Reblova, 2008; Buricova et al. 2011) tested the antioxidant activity and phenolic content of wild strawberry leaves infusion (1 g in in 50 ml), assessing total phenolics assay (Folin-Ciocalteu method) 62.4 mg of gallic acid/g; FRAP 23.3 mM $FeSO_4$/l; oxygen radical absorbance capacity (ORAC) µM Trolox/g and free radical scavenging ability by the use of a stable DPPH radical 110.1 mg of ascorbic acid in dry sample. The radical scavenging capacities (TPC, DPPH, ORAC, FRAP) of the wild strawberry leaves infusions were determined to be in the range of about 50% of the antioxidant capacity of green tea water extract. (+)-Catechin, and ellagic acid significantly participated in the antioxidant activity of the infusion. Raudonis et al. (2012) estimated antioxidant activity with the range of total TEAC values 191.23–609.36 mol/g and 178.63–642.20 mol/g of ABTS and FRAP for strawberry leaf extracts.

3.1.3. Pharmacodynamic interactions

No data available.

3.1.4. Conclusions

The leaves from *Fragaria vesca* L.*, Fragaria moschata* Weston*, Fragaria viridis* Weston*, Fragaria x ananassa* (Weston) Duchesne ex Rozier, are traditionally used for drinking as herbal tea in Europe for promoting diuresis and to treat mild diarrhoeas in children.

The scientific information available on the pharmacological activity of *Fragraria* leaves is limited. One study was performed with a dosage of 1 g/kg in rats after oral administration showed no significant influence in diuresis. However, some reported pharmacological effects are partially consistent with the traditional use.

The astringent effect of strawberry may be due to the free or condensed tannoids content (at least 3% refererred to dried drug), although no pharmacology studies proving this activity have been published.

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

No data available.

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

3.3.1. Single dose toxicity

Herbal preparations

There are no data available on the acute toxicity of *Fragaria* leaves.

3.3.2. Repeated dose toxicity

Subacute, Chronic Toxicity

There are no data available.

3.3.3. Genotoxicity

Mutagenicity

There are no data available on the preparations covered by the monograph.

3.3.4. Carcinogenicity

No data available.

3.3.5. Reproductive and developmental toxicity

No data available.

3.3.6. Local tolerance

No data available.

3.3.7. Other studies

Cytotoxic activity - in vitro

Liberal et al (2015) studied cytotoxic activity of an ellagitannin-enriched fraction (EEF) from hydroalcoholic extract Fragaria vesca leaves on the cultured human hepatic carcinoma cell line HepG2 (ATCC HB-8065). The hepatic cells viability after treatment with of both EEF and crude hydroalcoholic

extract was determined and the IC_{50} was evaluated. It was found that different concentrations of EEF during 24 hours exposure induced: IC_{50}=113 µg/ml; IC_{45}=80 µg/ml; IC_{40}=56 µg/ml; IC_{25}=23 µg/ml; IC_{15}=9 µg/ml. Influence of the EEF on the distribution of G0/G1, S and G2/M phases cycle of HepG2 cells was also analysed via flow cytometry. The proliferation of the cells was dose-dependently decreased. Higher concentrations of the EEF induced an increase in cells in the G2/M phase whereas lower doses promoted a significant increase in cells in G1 phase when compared to control cells. In order to evaluate cell death and to discriminate between apoptosis and necrosis, cells were incubated with different concentrations of EEF for 24 h and then stained with annexin V-FITC/PI. The two higher concentrations of EEF promoted an increase in necrotic cells (annexin V-negative/PI-positive cells) and this increase was accompanied by a rise (statistically unsignificant) of annexin V-positive/PI-positive cells that correspond to late apoptotic/necrotic cells. Thus, EEF induced features of necrosis and to some extent apoptosis in HepG2 cells. Cytotoxic activity of strawberry leaves extract was also detected on mouse L1210 leukemia cells 910mg gave 60-79% inhibition) (Goun et al., 2002). Skupień et al. (2006) observed strawberry leaf extract cytotoxic for HL60 cell line and its MDR sublines and Liberal et al. (2015) found strawberry leaf extract cytotoxic in a human hepatic carcinoma cell line (HepG2–ATCC HB-8065).

