

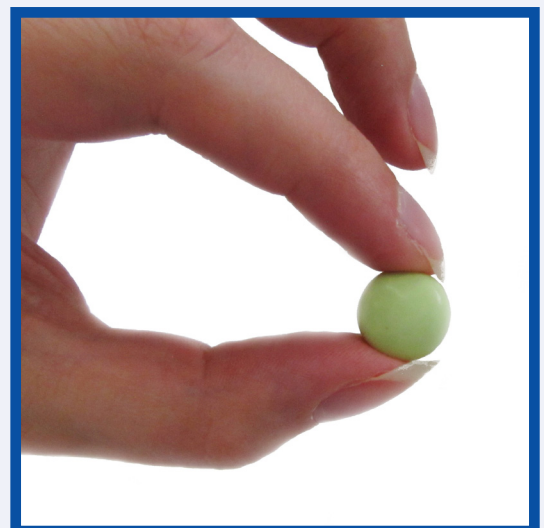
E/S/C/O/P MONOGRAPHS

ONLINE
SERIES

The Scientific Foundation for Herbal Medicinal Products

Menthae piperitae folium Peppermint Leaf

2019



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

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MENTHAE PIPERITAE FOLIUM **Peppermint Leaf**

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Plant illustrated on the cover: *Mentha × piperita*

FOREWORD

It is a great pleasure for me, on behalf of my colleagues in ESCOP, 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.

Dr. Tankred Wegener
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 the production of ESCOP monographs and other 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
CAT	catalase
CCl ₄	carbon tetrachloride
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
DMSO	dimethyl sulfoxide
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.	intra-peritoneal
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 <i>Staphylococcus aureus</i>
MTD	maximum tolerated dose
MTT	3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide
MW	molecular weight
NBT	nitro blue tetrazolium
NF-κB	nuclear factor kappa-B
NO	nitric oxide
NOAEL	no observed adverse effect level
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
PARP	poly (ADP-ribose) polymerase
PBMC	peripheral blood mononuclear cells
PCR	polymerase chain reaction
PEG	polyethylene glycol
PGE	prostaglandin E
Pgp	P-glycoprotein
PHA	phythaemagglutinin
p.o.	per os
POMS	profile of mood states
PVPP	polyvinylpyrrolidone
RANKL	receptor activator of nuclear factor kappa-B ligand
RNA	ribonucleic acid
ROS	reactive oxygen species
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
TC	total cholesterol
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

Peppermint Leaf

DEFINITION

Peppermint leaf consists of the whole or cut dried leaves of *Mentha × piperita* L. The whole drug contains not less than 12 mL/kg of essential oil. The cut drug contains not less than 9 mL/kg of essential oil.

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

Fresh material may also be used, provided that when dried it complies with the monograph of the European Pharmacopoeia.

CONSTITUENTS

The main active component is essential oil (0.5-4%), of which the principal constituent is usually menthol, in the form of (-)-menthol (30.0-55.0%) with smaller amounts of stereoisomers such as (+)-neomenthol (2.5-3.5%) and (+)-isomenthol (approx. 3%), together with menthone (14.0-32.0%), isomenthone (1.5-10.0%), menthyl acetate (2.8-10.0%), 1,8-cineole (3.5-8.0%), limonene (1.0-3.5%), menthofuran (1.0-8.0%), pulegone (max 3.0%) and other monoterpenes. Small amounts of sesquiterpenes, notably β-caryophyllene, germacrene D and viridoflorol [Lawrence 1993; Peppermint Oil; Stahl-Biskup 2011, 2016].

Various flavonoids including luteolin and its 7-glycosides, rutin, hesperidin, eriocitrin and highly oxygenated flavones; phenolic acids such as rosmarinic acid and lithospermic acid and small amounts of triterpenes [Croteau 1973; Hoffmann 1984; Litvinenko 1975; Jullien 1984; Barberan 1986; Duband 1992; Hänsel 2010; Guédon 1994; Fecka 2007].

CLINICAL PARTICULARS

Therapeutic indications

Symptomatic treatment of digestive disorders such as dyspepsia, flatulence and gastritis [Demling 1969; Forster 1980; Forster 1983; Bradley 1992; Hänsel 2010; Stahl-Biskup 2016]. In these indications, the efficacy is plausible on the basis of human experience and long-standing use.

