E/S/C/O/P Monographs

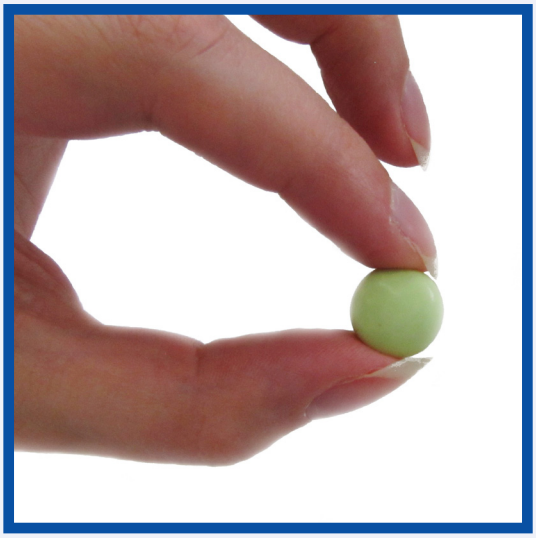
Online Series

The Scientific Foundation for Herbal Medicinal Products

Filipendulae ulmariae herba

Meadowsweet

2015



E/S/C/O/P

European Scientific Cooperative On Phytotherapy

www.escop.com

E/S/C/O/P
MONOGRAPHS

***The* Scientific Foundation for**
Herbal Medicinal Products

FILIPENDULAE ULMARIAE HERBA
Black Cohosh

2015

E/S/C/O/P
EUROPEAN SCIENTIFIC COOPERATIVE
ON PHYTOTHERAPY

ESCOP Monographs were first published in loose-leaf form progressively
from 1996 to 1999 as Fascicules 1-6, each of 10 monographs

Second Edition, completely revised and expanded

Second Edition, Supplement 2009

ONLINE SERIES

ISBN 978-1-901964-37-0

Filipendulae ulmariae herba - Meadowsweet

Published by the European Scientific Cooperative on Phytotherapy (ESCOP)
Notaries House, Chapel Street, Exeter EX1 1EZ, United Kingdom
www.escop.com

Important Note: Medical knowledge is ever-changing. As new research and clinical experience broaden our knowledge, changes in treatment may be required. In their efforts to provide information on the efficacy and safety of herbal drugs and herbal preparations, presented as a substantial overview together with summaries of relevant data, the authors of the material herein have consulted comprehensive sources believed to be reliable. However, in view of the possibility of human error by the authors or publisher of the work herein, or changes in medical knowledge, neither the authors nor the publisher, nor any other party involved in the preparation of this work, warrants that the information contained herein is in every respect accurate or complete, and they are not responsible for any errors or omissions or for results obtained by the use of such information. Readers are advised to check the product information included in the package of each medicinal preparation they intend to use, to be certain that the information contained in this publication is accurate and that changes have not been made in the recommended dose or in the contraindications for administration.

Edited by Simon Mills and Roberta Hutchins
Cover photographs by Ivar Leidus (Own work) [Public domain],
via Wikimedia Commons (*Filipendula ulmaria*) and Martin Willoughby
Cover and text design by Martin Willoughby
Typeset in Optima by Roberta Hutchins

Plant illustrated on the cover: *Filipendula ulmaria*

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
Back cover

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
C_{max}	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
ED_{50}	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)
IC_{50}	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_{50}	the dose lethal to 50% of animals tested
LDH	lactate dehydrogenase
LDL	low density lipoprotein
LH	luteinizing hormone
5-LOX	5-lipoxygenase
LPS	lipopolysaccharide
LTB_4	leukotriene B_4
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-κB	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
$t_{1/2}$	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 2015

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 kaempferol 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 [Decaux 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.

E/S/C/O/P
MONOGRAPHS

Contra-indications
Due to the presence of salicylates, the drug should not be used in cases of hypersensitivity to salicylates [Meier 1993; Wichtl 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 – 6mg/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 MIC_{50} 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 ^{14}C-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 indometacin 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 [Tunòn 1995].

An aqueous extract was incubated with human faeces to convert ellagitannins 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 at 10 µM ($p<0.001$) compared to stimulated but untreated cells [Piwowarski 2014].

