Filipendulae ulmariae herba
Meadowsweet
Filipendulae ulmariae herba - Meadowsweet

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FOREWORD

It is a great pleasure for me to introduce the online era of ESCOP Monographs. Interest in herbal medicinal products continues to stimulate research on herbal substances and the body of knowledge in this field is steadily growing. ESCOP takes account of this by preparing new monographs and - as the only organisation in the field at the moment - particularly through regular revision of our published monographs. In order to provide readers and authorities with balanced compilations of scientific data as rapidly as possible, ESCOP Monographs will be published online from now on. This contemporary way of publishing adds further momentum to ESCOP’s endeavours in the harmonization of European standards for herbal medicinal products.

The Board of ESCOP wishes to express its sincere gratitude to the members of the Scientific Committee, external experts and supervising editors, and to Peter Bradley, the final editor of every monograph published up to March 2011. All have voluntarily contributed their time and scientific expertise to ensure the high standard of the monographs.

Liselotte Krenn
Chair of the Board of ESCOP

PREFACE

Over the 15 years since ESCOP published its first monographs, initially as loose-leaf documents then as two hardback books, ESCOP Monographs have achieved a reputation for well-researched, comprehensive yet concise summaries of available scientific data pertaining to the efficacy and safety of herbal medicinal products. The Second Edition, published in 2003 with a Supplement in 2009, covered a total of 107 herbal substances.

The monograph texts are prepared in the demanding format of the Summary of Product Characteristics (SPC), a standard document required in every application to market a medicinal product for human use within the European Union and ultimately providing information for prescribers and users of individual products.

As a change in style, literature references are now denoted by the name of the first author and year of publication instead of reference numbers; consequently, citations at the end of a monograph are now in alphabetical order. This is intended to give the reader a little more information and perspective when reading the text.

Detailed work in studying the pertinent scientific literature and compiling draft monographs relies to a large extent on the knowledge, skills and dedication of individual project leaders within ESCOP Scientific Committee, as well as invited experts. After discussion and provisional acceptance by the Committee, draft monographs are appraised by an eminent Board of Supervising Editors and all comments are taken into account before final editing and approval. In this way a wide degree of consensus is achieved, but it is a time-consuming process.

To accelerate the publication of new and revised monographs ESCOP has therefore decided to publish them as an online series only, commencing in 2011. We trust that rapid online access will prove helpful and convenient to all users of ESCOP Monographs.

As always, ESCOP is indebted to the many contributors involved in the preparation of monographs, as well as to those who provide administrative assistance and hospitality to keep the enterprise running smoothly; our grateful thanks to them all.
NOTES FOR THE READER

From 2011 new and revised ESCOP Monographs are published as an online series only. Earlier monographs are available in two books, ESCOP Monographs Second Edition (2003) and the Second Edition Supplement 2009, but are not available online for copyright reasons.

After purchase of a single monograph, the specific items to be downloaded are:

- Front cover
- Title page
- Verso
- Foreword and Preface
- Notes for the Reader
- Abbreviations
- The monograph text
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Information on the member organizations and people involved in ESCOP’s activities can be found on the website (www.escop.com):

- Members of ESCOP
- Board of Supervising Editors
- ESCOP Scientific Committee
- Board of Directors of ESCOP
ABBREVIATIONS used in ESCOP monographs