Posology and method of administration

Dosage

Adults: As an infusion, 1.5-3 g of the drug to 150 mL of water, three times daily [Bradley 1992; Stahl-Biskup 2016]. Tincture (1:5, 45% ethanol), 2-3 mL, three times daily [Bradley 1992].

Elderly: Dose as for adults.

Children from 4 years of age, daily dose as infusions only: *4-10 years:* 3-5 g; *10-16 years:* 3-6 g [Dorsch 2002].

Method of administration

For oral administration.

Duration of administration

If symptoms persist or worsen, medical advice should be sought.

Contra-indications

Known hypersensitivity to peppermint or to menthol.

Special warnings and special precautions for use

None required.

Interaction with other medicaments and other forms of interaction

None reported.

Pregnancy and lactation

No data available. In accordance with general medical practice, the product 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

The pharmacological actions of peppermint leaf are largely, but not exclusively, attributable to the essential oil; other components such as flavonoids also appear to play a role [Bradley 1992; Stahl-Biskup 2016]. Pharmacodynamic data relating to the essential oil are given in the monograph on Peppermint Oil.

In vitro experiments

Antispasmodic activity

An extract (ethanol 30%; not further specified) exhibited antispasmodic activity at concentrations of 2.5 and 10.0 mL/L, causing significant and dose-dependent increases in ED₅₀ values for acetylcholine- and histamine-induced contractions of isolated guinea pig ileum (p<0.01 and p<0.0005 respectively for histamine-induced contractions), and a significant decrease in the maximum possible contractility (p<0.05 and p<0.001 respectively for histamine-induced contractions). The effect of the extract at 10.0 mL/L corresponded to that of 1.6 µg/L of atropine [Forster 1980]. A similar peppermint leaf extract inhibited carbachol-induced contractions of isolated guinea pig ileum [Forster 1983].

A total flavonoid fraction from peppermint leaf, dissolved in water so that 1 mL corresponded to about 0.5 g of dried leaf, inhibited barium chloride-induced contractions of isolated guinea pig ileum [Lallement-Guilbert 1970].

Antimicrobial activity

A methanolic extract (not further specified) inhibited growth of *Candida albicans* with a MIC value of 7 µg/mL [Höfling 2010].

A dichloromethane fraction of a methanolic extract (not further specified) showed inhibitory activity against *Giardia lamblia* trophozoites with an IC₅₀ of 0.75 µg/mL after 48 hours of incubation compared to metronidazole with an IC₅₀ of 0.8 µg/mL after 24 hours of incubation. In an adherence inhibition assay the same fraction at a concentration of 1 µg/mL significantly (p<0.01) reduced adherence of trophozoites on coverslips after 48h [Vidal 2007].

Three aqueous extracts (not further specified) significantly (p<0.01) reduced the growth of *Chlamydia pneumoniae* in the range of 51.2-69.5% of rifampicin activity (at a dose of 9 ng/sample). The IC₅₀ values ranged between 98 und 224 µg/mL [Kapp 2013].

Antiviral activity

An aqueous extract (not further specified) exhibited activity against HSV-1 and HSV-2 with IC₅₀ values of 0.041 µg/mL and 0.227 µg/mL respectively, in a plaque reduction assay using RC-37 cells. Plaques were reduced by > 90% for HSV-1 and HSV-2 and > 85% for an acyclovir-resistant strain of HSV-1.

Effects were time-dependent and best results were observed after two hours of incubation prior to the infection. The effective concentrations were far below cytotoxic concentrations (EC₅₀ =107 µg/mL) [Nolkemper 2006].

An infusion (10 g/100 mL) added to HIV-1 virions prior to infection of cells led to a concentration-dependent reduction of HIV-1 virion replication in Sup-T1 T-cells (IC₅₀=0.190 ± 0.124% [1%=1mL stock-solution/100mL culture medium]), C8166 T-cells (IC₅₀=0.026 ± 0.016%) and primary human lymphoid aggregate culture (HLAC) from tonsil tissue (IC₅₀=0.666 ± 0.156%) monitored by p24 ELISA. These concentrations did not affect cell viability. Extracts were active against infection of virions carrying diverse envelopes (X4 and R5 HIV-1), but not against non-enveloped adenovirus. The extract induced an increase of the virion's density [Geuenich 2008].