An aqueous extract as well as isolated constituents were investigated for their ability to inhibit production of inflammatory biomarkers in monocyte derived macrophages. Apigenin and quercetin significantly reduced the production of TNF-α in the stimulated cells at the highest concentration (50 µM) by 89% ±4 and 84% ±2 and of Interleukin-6 by 97% ±3 and 96% ±1, respectively ($p<0.05$). The extract, containing 3 µM quercetin, reduced production of TNF-α by 34% ±11, IL-1β by 45% and IL-6 by 16% ±11. [Drummond 2013].

Immunomodulatory activity
Dry extracts from meadowsweet flowers and herb exhibited strong inhibitory activity towards the classical pathway of the complement system, ethyl acetate (IC_{50}: 5.4 µg/mL) and methanolic (IC_{50}: 14.6 µg/mL) extracts of the flowers, and the methanolic extract (IC_{50}: 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].

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 IC_{50} 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 IC_{50} 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].

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 (IC^{50}: 2.9 µg/mL), followed by the ether (IC^{50}: 9.8 µg/mL), light petroleum (IC^{50}: 12.0 µg/mL), methanol (IC^{50}: 12.8 µg/mL) and aqueous (IC^{50}: 53.5 µg/mL) extracts. A purified fraction from the ethyl acetate extract (constituents not identified) also showed strong inhibitory activity (IC^{50}: 0.46 µg/mL), even stronger than that of isolated flavonoids (of which quercetin was the most potent with an IC^{50} 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 anti-proliferative 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 tellimagradinin II) were tested for inhibition of human histidine decarboxylase which catalyses the formation of histamine from histidine. The inhibition constant values (Ki) of the non-competitive reaction ranged from 0.35-1µM, comparable with the potency of the substrate analogue inhibitor histidine methyl ester (Ki 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-galloyl-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 (50-1000 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 trypan 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-nitroso-urea 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 intraperitoneally with 10^5 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 [Piwowarski 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

Barnaulov OD, Boldina I, Galushko VV, Karamysina GK, Komkov AV, Limarenka AY et al. Pharmacological properties of galenic preparations from the flowers of *Filipendula ulmaria* (L.) Maxim. Rastit Resur 1979;15:399-407.

Barnaulov OD, Denisenko PP. Antiulcerogenic action of the decoction from flowers of *Filipendula ulmaria* (L.) Maxim. Farmakol Toksikol 1980;43:700-5.

Barnaulov OD, Kumkov AV, Khalikova NA, Kozhina IS, Shukhobodskij BA. Chemical composition and primary assessment of the pharmacological properties of preparations from *Filipendula ulmaria* (L.) Maxim. Rastit Resur 1977;13:661-9 [RUSSIAN].

Barnaulov OD, Manicheva OA, Shelyuto VL, Konopleva MM, Glyzin VI. Effects of flavonoids on the development of experimental gastric dystrophies in mice. Khim Farm Zh 1984;18:935-41 [RUSSIAN].

Beart JE, Lilley TH, Haslam E. Plant polyphenols - secondary metabolism and chemical defence: some observations. Phytochemistry 1985;24:33-8. http://dx.doi.org/10.1016/S0031-9422(00)80802-X

Bespalov VG, Limarenko AY, Voitenkov BL. Anticarcinogenic, antitumour and immunomodulating activities of dropwort *Filipendula ulmaria* flower decoction. Khim Farm Zh 1992;26:59-61, through Chem Abstr 1992;116:227822.

Csedö K, Monea M, Sabau M, Esianu S. The antibiotic activity of *Filipendula ulmaria*. Planta Med 1993;59(Suppl):A675. http://dx.doi.org/10.1055/s-2006-959953

Decaux F. Les propriétés thérapeutiques de la reine de prés (*Spiraea ulmaria* L.). Rev Phytothérapie 1941;25:13-7.

Denev P, Maria Kratchanova, Milan Ciz, Antonin Lojek, Ondrej Vasicek, Denitsa Blazheva, et al. Antioxidant, antimicrobial and neutrophil-modulating activities of herb extracts. Acta Biochim Pol 2014;61(2):359-67.

Dorsch W, Loew D, Meyer E, Schilcher H. Filipendulae ulmariae flos (Mädesüß). In: Kinderdosierungen von Phytopharmaka, 2nd ed. Bonn: Kooperation Phytopharmaka 1998:62-3.