Assessor's comments:

The studies on cytotoxic activity of several herbal fractions were focused on possible antileukemic use, not on safety aspects of the preparations when they are used in patients. For this reason, the value of the data for the assessment of herbal infusions which have been used traditionally by patients, is limited.

3.3.8. Conclusions

No toxicity studies are available for *Fragaria* leaves water extract and other extracts.

Tests on toxicity, genotoxicity and carcinogenicity have not been performed.

The US American Herbal Products Association considers strawberry leaf as safe (Class 1) and no clinically-relevant interactions are expected (Class A) (Gardner and McGuffin 2013).

3.4. Overall conclusions on non-clinical data

The scientific information available on the pharmacological activity of *Fragraria* leaves is scarce. The content of polyphenols such as elagitanins, agrimoniin, pedunculagin, gallic and elagic acids and procyanidins may partially explain the traditional use of the wild strawberry leaf teas as antidiarrheic and diuretic.

Results from relevant non-clinical experimental studies are scarce and non conclusive, but the astringent, anti-inflammatory and antimicrobial properties of the tannins present in the herbal substance could explain the traditional uses of the wild strawberry leaves for symptomatic treatment of mild diarrhoea.

There is no non-clinical information on the safety of *Fragaria* leaves. As there is no information on reproductive and developmental toxicity, the use during pregnancy and lactation cannot be recommended.

Tests on genotoxicity and carcinogenicity have not been performed.

4. Clinical Data

*4.1. Clinical pharmacology*Overview of pharmacodynamic data regarding the herbal substance(s)/preparation(s) including data on relevant constituents

No data available.

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

No data available.

4.2. Clinical Efficacy

4.2.1. Dose response studies

No data available.

4.2.2. Clinical studies (case studies and clinical trials)

Studies with potential relevance for WEU indication(s)

Not available.

Other studies

Pilot data are available from the abstract of the PhD thesis of Sneha (2019) from University of Health Sciences in Bangalore. The author observed 60 patients with diagnosed minor aphthous ulcers, divided into 3 groups for 20 patients, administered strawberry leaf extract and raspberry leaf extract topically on mucosa in a form of cellulose gel, and as a control cellulose gel alone. The patients were advised to use the gel 3 times per day. Clinical evaluation contained pain assessment (on a base of VAS), ulcer size and questionnaire about acceptability, taste, texture and ease of use. The author observed significant reduction of pain on day 4^{th} ($p=0.001$) and on day 7^{th} ($p=0.020$). Strawberry leaf extract gel, in compared to the control gel was declared to give significant pain reduction to day 2 ($p=0.001$ and day 4 ($P=0.002$). The taste, texture and lolerability were acceptable by majority of the patients.

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

No data available.

4.4. Overall conclusions on clinical pharmacology and efficacy

No data available.

5. Clinical Safety/Pharmacovigilance

5.1. Overview of toxicological/safety data from market overview

No data available.

5.2. Patient exposure

No data available.

5.3. Adverse events, serious adverse events and deaths

There are no data available with respect to adverse effects related to Fragaria leaves or corresponding preparations use (Blaschek et al. 2006); also AHPA Satety Handbook (Gardner and McGuffin 2013) indicated strawberry leaves can be safely consumed when used appropriately and there are no restrictions to use it as flavouring agent in herbal teas (Bundesanzeiger 1990, DeSmet et al. 1993; Grattan and Harman 1985; Rossoff et al. 2002; Van Wyk and Wink 2004).

No reports on adverse rections for Fragariae folum or wild strawberry leaf were found in the pharmacovigilnce databases in years 2018-2024.

5.4. Laboratory findings

No data available.

5.5. Safety in special populations and situations

5.5.1. Use in children and adolescents

For indication 1). The use in children under 12 has been reported in bibliography but without posology details in the age groups. Thus, it can be only accepted for adolescents, adults and elderly.

For indication 2). The use in children has been reported and thus, it can be recommended for adolescents.

5.5.2. Contraindications

Hypersensitivity to the strawberry leaf has not been reported.

However, hypersensitivity to strawberry fruit is known but it is not a subject of the assessment. Strawberry leaf should not contain fruits. Some allergene genes were found in a wild strawberry fruit proteins (PR-10, nsLTP and profiling) what neeed to be further studied (Hyun and Kim 2011).