Other effects

Acetonitrile and methanolic extracts (not further specified) showed radical-scavenging activity in DPPH assay with IC₅₀ values of 0.24 mg/mL and 0.21 mg/mL respectively [Dorman 2009].

A chloroform and an ethyl acetate extract (not further specified) were tested for their cytotoxicity against cervical adenocarcinoma (HeLa), breast adenocarcinoma (MCF-7), T-cell lymphoblast (Jurkat), urinary bladder carcinoma (T24), colon adenocarcinoma (HT-29), pancreatic adenocarcinoma (MIAPaCa-2), normal lung fibroblast (IMR-90), and kidney epithelial (HEK-293) cells using the Annexin-V-FITC/PI assay. Both extracts showed significant increases (p<0.01) in the apoptotic index within all cancer cell lines. No effect was observed in normal IMR-90 and HEK-293 cells [Jain 2011].

In vivo experiments

Choleretic effects

In experiments with cannulated dogs, peppermint tea (0.4 g/kg b.w.) increased the secretion of bile [Steinmetzer 1926]. Flavonoids, as well as the essential oil, contribute to this action [Pasechnik 1966; Pasechnik 1966b; Hänsel 2010].

Mixed flavonoids from peppermint leaf (optimum dose 2 mg/kg) showed choleretic activity in dogs [Pasechnik 1966]. Flavomentin, a flavonoid preparation from peppermint leaf, stimulated bile secretion and the synthesis of bile acids in dogs at doses of 0.5-6 mg/kg (optimum 2 mg/kg) [Pasechnik 1966b].

In experiments with cannulated rats, intravenous injection of a peppermint tea at 0.5 mL/rat or a flavonoid preparation (corresponding to a dose of 3.3 g of peppermint leaf per kg b.w.) proved effective in increasing the amount of bile acids [Lallement-Guilbert 1970].

Anti-ulcerogenic effect

Oral pre-treatment of rats with an ethanolic liquid extract (not further specified) at 2.5-10 mL/kg b.w. dose-dependently protected against oral indometacin-induced gastric ulcers (80% protection at 10 mL/kg); this was confirmed histologically. The extract also had gastric antisecretory and cytoprotective effects; compared to rats treated intraperitoneally with indometacin (10 mg/kg), analysis of the gastric contents of animals pre-treated orally with the extract indicated reduced acid output, an increase in PGE₂ release and a decrease in leukotrienes (all p<0.05 at 2.5 mL/kg) [Khayyal 2001].

Antinociceptive effects

An aqueous extract (not further specified) administered i.p. at doses of 200 mg/kg and 400 mg/kg b.w. to albino mice

significantly ($p < 0.01$) lowered acetic acid-induced abdominal writhing. There was no significant difference between the two doses. In a hot-plate test, the extract at both doses significantly ($p < 0.001$) increased the latency to a response to thermal stimulation compared to controls (20.2% and 17.1% protection respectively) [Taher 2012].

In a similar experiment, a dry extract (ethanol 80%; not further specified) administered orally at 200 mg/kg or 400 mg/kg b.w. to mice significantly reduced acetic acid-induced writhing ($p < 0.01$ and $p < 0.001$ respectively) as well. The response time of mice to thermal stimulation in the hot-plate test also increased significantly 45 and 60 minutes after i.p. administration of the extract at 400 mg/kg ($p < 0.01$ and $p < 0.001$ respectively) [Atta 1998].

Anti-inflammatory activity

A dry extract (ethanol 80%; not further specified) showed anti-inflammatory activity against acute and chronic inflammation in rodents. After oral administration, it reduced xylene-induced ear oedema in mice (acute model) by 49% at 200 mg/kg and 50% at 400 mg/kg b.w. (both $p < 0.05$). After i.p. administration in the cotton pellet granuloma test in rats (chronic model), only the higher dose of 400 mg/kg had a significant inhibitory effect ($p < 0.01$) [Atta 1998].