Drummond EM, Harbourne N, Marete E, Martyn D, Jacquier JC, O`Riordan D, Gibney ER. Inhibition of proinflammatory biomarkers in THP1 macrophages by polyphenols derived from chamomile, meadowsweet and willow bark. Phytother Res 2013;27:588-94. http://dx.doi.org/10.1002/ptr.4753

Fecka I. Qualitative and quantitative determination of hydrolysable tannins and other polyphenols n herbal products from meadowsweet and dog rose. Phytochem Anal 2009; 20:177-90. http://dx.doi.org/10.1002/pca.1113

Gniewosz M, Synowiec A, Krasniewska K, Przybyl J, Baczek K, Weglarz Z. The antimicrobial activity of pullulan film incorporated with meadowsweet flower extracts (Filipendulae ulmariae flos) on postharvest quality of apples. Food Control 2014;37: 351–61

Gupta RK, Al-Shafi SMK, Layden K, Haslam E. The metabolism of gallic acid and hexahydroxydiphenic acids in plants. Part 2. Esters of (*S*)-hexahydroxydiphenic acid with D-glucopyranose ($^4C_1$). J Chem Soc Perkin Trans I 1982:2525-34. http://dx.doi.org/10.1039/p19820002525

Halkes SBA, Beukelman CJ, Kroes BH, van den Berg AJJ, Labadie RP, van Dijk H. *In vitro* immunomodulatory activity of *Filipendula ulmaria*. Phytotherapy Res 1997a;11:518-20. http://dx.doi.org/10.1002/(SICI)1099-1573(199711)11:7<518::AID-PTR136>3.0.CO;2-9

Halkes SBA, Beukelman CJ, Kroes BH, van den Berg AJJ, van Dijk H, Labadie RP. A strong complement inhibitor from the flowers of *Filipendula ulmaria* (L.) Maxim. Pharm Pharmacol Lett 1997b;7:79-82.

Haslam E, Lilley TH, Cai Y, Martin R, Magnolato D. Traditional herbal medicines the role of polyphenols. Planta Med 1989;55:1-8. http://dx.doi.org/10.1055/s-2006-961764

Haslam E. Natural polyphenols (vegetable tannins) as drugs: possible modes of action. J Nat Prod 1996;59:205-15. Hintz IC, Hodisan V, Tamas M. Clujul Medical 1983;56:381-4 (cited in [9]). http://dx.doi.org/10.1021/np960040+

Hörhammer L, Hänsel R, Endres W. Über die Flavonglykoside der Gattungen Filipendula und Spiraea. Arch Pharmaz 1956;289/61:133-40. http://dx.doi.org/10.1002/ardp.19562890305

Hörhammer L, Hänsel R, Kriesmair G, Endres W. Zur Kenntnis der Polygonaceenflavone. I. Über ein mittels α-Glykosidasen spaltbares Querzetinarabinosid aus *Polygonum polystachum*. Arch Pharmaz Ber deutsch pharmaz Ges 1955;288/60:419-25.

Kazazi F, Halkes SBA, Quarles van Ufford HC, Beukelmann CJ, Van den Berg AJJ. Inhibition of xanthine oxidase activity by Filipendula species. Planta Med 2009,75:903. http://dx.doi.org/10.1055/s-0029-1234328

Kozhin SA, Sulina YG. Composition of essential oil from *Filipendula ulmaria* inflorescences. Rastit Resur 1971;567 71; through Chem Abstr 1972;76:297.

Kudrjashov BA, Amosova YM, Lyapina LA, Osipova NN, Azieva LD, Lyapin GY, Basanova AV. Heparin from *Filipendula ulmaria* and its properties. Izvest Akad Nauk SSSR, Ser Biol 1991:939-43, through Chem Abstr 1992;116:165953.

Kudrjashov BA, Lyapina LA and Aziyeva LD. Heparin-like anticoagulant content in *Filipendula ulmaria* flowers. Farmakol Toksikol 1990;53(4):39-41.

Lamaison JL, Carnat A, Petitjean-Freytet C. Teneur en tanins et activité inhibitrice de l'élastase chez les Rosaceae. Ann Pharm Fr 1990;48:335-40.

Lamaison JL, Carnat A, Petitjean-Freytet C. Teneurs en principaux flavonoides de lots commerciaux de *Filipendula ulmaria* (L.) Maxim. Plantes Méd Phytothér 1991;25:1-5.