AA   arachidonic acid
ABTS  2,2’-azino-bis(3-ethylbenzthiazoline-6-sulphonic acid)
ACE  angiotensin converting enzyme
ADP   adenosine diphosphate
ALAT or ALT  alanine aminotransferase (= SGPT or GPT)
ALP  alkaline phosphatase
anti-IgE  anti-immunoglobulin E
ASA   acetylsalicylic acid
ASAT or AST  aspartate aminotransferase (= SGOT or GOT)
ATP   adenosine triphosphate
AUC   area under the concentration-time curve
BMI  body mass index
BPH   benign prostatic hyperplasia
b.w.  body weight
cAMP  cyclic adenosine monophosphate
CI  confidence interval
Cmax  maximum concentration of a substance in serum
CNS   central nervous system
CoA  coenzyme A
COX  cyclooxygenase
CSF  colony stimulating factor
CVI  chronic venous insufficiency
CYP  cytochrome P450
d  day
DER  drug-to-extract ratio
DHT  dihydrotestosterone
DNA  deoxyribonucleic acid
DPPH  diphenylpicrylhydrazyl
DSM  Diagnostic and Statistical Manual of Mental Disorders (American Psychiatric Association)
ECG  electrocardiogram
ED50  effective dose in 50% of cases
EDTA  ethylenediamine tetraacetate
EEG  electroencephalogram
EMA  European Medicines Agency
ENT  ear, nose and throat
ER  oestrogen receptor
ERE  oestrogen-responsive element
FSH  follicle-stimulating hormone
GABA  gamma-aminobutyric acid
Gal  galactose
GFR  glomerular filtration rate
GGTP  gamma-glutamyl transpeptidase
GOT  glutamate oxalacetate transaminase (= SGOT)
GPT  glutamate pyruvate transaminase (= SGPT)
GSH  glutathione (reduced)
GSSG  glutathione (oxidised)
HAMA  Hamilton Anxiety Scale
12-HETE  12-hydroxy-5,8,10,14-eicosatetraenoic acid
HDL  high density lipoprotein
HIV  human immunodeficiency virus
HMPC  Committee on Herbal Medicinal Products (of the EMA)
HPLC  high-performance liquid chromatography
5-HT  5-hydroxytryptamine (= serotonin)
IC50  concentration leading to 50% inhibition
ICD-10  International Statistical Classification of Diseases and Related Health Problems, Tenth Revision
ICH  The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
ICSD  International Classification of Sleep Disorders
IFN  interferon
IL  interleukin
i.m.  intramuscular
iNOS  inducible nitric oxide synthase
INR  International Normalized Ratio, a measure of blood coagulation (clotting) tendency
i.p. intraperitoneal
IPSS International Prostate Symptom Score
i.v. intravenous
kD kiloDalton
KM Index Kuppermann Menopausal Index
kPa kiloPascal
LC-MS liquid chromatography-mass spectrometry
LD the dose lethal to 50% of animals tested
LDH lactate dehydrogenase
LDL low density lipoprotein
LH luteinizing hormone
5-LOX 5-lipoxygenase
LPS lipopolysaccharide
LTB4 leukotriene B4
M molar (concentration)
MAO monoamine oxidase
MBC minimum bactericidal concentration
MDA malondialdehyde
MFC minimum fungicidal concentration
MIC minimum inhibitory concentration
Mr molecular
MRS Menopause Rating Scale
MRSA methicillin-resistant Staphylococcus aureus
MTD maximum tolerated dose
MTT 3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide
MW molecular weight
NBT nitro blue tetrazolium
NF-kB necrosis factor kappa-B
NO nitric oxide
NOS nitric oxide synthase
n.s. not significant
NSAID non-steroidal anti-inflammatory drug
ovx ovariectomy or ovariectomized
ORAC oxygen radical absorbance capacity
PA pyrrolizidine alkaloid
PAF platelet activating factor
PCR polymerase chain reaction
PEG polyethylene glycol
PGE prostaglandin E
PHA phythaemagglutinin
p.o. per os
POMS profile of mood states
PVPP polyvinylpolypyrrolidone
RANKL receptor activator of nuclear factor kappa-B ligand
RNA ribonucleic acid
RT-PCR reverse transcription polymerase chain reaction
s.c. subcutaneous
SCI spinal cord injury
SERM selective oestrogen receptor modulator
SGOT or GOT serum glutamate oxalacetate transaminase (= ASAT or AST)
SGPT or GPT serum glutamate pyruvate transaminase (= ALAT or ALT)
SHBG sex hormone binding globulin
SOD superoxide dismutase
SSRI selective serotonin reuptake inhibitor
STAI state-trait anxiety inventory
t1/2 elimination half-life
TBARS thiobarbituric acid reactive substances
TGF-β transforming growth factor-beta
TNF tumour necrosis factor
TPA 12-O-tetradecanoylphorbol-13-acetate
URT upper respiratory tract
URTI upper respiratory tract infection
UTI urinary tract infection
VAS visual analogue scale
VLDL very low density lipoprotein
FILIPENDULAE ULMARIAE HERBA

Meadowsweet

DEFINITION

Meadowsweet consists of the whole or cut, dried flowering tops of *Filipendula ulmaria* (L.) Maxim. (= *Spiraea ulmaria* L.). It contains not less than 1 mL/kg of essential oil, calculated with reference to the dried drug.

The material complies with the monograph of the European Pharmacopoeia [Meadowsweet].