Sedative effects

A dry aqueous extract (not further specified), administered orally to mice at single doses of 300 or 1000 mg/kg b.w., caused weak sedative effects in several tests: hexobarbital-induced sleep, exploratory behaviour, spontaneous motility and motor coordination. The same extract had a significant diuretic effect in mice at 100 and 300 mg/kg ($p < 0.05$), but not at 1000 mg/kg [Della Loggia 1990].

Effects on blood lipid profile

An aqueous extract (not further specified) at a dose of 250 mg/kg b.w. administered orally to rats with fructose-induced hyperlipidaemia significantly ($p < 0.05$) decreased elevated body weight and levels of glucose, serum cholesterol, triglycerides, VLDL, LDL as well as the atherogenic index and increased the level of serum HDL. The extract also significantly ($p < 0.05$) increased the activity of SOD as well as the concentration of GSH and significantly ($p < 0.05$) decreased lipid peroxidation, as shown by a reduced level of TBARS [Badal 2011].

Antiallergic effects

An extract of leaves and stems previously depleted of essential oils by steam distillation (ethanol 50%; not further specified) reduced experimentally increased histamine release by compound 48/80 from peritoneal mast cells of male Wistar rats with an IC_{50} value of 4.72 $\mu\text{g}/\text{mL}$ (95% confidence interval 2.54 – 7.65 $\mu\text{g}/\text{mL}$). A fraction of the extract, administered orally at doses of 300 and 1000 mg/kg, significantly ($p < 0.01$) decreased sneezing, nasal rubbing and dye leakage induced by an antigen. No significant effect was seen in sneezing and nasal rubbing induced by histamine [Inoue 2001].

Tumour-preventive effects

Male albino mice were divided into 3 groups. The first group ($n=8$) received no treatment; in the second and third groups ($n=36$ each) the mice had the ventral and dorsal surfaces of their tongues painted 3 days a week for 9 weeks with the carcinogens 7,12-dimethylbenz[a]anthracene (DMBA) and formaldehyde (starting on day 9); the third group were additionally treated at the same time with an aqueous extract (not further specified) at an oral dose of 1 g/kg b.w. The extract non-significantly reduced dysplastic cellular changes in the tongue epithelium by 61% and inhibited tumour incidence by 100% as compared to group 2

in histological analysis. Immunohistochemical evaluation after 6 weeks showed significantly ($p \leq 0.001$) reduced expression of caspase 3 in the extract treated group compared to group 2 [Kasem 2014].

Protective effects against irradiation

Adult male Swiss albino mice were treated orally with an aqueous extract (not further specified) at a dose of 1 g/kg b.w. per day for three days and subsequently exposed to whole-body gamma-irradiation (8 Gy). Ten days after irradiation, pretreatment with the extract showed significant increases ($p < 0.001$) in total erythrocyte and leucocyte counts, haemoglobin concentration and haematocrit value compared to irradiation only. Glutathione levels in blood and liver were significantly elevated ($p < 0.005$ and $p < 0.001$ respectively) in the extract + irradiation group in contrast to the irradiation only group [Samarth 2003].

Irradiated mice showed significantly ($p < 0.001$) decreased levels of pronormoblasts and normoblasts of the erythroid series as well as increased levels of leucoblasts and myelocytes compared to normal values, whereas these irradiation-caused changes in blood values were significantly ($p < 0.001$) reduced by pre-treatment with the above-mentioned extract [Samarth 2007].

Under the same conditions, the testicles of extract-pretreated, irradiated mice showed normal testicular morphology with regular arrangement of germ cells and a slight degeneration of seminiferous epithelium. There was a significant decrease in the testicular weight of mice exposed to radiation ($p < 0.001$) compared to the group treated with distilled water only. Extract pre-treatment plus irradiation led to significantly ($p < 0.001$) elevated testicular weight compared to the irradiation only group, 14 days after irradiation. A significant decrease of lipid peroxidation ($p < 0.001$) and of acid phosphatase ($p < 0.01$) and a significant increase of alkaline phosphatase ($p < 0.001$) were also observed in testicular tissue fourteen days after irradiation as compared to irradiated mice without pre-treatment [Samarth 2009].