Lamaison JL, Petitjean-Freytet C, Carnat A. Teneurs en principaux flavonoïdes de parties aériennes *Filipendula ulmaria* (L.) Maxim. subsp. *ulmaria* et subsp. *denudata* (J. & C: Presl) Hayek. Pharm Acta Helv 1992;67:218-22.

Leclerc H. Ulmaire. In: Précis de Phytothérapie, 5th ed. Paris: Masson, 1976:55-6.

Lima MJ, Sousab D, Lima RT, Carvalhod AM, Ferreirad I, Vasconcelosa MH. Flower extracts of *Filipendula ulmaria* (L.) Maxim inhibit the proliferation of the NCI-H460 tumour cell line. Industrial Crops and Products 2014;59:149–153.

Lindeman A, Jounela-Eriksson P, Lounasmaa M. The aroma composition of the flower of meadowsweet (*Filipendula ulmaria* (L.) Maxim.). Lebensm Wiss Technol 1982;15:286-9.

McManus JP, Davis KG, Beart JE, Gaffney SH, Lilley TH, Haslam E. Polyphenol interactions. Part 1. Introduction: Some observations on the reversible complexation of polyphenols with proteins and polysaccharides. J Chem Soc Perkin Trans II 1985:1429-38. http://dx.doi.org/10.1039/p29850001429

Meadowsweet - Filipendulae ulmariae herba. European Pharmacopoeia, Council of Europe.

Meier B, Lehmann L, Sticher O, Bettschart A. Salicylate in Arzneipflanzen. Screening-Methoden (HPLC, DC) zum Nachweis. Dtsch Apoth Ztg 1987a;127:2401-7.

Meier B, Meier-Liebi M. Filipendula. In: Hänsel R, Keller K, Rimpler H, Schneider G, editors. Hagers Handbuch der pharmazeutischen Praxis, 5th ed. Volume 5: Drogen E-O. Berlin: Springer-Verlag, 1993:147-56.

Meier B. Analytik, chromatographisches Verhalten und potentielle Wirksamkeit der Inhaltsstoffe salicylathaltiger Arzneipflanzen Mitteleuropas [Habilitationsschrift]. Eidg Techn Hochschule (ETH) Zürich, 1987b:161-9.

Mills S, Bone K. Meadowsweet (*Filipendula ulmaria* L.). In: Principles and Practice of Phytotherapy. Edinburgh-London-New York: Churchill Livingstone, 2000:479-82.

Miyamoto K, Kishi N, Koshiura R, Yoshida T, Hatano T, Okuda T. Relationship between the structures and the antitumor activities of tannins. Chem Pharm Bull 1987;35:814-22. http://dx.doi.org/10.1248/cpb.35.814

Nitta Y, Kikuzaki H, Azuma T, Ye Y, Sakaue M, Higuchi Y et al. Inhibitory activity of *Filipendula ulmaria* constituents on recombinant human histidine decarboxylase. Food Chem 2013;138:1551-6.

Okuda T, Yoshida T, Hatano T. Classification of oligomeric hydrolysable tannins and specificity of their occurrence in plants. Phytochemistry 1993;32:507-21. http://dx.doi.org/10.1016/S0031-9422(00)95129-X

Peresun'ko AP, Bespalov VG, Limarenko AI, Aleksandrov VA. Clinico-experimental study of using plant preparations from the flowers of *Filipendula ulmaria* (L.) Maxim for the treatment of precancerous changes and prevention of uterine cervical cancer. Vopr Onkol 1993;39:291-5 [RUSSIAN].

Piette JL, Lecomte J. Salicyles de la spirée ulmaire et composition du sol. Bull Soc Roy Sci Liège 1981;50:178-84.

Piwowarski JP, Granica S, Zwierzyńska M, Stefańska J, Schopohl P, Melzig MF, Kiss AK. Role of human gut microbiota metabolism in the anti-inflammatory effect of traditionally used ellagitannin-rich plant materials. J Ethnopharmacol 2014;155:801-9. http://dx.doi.org/10.1016/j.jep.2014.06.032

Poukens-Renwart P, Tits M, Wauters J-N, Angenot L. Densitometric evaluation of spiraeoside after derivatization in flowers of *Filipendula ulmaria* (L.) Maxim. J Pharmaceut Biomed Analysis 1992;10:1085-8. http://dx.doi.org/10.1016/0731-7085(91)80125-S

Scheer T, Wichtl M. Zum Vorkommen von Kämpferol-4'-O-β-D-glucopyranosid in *Filipendula ulmaria* und *Allium cepa*. Planta Med 1987;53:573-4. http://dx.doi.org/10.1055/s-2006-962817

Schilcher H. Fiebersenkende Phytopharmaka. In: Phytotherapie in der Kinderheilkunde, 2nd ed. Stuttgart: Wissenschaftliche Verlagsgesellschaft, 1992:40-1.