CONSTITUENTS

Flavonoids, up to 6% in the flowers, particularly spiraeoside (quercetin 4’-glucoside), and approx. 3-4% in the flowering herb, including hyperoside, other quercetin derivatives and kaemperol 4’-glucoside [Hörhammer 1955, 1956; Shelyuto 1977; Scheer 1987; Lamaison 1991, 1992; Poukens-Renwart1992; Fecka 2009].

Glycosides of salicylaldehyde (monotropitin = gaultherin), of methyl salicylate (spiraein) and of salicyl alcohol (isosalicin) (up to 0.5% in total) [Thieme 1965, 1966; Meier 1987a, 1987b, 1993].

Steam distillation of the dried flowers yields a small amount (0.2%) of volatile oil (arising from the phenolic glycosides during drying and storage), of which about 75% is salicylaldehyde [Kozhin 1971; Lindeman 1982; Meier1987b]. Previous findings, however, stated that such compounds are only present in fresh flowers [Piette 1981]; after steam distillation of fresh flowering tops, the proportion of salicylaldehyde in the oil was 36% [Valle 1988].

Ellagitannins (10-15%) derived from galloyl-4,6-hexahydroxydiphenoyl-β-D-glucose units, the major one being the dimeric rugosin D [Gupta 1982; Haslam 1982,1996; Meier 1993; Okuda 1993; Wichtl 1997, 2009; Fecka 2009].

The flowers also contain a heparin-like substance, which is bound to plant proteins in the form of a complex [Kudrjashov 1990, 1992].

CLINICAL PARTICULARS

Therapeutic indications

Filipendula is used as supportive therapy for the common cold [Schilcher 1992; Meier 1993; Wichtl 1997; Zeylstra 1998; Schulz 2001; Wichtl 2009]. Meadowsweet is also used to enhance the renal elimination of water [Dechaux 1941; Leclerc 1976; Valnet 1976; Meier 1993; Wichtl 1997, 2009; Zeylstra 1998], although published scientific evidence does not adequately support this indication.

Posology and method of administration

Dosage

Unless otherwise prescribed, the daily dose as a tea infusion is:

**Adults**: 2-6 g of the drug daily [Mills 2000; Wichtl 2009].
**Children 1-4 years of age**: 1-2 g daily [Dorsch 1998].
**Children 4-10 years of age**: 2-3 g daily [Dorsch 1998].
**Children 10-16 years of age**: adult dose [Dorsch 1998].

Liquid extract (1:2), 3-6 mL daily; tincture (1:5), 7.5-15 mL daily [Mills 2000].

Method of administration

For oral administration.

Duration of administration

No restriction.
Contra-indications
Due to the presence of salicylates, the drug should not be used in cases of hypersensitivity to salicylates [Meier 1993; Wichl 2009].

Special warnings and special precautions for use
None required.

Interaction with other medicaments and other forms of interaction
None reported. The level of salicylate derivatives makes interaction with anticoagulant agents unlikely.

Pregnancy and lactation
No data available. In accordance with general medical practice, the products should not be used during pregnancy and lactation without medical advice.

Effects on ability to drive and use machines
None known.

Undesirable effects
None reported.

Overdose
No toxic effects reported.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

In vitro experiments

Antimicrobial activity
Combined 70%-ethanolic and aqueous extracts (1 mL corresponding to 1 g of herb), tested at 5% in the culture medium, inhibited the growth of Staphylococcus aureus haemolyticus, Streptococcus pyogenes haemolyticus, Escherichia coli, Shigella flexneri, Klebsiella pneumoniae and Bacillus subtilis [Csedö 1993].

A tincture from the flowers (70% ethanol, diluted 1:10 and 1:25) inhibited the growth of Staphylococcus aureus and S. epidermis at both concentrations, and of Proteus vulgaris and Pseudomonas aeruginosa at the higher concentration only. No effect was seen with E. coli or Klebsiella [Hintz 1983].

Dried ethanolic extracts (96% and 40% V/V) showed antimicrobial activity at concentrations from 0.1 – 0.8 mg/mL in Gram-positive bacteria (Staphylococcus aureus and Bacillus subtilis). Higher concentrations were needed to inhibit growth of Gram-negative bacteria (0.6 – 8mg/mL; Salmonella enteritidis and Escherichia coli) and fungi (6 – 48mg/mL; Penicillium expansum and Rhizopus arrhizus). The 40% ethanolic extract contained higher amounts of phenolic compounds and showed better results in the inhibition of tested bacteria and fungi [Gniewosz 2013].

A methanolic extract showed a MIC50 of 0.08% on the Gram negative pathogens Proteus vulgaris and Klebsiella pneumoniae [Denev 2014].