In the bibliography is cited opinion on the Strawberry leaf risk from Commission E monograph: *Strawberry leaf may ellicit allergic reactions in persons hypersensitive to strawberry fruit* (Wichtl 1994) although the source of the information is not available. Hypersensitivity to strawberry leaf can’t be excluded.

5.5.3. Special Warnings and precautions for use

There are no adverse effects reported derived from the use of strawberry leaves.

The use in children under 12 years of age has not been established.

For Indication 1)

To ensure an increase of the amount of urine, adequate fluid intake is required during treatment.

If complaints or symptoms such as fever, dysuria, spasms or blood in urine occur during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

Because adequate fluid intake is required during treatment (see section 4.2. Method of administration), Fragaria vesca L.; Fragaria moschata West.; Fragaria viridis West.; Fragaria x ananassa (West.)

Duchesne ex Rozier, folium (wild strawberry leaf) is not recommended for patients with conditions where reduced fluid intake is advised.

For Indication 2)

If diarrhoea recurs or bloody stools occur, a doctor or qualified health care practitioner should be consulted.

5.5.4. Drug interactions and other forms of interaction

No data available.

5.5.5. Fertility, pregnancy and lactation

No data available.

5.5.6. Overdose

No cases of overdose have been reported.

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

No data available.

5.5.8. Safety in other special situations

Not applicable

5.6. Overall conclusions on clinical safety

On the basis of the information on traditional use, comminuted *Fragaria* leaves, are not considered harmful in the specified condition of use.

The traditional use for the relief of symptoms associated with minor urinary tract complaints and for product for the symptomatic treatment of mild diarrhoea is documented for adolescents, adults and elderly. The use in children under 12 years of age has not been established.

The use is contraindicated for patients with hypersensitivity to the active substance.

For Indication 1)

If complaints or symptoms such as fever, dysuria, spasms or blood in urine occur during the use of the medicinal product, a doctor or a qualified health care practitioner should be consulted.

Because adequate fluid intake is required during treatment (see section 4.2. Method of administration), Fragaria vesca L.; Fragaria moschata West.; Fragaria viridis West.; Fragaria x ananassa (West.) Duchesne ex Rozier, folium (wild strawberry leaf) is not recommended for patients with conditions where reduced fluid intake is advised.

For Indication 2)

If recurrent diarrhoea or bloody stools occur, a doctor or a qualified health care practitioner should be consulted.

Safety data in special populations and situations are not available.

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

6. Overall conclusions

Well-established use cannot be accepted for *Fragaria vesca* L., *Fragaria moschata* Weston*, Fragaria viridis* Weston*, Fragaria x ananassa* (Weston) Duchesne ex Rozier, folium, due to the lack of data to recognise efficacy and the absence of medicinal products in the European Union.

The requirements for traditional medicinal use according to Article 16d(1), Article 16f and Article 16h of Directive 2001/83/EC are considered fulfilled. Traditional medicinal use of *Fragaria vesca* L., *Fragaria moschata* Weston*, Fragaria viridis* Weston*, Fragaria x ananassa* (Weston) Duchesne ex Rozier, folium, is documented in several handbooks throughout a period of at least 30 years. The comminuted herbal substance from *Fragaria* can be considered as safe when used in recommended dosages under the conditions specified in the monograph.

The comminuted herbal substance of *Fragaria vesca*, *F. moschata*, *F. viridis* and *Fragaria x ananassa* leaves for use in aqueous preparations (infusions and decoctions) is described in handbooks to increase the amount of urine in adolescents and adults and to treat mild or acute diarrhea in children and adolescents, with relevant information information regarding preparation and posology.

Long-standing traditional medicinal use of the wild strawberry leaves within the European Union for at least 30 years according to Directive 2004/24/EC is considered fulfilled for the comminuted herbal substance and indications:

1) *Traditional herbal medicinal product used for the relief of symptoms associated with minor urinary tract complaints in addition to the general recommendation of a sufficient fluid intake to increase the amount of urine.*

2) Traditional herbal medicinal product for the symptomatic treatment of mild diarrhea.

The use of wild strawberry leaves infusions and decoctions cannot be established for children below 12 years.

Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use during pregnancy and lactation is not recommended. No fertility data are available.

A European Union list entry is not supported due to lack of adequate data on genotoxicity.

Annex

List of references