Schulz V, Hänsel R, Tyler VE. Meadowsweet flowers. In: Rational Phytotherapy - a physicians' guide to herbal medicine, 4th ed. Berlin-Heidelberg-New York: Springer-Verlag, 2001:173-4. http://dx.doi.org/10.1007/978-3-642-98093-0

Shelyuto VL, Glyzin VI, Filipchik VN, Smirnova LP, Ban'kovskii AI. Structure of a flavonoid glycoside from *Filipendula ulmaria*. Khim Prir Soedin 1977;(1):113, through Chem Abstr 1977;87:50194.

Thieme H. Isolierung eines neuen phenolischen Glykosids aus den Blüten von *Filipendula ulmaria* (L.) Maxim. Pharmazie 1966;21:123.

Thieme H. Isolierung und Strukturaufklärung des Spiraeins, eines Phenolglykosids aus den Blüten von *Filipendula ulmaria* (L.) Maxim. Pharmazie 1965;20:113-4.

Tunón H, Olavsdotter C, Bohlin L. Evaluation of anti-inflammatory activity of some Swedish medicinal plants. Inhibition of prostaglandin biosynthesis and PAF-induced exocytosis. J Ethnopharmacol 1995;48:61-76. http://dx.doi.org/10.1016/0378-8741(95)01285-L

Valle MG, Nano GM, Tira S. Das ätherische Öl aus *Filipendula ulmaria*. Planta Med 1988;54:181-2. http://dx.doi.org/10.1055/s-2006-962390

Valnet J. Reine-des-prés. In: Phytothérapie - Traitement des maladies par les plantes. Paris: Editions Maloine, 1976:671-2.

Wichtl M, Loew D. Spiraeae flos - Mädesüßblüten. In: Wichtl M, editor. Teedrogen und Phytopharmaka, 5th ed. Stuttgart: Wissenschaftliche Verlagsgesellschaft, 2009:262-4.

Wichtl M. Monographien-Kommentar: Mädesüßblüten. In: Standardzulassungen für Fertigarzneimittel. Stuttgart: Deutscher Apotheker Verlag, Frankfurt: Govi-Verlag, 1997.

Zeylstra H. *Filipendula ulmaria*. Br J Phytotherapy 5:8-12.