Anti-inflammatory activity
Extracts (50% ethanolic) of meadowsweet flowers and leaves inhibited the activity of the proteolytic enzyme elastase by 100% and 92% respectively, measured by spectrophotometry using an amino acid-nitroanilide substrate and attributed to the tannin content of the materials [Lamaison 1990].

An aqueous, lyophilized extract of meadowsweet leaves inhibited prostaglandin biosynthesis from 14C-arachidonic acid (i.e. inhibited cyclooxygenase) in bovine seminal vesicle microsomes by 36% at 0.2 mg/mL, a relatively low level of activity compared to 88% inhibition by indomethacin at 2.8 μM. The same extract strongly inhibited PAF-induced exocytosis (and hence release of the enzyme elastase) in neutrophils from human peripheral blood by 93% at 0.25 mg/mL [Tunon 1995].

An aqueous extract was incubated with human faeces to convert ellagitanins into urolithins by the gut microflora. Results of inhibition studies in monocyte-derived macrophages showed a significant decrease of TNF-α production. The most potent derivative urolithin A reached an inhibition of 29.2% ±6.2 (p<0.05) at 0.625 μM. Urolithin C significantly decreased Interleukin-6 production by 25.5% ±4 as well as at 10 μM (p<0.001) compared to stimulated but untreated cells [Piwowarski 2014].

In the same series of experiments, meadowsweet dry extracts from flowers and herb prepared with ether, ethyl acetate, methanol or water inhibited luminol-dependent chemiluminescence (an indicator of the production of reactive oxygen species) generated by zymosan-stimulated human polymorphonuclear leukocytes (PMNs) with IC50 values of 66.3 μg/mL, 42.3 μg/mL, 39.8 μg/mL and 37.4 μg/mL respectively for the flower extracts and 81.9 μg/mL, 44.5 μg/mL, 59.5 μg/mL and 60.8 μg/mL respectively for the herb extracts. The extracts also inhibited t-cell proliferation, with IC50 values of 100.4 μg/mL, 173.9 μg/mL and 210.5 μg/mL respectively for ethyl acetate, methanol and aqueous extracts of the flowers, and 195.1 μg/mL, 150.0 μg/mL and 195.2 μg/mL respectively for ether, ethyl acetate and methanolic extracts of the herb [Halkes 1997a].

In vivo

Immunomodulatory activity
Dry extracts from meadowsweet flowers and herb exhibited strong inhibitory activity towards the classical pathway of complement system, ethyl acetate (IC50: 5.4 μg/mL) and methanolic (IC50: 14.6 μg/mL) extracts of the flowers, and the methanolic extract (IC50: 14.5 μg/mL) of the herb, being the most effective. As the ethyl acetate extract of the flowers retained its activity after treatment with skin powder, it was concluded that complement inhibitory activity of this fraction is not attributable to tannins [Halkes 1997a].

Various extracts of meadowsweet flowers were investigated for in vitro modulatory activity towards the classical pathway of complement activation. The highest inhibitory activity was found in the ethyl acetate extract (IC50: 2.9 μg/mL) followed by the ether (IC50: 9.8 μg/mL), light petroleum (IC50: 12.0 μg/mL), methanol (IC50: 12.8 μg/mL) and aqueous (IC50: 33.5 μg/mL) extracts. A purified fraction from the ethyl acetate extract (constituents not identified) also showed strong inhibitory activity (IC50: 0.46 μg/mL), even stronger than that of isolated flavonoids (of which quercetin was the most potent with an IC50 of 16.7 μg/mL) [Halkes 1997b].

A decoction of the flowers enhanced the growth-stimulating activity of mice peritoneal macrophages in vitro and in vivo [Bespalow 1992].
A decoction (1g/200 mL) was investigated for growth inhibition of non-small cell lung cancer (NCI-H460) cells. The antiproliferative potential was measured by reduction of the percentage of bromodeoxyuridine positive cells. The treatment showed an effect on the cell cycle profile by increase of cells in 
G1 proliferation phase. The extract had no effect on programmed cell death but a significant increase of the protein p21 was found ([p<0.05] [Lima 2014].

**Antihistaminic effect**

Four isolated ellagitannins (rugosin A, rugosin D, rugosin A methyl ester and tellimagrandin II) were tested for inhibition of human histidine decarboxylase which catalyses the formation of histamine from histidine. The inhibition constant values (K_i) of the non-competitive reaction ranged from 0.35-1μM, comparable with the potency of the substrate analogue inhibitor histidine methyl ester (K_i 0.46 μM) [Nitta 2013].