E/S/C/O/P
MONOGRAPHS

MOST RECENT VERSIONS

Title	Common name	Publication
ABSINTHII HERBA	Wormwood	Second Edition, 2003
AGNI CASTI FRUCTUS	Agnus Castus	Second Edition, 2003
AGRIMONIAE HERBA	Agrimony	Supplement 2009
ALCHEMILLAE HERBA	Lady's Mantle	Online Series, 2013
ALLII SATIVI BULBUS	Garlic	Second Edition, 2003
ALOE BARBADENSIS	Barbados Aloes	Online Series, 2014
ALOE CAPENSIS	Cape Aloes	Online Series, 2014
ALTHAEAE RADIX	Marshmallow Root	Second Edition, 2003
ANGELICAE RADIX	Angelica Root	Supplement 2009
ANISI FRUCTUS	Aniseed	Online Series, 2014
ARNICAE FLOS	Arnica Flower	Second Edition, 2003
BALLOTAE NIGRAE HERBA	Black Horehound	Online Series, 2015
BETULAE FOLIUM	Birch Leaf	Online Series, 2015
BOLDI FOLIUM	Boldo Leaf	Second Edition, 2003
CALENDULAE FLOS	Calendula Flower	Second Edition, 2003
CAPSICI FRUCTUS	Capsicum	Supplement 2009
CARVI FRUCTUS	Caraway Fruit	Second Edition, 2003
CARYOPHYLLI AETHEROLEUM	Clove Oil	Online Series, 2014
CENTAURII HERBA	Centaury	Online Series, 2015
CENTELLAE ASIATICAE HERBA	Centella	Supplement 2009
CHELIDONII HERBA	Greater Celandine	Second Edition, 2003
CIMICIFUGAE RHIZOMA	Black Cohosh	Online Series, 2011
CINNAMOMI CORTEX	Cinnamon	Second Edition, 2003
COLAE SEMEN	Cola	Online Series, 2014
CRATAEGI FOLIUM CUM FLORE	Hawthorn Leaf and Flower	Second Edition, 2003
CRATAEGI FRUCTUS	Hawthorn Berries	Supplement 2009
CUCURBITAE SEMEN	Pumpkin Seed	Supplement 2009
CURCUMAE LONGAE RHIZOMA	Turmeric	Second Edition, 2003
CURCUMAE XANTHORRHIZAE RHIZOMA	Javanese Turmeric	Supplement 2009
CYNARAE FOLIUM	Artichoke Leaf	Supplement 2009
ECHINACEAE ANGUSTIFOLIAE RADIX	Narrow-leaved Coneflower Root	Supplement 2009
ECHINACEAE PALLIDAE RADIX	Pale Coneflower Root	Supplement 2009
ECHINACEAE PURPUREAE HERBA	Purple Coneflower Herb	Supplement 2009
ECHINACEAE PURPUREAE RADIX	Purple Coneflower Root	Supplement 2009
ELEUTHEROCOCCI RADIX	Eleutherococcus	Supplement 2009
EUCALYPTI AETHEROLEUM	Eucalyptus Oil	Second Edition, 2003
FILIPENDULAE ULMARIAE HERBA	Meadowsweet	Online Series, 2015
FOENICULI FRUCTUS	Fennel	Second Edition, 2003
FRANGULAE CORTEX	Frangula Bark	Second Edition, 2003
FUMARIAE HERBA	Fumitory	Supplement 2009
GENTIANAE RADIX	Gentian Root	Online Series, 2014
GINKGO FOLIUM	Ginkgo Leaf	Second Edition, 2003
GINSENG RADIX	Ginseng	Second Edition, 2003
GRAMINIS RHIZOMA	Couch Grass Rhizome	Supplement 2009
GRINDELIAE HERBA	Grindelia	Online Series, 2015
HAMAMELIDIS AQUA	Hamamelis Water	Online Series, 2012
HAMAMELIDIS CORTEX	Hamamelis Bark	Online Series, 2012
HAMAMELIDIS FOLIUM	Hamamelis Leaf	Online Series, 2012
HARPAGOPHYTI RADIX	Devil's Claw Root	Supplement 2009
HEDERAE HELICIS FOLIUM	Ivy Leaf	Second Edition, 2003
HIPPOCASTANI SEMEN	Horse-chestnut Seed	Second Edition, 2003
HYDRASTIS RHIZOMA	Goldenseal rhizome	Online Series, 2013
HYPERICI HERBA	St. John's Wort	Second Edition, 2003
JUNIPERI PSEUDO-FRUCTUS	Juniper	Second Edition, 2003
LAVANDULAE FLOS/AETHEROLEUM	Lavender Flower/Oil	Supplement 2009
LICHEN ISLANDICUS	Iceland Moss	Second Edition, 2003
LINI SEMEN	Linseed	Second Edition, 2003