**Affinity for proteins**

Isolated rugosin D showed a high capacity for binding to bovine serum albumin (BSA), even higher than penta-O-galloyl-β-D-glucose, the tannin having the highest protein binding capacity in the simple galloyl-D-glucose series [46], whereas 1,2,3-tri-O-gallloyl-4,6-hexahydroxydiphenoyl-β-D-glucose had a weaker effect and 2,3-di-O-galloyl-4,6-hexahydroxydiphenoyl-β-D-glucose a low effect [Beart 1985].

**Antioxidant effect**

A methanolic extract inhibited xanthine oxidase (XO) with an IC_{50} value of 6.2 μg/mL ± 0.6, compared to allopurinol and its main metabolite oxypurinol of 2.6μg/mL ±0.9 and 1.0 μg/mL ±0.2 respectively [Kazazi 2009].

**In vivo experiments**

**Anticoagulant and fibrinolytic effects**

A heparin-like complex found in meadowsweet flowers showed some anticoagulant and fibrinolytic properties after intramuscular and intravenous administration to animals, the effect being neutralized by protamine sulphate [Kudrjashov 1990, 1991].

**Intestinal effects/effects on gastric ulcers**

Orally administered decoctions of meadowsweet flowers (1:10 and 1:20) at doses of 0.5 or 2.5 mL/100 g respectively reduced the formation of stomach lesions induced by fixation, immobilisation or subcutaneous injection of reserpine to rats and mice. The decoctions also prevented acetylsalicylic acid-induced lesions of the stomach and promoted healing of ethanol-induced stomach lesions in rats [Barnaulov 1980].

An ethanolic spissum extract from meadowsweet, administered to mice (50-10000 mg i.p.), rats (2500 mg/kg orally) and rabbits (15-30 mg/kg i.v.) as a 5% aqueous solution and a decoction (1:20), showed a positive effect on the permeability of vessels provoked by histamine in the trypsin blue test system [Barnaulov 1977].

Quercetin-3'-glucoside from meadowsweet, orally administered as a dose of 0.5 mL of a 5% solution per 10 g b.w., reduced by 50% the occurrence of serious lesions of the rat stomach provoked by immobilisation and intraperitoneal injection of reserpine (2.5 mg/kg) [Barnaulov 1984].

**CNS effects**

In various animals, a 5% aqueous solution of an ethanolic spissum extract and a decoction (1:20) from meadowsweet showed suppressive effects on the central nervous system, such as reduction of motor activity and rectal temperature, myorelaxation and potentiation of the activity of narcotic agents, and prolongation of the life time of mice in closed cages [Barnaulov 1977].

**Anticarcinogenic effects**

Long-term oral administration of a decoction of meadowsweet flowers inhibited the growth of brain and spinal cord tumours induced by transplacental administration of N-ethyl-N-nitrosourea in rats. It did not affect the development of cervical and vaginal tumours induced by intravaginal application of 7,12-dimethylbenz[a]anthracene in mice but, when applied intravaginally, the decoction inhibited cervical and vaginal carcinogenesis induced by this compound. Tubal oral administration of the decoction suppressed the growth of transplanted sarcoma-180 as well as the growth and metastasis of transplanted Lewis’ carcinoma in mice [Bespalov 1992].

Local administration of a decoction of meadowsweet flowers resulted in a 39% decrease in the frequency of squamous-cell carcinoma of the cervix and vagina induced in mice by 7,12-dimethylbenz[a]anthracene treatment [Peresun’ko 1993].

Isolated rugosin D was administered as a single i.p. dose of 10 mg/kg b.w. to 6 female mice: 4 days later and at weekly intervals thereafter for 60 days the mice were injected intra-peritoneally with 10^6 sarcoma-180 tumour cells. Antitumour activity was calculated as the percentage increase in life-span, %ILS = 100 × (mean survival days of the treated group - mean survival days of the vehicle control group)/mean survival days of the vehicle control group. The vehicle control group had a mean survival period of 12.9 days. After 10 mg of rugosin D, the %ILS value was 171.5 and one animal showed no tumours on day 60. The authors suggested that the antitumour activity was likely to be through potentiation of the immunity of host animals rather than direct activity on the tumour cells [Miyamoto 1987].

**Clinical studies**

After local application of an ointment containing a decoction of meadowsweet flowers to 48 patients with cervical dysplasia, a positive response was recorded in 32 patients (67%), including 25 cases (52%) of complete regression of dysplasia. No recurrence was observed within 12 months in 10 completely cured patients [Peresun’ko 1993].

**Pharmacokinetic properties**

Ellagitannins are converted into urolithins by decarboxylation of the lactone rings by the gut microflora [Piwowskarski 2014].

**Preclinical safety data**

For an ethanolic spissum extract of meadowsweet as a 5% aqueous solution, the i.p. LD_{50} in mice and i.v. LD_{50} in rabbits were determined as 1770 mg/kg and 75.7 mg/kg respectively. For a decoction (1:20), the i.p. LD_{50} in male and female mice, and the i.v. LD_{50} in rabbits, were found to be 535 mg/kg, 1050 mg/kg and 141.5 mg/kg respectively [Barnaulov 1977].

Pharmacological studies of meadowsweet flowers and their extracts in rats and rabbits did not show any influence on liver function [Barnaulov 1984].

**REFERENCES**

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<td>MENYANTHIDIS TRIFOLIATAE FOLIUM</td>
<td>Bogbean Leaf</td>
<td>Online Series, 2013</td>
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<tr>
<td>MICLEFOLII HERBA</td>
<td>Yarrow</td>
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<td>MYRRHA</td>
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<tr>
<td>MYRTILLI FRUCTUS</td>
<td>Bilberry Fruit</td>
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<tr>
<td>OLIBANUM INDICUM</td>
<td>Indian Frankincense</td>
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<td>ORTHOSIPHONIS FOLIUM</td>
<td>Restharrow Root</td>
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<td>PASSIFLORA HERBA</td>
<td>Java Tea</td>
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<tr>
<td>PELARGONII RADIX</td>
<td>Pelargonium Root</td>
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<tr>
<td>PLANTAGINIS LANCEOLATAE FOLIUM/HERBA</td>
<td>Ribwort Plantain Leaf/Herb</td>
<td>Online Series, 2013</td>
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<tr>
<td>PRUNI AFRICANAE CORTEX</td>
<td>Pygeum Bark</td>
<td>Supplement, 2009</td>
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<td>RATEHANIIAE RADIX</td>
<td>Rhatany Root</td>
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<td>RHAMNI PURSHIANI CORTEX</td>
<td>Cascara</td>
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<tr>
<td>ROSAE PSEUDO-FRUCTUS</td>
<td>Dog Rose Hip</td>
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<td>SAMBUCI FLOS</td>
<td>Elder flower</td>
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<td>SALVIA TRIOLOBAE FOLIUM</td>
<td>Sage Leaf, Three-lobed</td>
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<td>SERPYLLI HERBA</td>
<td>Wild Thyme</td>
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<td>SLYBI MARIANI FRUCTUS</td>
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<td>TANACETI PARTHENII HERBA</td>
<td>Feverfew</td>
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<td>VACCINI Macrocarpi Fructus</td>
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<td>VALERIANAE RADIX</td>
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<td>ZINGIBERIS RHIZOMA</td>
<td>Ginger</td>
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The second edition of ESCOP Monographs, published as a hardback book in 2003 with a Supplement in 2009, has been widely acclaimed for its authoritative information on the therapeutic uses of herbal medicines. Monographs covering a total of 107 herbal substances include extensive summaries of pharmacological, clinical and toxicological data, and copious references to scientific literature form an important part of each text.

Although publication in the form of books was convenient in the past, ESCOP recognizes that online publication now offers a number of advantages, not least in facilitating rapid publication of individual monographs as soon as all stages of preparation have been completed. Commencing from 2011, therefore, new and revised monographs will be published online only.

The European legislative framework for herbal medicines has advanced considerably over the past decade. Directive 2004/24/EC introduced a simplified registration procedure for traditional herbal medicinal products in EU member states and imposed a 2011 deadline for the registration of certain products on the market. The Committee on Herbal Medicinal Products (HMPC), established in 2004 as part of the European Medicines Agency, has made substantial progress in the preparation of Community Herbal Monographs and associated documentation to provide a more harmonized approach to the scientific assessment of herbal medicinal products throughout the European Community.

Whether the evaluation of a herbal medicine is based on evidence of clinical efficacy (well-established use) or on experience and historical use of that product (traditional use) those involved at all levels of the regulatory process need access to detailed, reliable and structured summaries of the available efficacy and safety data. ESCOP monographs meet that requirement and offer an invaluable source of scientific information on herbal medicines to regulators, manufacturers, academics, researchers, health professionals and numerous others.