LIQUIRITIAE RADIX	Liquorice Root	Second Edition, 2003
LUPULI FLOS	Hop Strobile	Second Edition, 2003
MALVAE FLOS	Mallow Flower	Supplement 2009
MARRUBII HERBA	White horehound	Online Series, 2013
MATRICARIAE FLOS	Matricaria Flower	Second Edition, 2003
MELALEUCAE AETHEROLEUM	Tea Tree Oil	Supplement 2009
MELILOTI HERBA	Melilot	Second Edition, 2003
MELISSAE FOLIUM	Melissa Leaf	Online Series, 2013
MENTHAE PIPERITAE AETHEROLEUM	Peppermint Oil	Second Edition, 2003
MENTHAE PIPERITAE FOLIUM	Peppermint Leaf	Second Edition, 2003
MENYANTHIDIS TRIFOLIATAE FOLIUM	Bogbean Leaf	Online Series, 2013
MILLEFOLII HERBA	Yarrow	Supplement 2009
MYRRHA	Myrrh	Online Series, 2014
MYRTILLI FRUCTUS	Bilberry Fruit	Online Series, 2014
OLIBANUM INDICUM	Indian Frankincense	Supplement 2009
ONONIDIS RADIX	Restharrow Root	Online Series, 2015
ORTHOSIPHONIS FOLIUM	Java Tea	Online Series, 2014
PASSIFLORAE HERBA	Passion Flower	Second Edition, 2003
PAULLINIAE SEMEN	Guarana Seed	Supplement 2009
PELARGONII RADIX	Pelargonium Root	Online Series, 2015
PIPERIS METHYSTICI RHIZOMA	Kava-Kava	Second Edition, 2003
PLANTAGINIS LANCEOLATAE FOLIUM/HERBA	Ribwort Plantain Leaf/Herb	Online Series, 2013
PLANTAGINIS OVATAE SEMEN	Ispaghula Seed	Second Edition, 2003
PLANTAGINIS OVATAE TESTA	Ispaghula Husk	Second Edition, 2003
POLYGALAE RADIX	Senega Root	Second Edition, 2003
PRIMULAE RADIX	Primula Root	Second Edition, 2003
PRUNI AFRICANAE CORTEX	Pygeum Bark	Supplement 2009
PSYLLII SEMEN	Psyllium Seed	Second Edition, 2003
RATANHIAE RADIX	Rhatany Root	Supplement 2009
RHAMNI PURSHIANI CORTEX	Cascara	Online Series, 2015
RHEI RADIX	Rhubarb	Second Edition, 2003
RIBIS NIGRI FOLIUM	Blackcurrant Leaf	Second Edition, 2003
ROSAE PSEUDO-FRUCTUS	Dog Rose Hip	Supplement 2009
ROSMARINI FOLIUM	Rosemary Leaf	Second Edition, 2003
RUSCI RHIZOMA	Butcher's Broom	Second Edition, 2003
SALICIS CORTEX	Willow Bark	Second Edition, 2003
SAMBUCI FLOS	Elder flower	Online Series, 2013
SALVIAE OFFICINALIS FOLIUM	Sage Leaf	Second Edition, 2003
SALVIA TRILOBAE FOLIUM	Sage Leaf, Three-lobed	Online Series, 2014
SENNAE FOLIUM	Senna Leaf	Second Edition, 2003
SENNAE FRUCTUS ACUTIFOLIAE	Alexandrian Senna Pods	Second Edition, 2003
SENNAE FRUCTUS ANGUSTIFOLIAE	Tinnevelly Senna Pods	Second Edition, 2003
SERENOAE REPENTIS FRUCTUS (SABAL FRUCTUS)	Saw Palmetto Fruit	Second Edition, 2003
SERPYLLI HERBA	Wild Thyme	Online Series, 2014
SOLIDAGINIS VIRGAUREAE HERBA	European Golden Rod	Second Edition, 2003
SILYBI MARIANI FRUCTUS	Milk Thistle Fruit	Supplement 2009
SYMPHYTI RADIX	Comfrey Root	Online Series, 2012
TANACETI PARTHENII HERBA	Feverfew	Online Series, 2014
TARAXACI FOLIUM	Dandelion Leaf	Second Edition, 2003
TARAXACI RADIX	Dandelion Root	Second Edition, 2003
THYMI HERBA	Thyme	Second Edition, 2003
TORMENTILLAE RHIZOMA	Tormentil	Online Series, 2013
TRIGONELLAE FOENUGRAECI SEMEN	Fenugreek	Second Edition, 2003
URTICAE FOLIUM/HERBA	Nettle Leaf/Herb	Second Edition, 2003
URTICAE RADIX	Nettle Root	Online Series, 2015
UVAE URSI FOLIUM	Bearberry Leaf	Online Series, 2012
VACCINII MACROCARPI FRUCTUS	Cranberry	Supplement 2009
VALERIANAE RADIX	Valerian Root	Supplement 2009
VERBASCI FLOS	Mullein Flower	Online Series, 2014
VIOLAE HERBA CUM FLORE	Wild Pansy	Online Series, 2015
VITIS VINIFERAE FOLIUM	Red Vine Leaf	Supplement 2009
ZINGIBERIS RHIZOMA	Ginger	Supplement 2009

E/S/C/O/P Monographs

Online Series

The Scientific Foundation for Herbal Medicinal Products

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.

E/S/C/O/P
European Scientific Cooperative On Phytotherapy

www.escop.com

ISBN 978-1-901964-37-0