Swiss albino mice treated orally with an aqueous extract (not further specified) at a dose of 1 g/kg b.w. per day for seven days and subsequently exposed to whole-body gamma-irradiation (6 Gy) showed significantly ($p < 0.05$) reduced expression of p53 and up-regulation of Bcl2, as well as significantly ($p < 0.05$) reduced levels of G2/M and G0/G1-Phase, and a significantly ($p < 0.05$) elevated level of S-phase in CNS cells, compared to an irradiation only group. Concentration of brain DNA, RNA, GSH and SOD significantly ($p < 0.05$) increased in the extract-treated irradiated group in contrast to irradiated mice [Hassan 2013].

Other effects

An aqueous extract (not further specified) was administered orally to albino mice at a dose of 1 g/kg b.w. per day for 10 days prior to sodium arsenite intoxication and continuously for 30 days afterwards. Treatment with the extract significantly ($p < 0.001$) ameliorated the sodium arsenite-induced decrease in body and liver weight after 30 days. The extract significantly ($p < 0.001$) lowered the sodium arsenite-induced enhancement of ALP, acid phosphatase (ACP), SGOT, SGPT and lipid peroxidation. Sodium arsenite-induced declines in LDH activity and GSH level were raised significantly ($p < 0.001$) by the extract [Sharma 2007].

An extract (ethanol 70% (V/V); not further specified) at a dose of 100 mg/kg b.w. per day administered orally for seven weeks to female Balb/c mice previously infected with *Schistosoma mansoni* caused significantly ($p < 0.05$) increased serum levels of IL-10, INF- γ , IgG2a and IgE and a significant ($p < 0.05$) decrease in egg counts in the faeces and intestine, compared to control [Dejani 2014].

Male rabbits were divided into 4 groups (n=6 each) and treated daily for 21 days with either saline (i.m.), gentamicin (80 mg/kg b.w. i.m.), an ethanolic extract (not further specified; 200 mg/kg b.w. p.o.) or the extract and gentamicin together. The significant increases (p<0.05 to p<0.0001) in the levels of serum creatinine, blood urea nitrogen, serum uric acid and urinary protein in the gentamicin group compared to control were significantly (p<0.05 to p<0.0001) decreased in the groups receiving the extract. Creatinine clearance, serum potassium and serum calcium levels were significantly (p<0.05 to p<0.0001) increased in both extract groups compared to the group treated with gentamicin only. Additionally, the extract did not reduce the antimicrobial activity of gentamicin [Ullah 2014].

An aqueous infusion (not further specified) showed antimutagenic activities against hydrogen peroxide in the Somatic Mutation and Recombination Test (SMART) in wings of *Drosophila melanogaster* [Romero-Jimenez 2005].

Pharmacological studies in humans

The carminative action of extracts (not further specified) is due to a reduction in tonus of the oesophageal sphincter, enabling release of entrapped air [Demling 1969].

The metabolic ratio of N-acetyltransferase-2 was significantly (p<0.05) reduced after six days by an aqueous extract (2 g dry leaves/200 mL water; not further specified) administered twice daily to healthy volunteers. The extract had no significant influence on the activity of CYP 1A2, CYP 2A6, xanthine oxidase and UDP-glucuronosyltransferase-1A1 and -1A6 [Begas 2017].

Pharmacokinetic properties

Pharmacokinetic data relating to the essential oil are given in the monograph on Peppermint Oil.

Preclinical safety data

After oral administration of an extract (not further specified) to mice (n=12) as a single dose at 4000 mg/kg b.w., none of the animals died and none showed macroscopic signs of toxicity over a 7-day period of observation [Della Loggia 1990].

An infusion (20 g/L) was provided to male Wistar albino rats (n=12) instead of drinking water for 30 days. Histological analysis of kidney tissue showed tubular epithelial cells with slight hydropic degeneration and epithelial cells with pyknotic nuclei and eosinophilic cytoplasm. Moderate tubular dilatation and enlargements in Bowman capsules were observed [Akdogan 2003].

In the same experimental setup, the infusion caused significantly (p<0.01) decreased plasma testosterone levels, whereas LH and FSH levels significantly (p<0.05) increased. Histological analysis showed changes in germinal epithelium and spermatogenesis arrest. Johnsen testicular biopsy score significantly decreased (p<0.01) [Akdogan 2004a].

In a similar trial, the same infusion caused a significant (p<0.05) decrease in serum iron and ferritin levels and a significant (p<0.01) increase in unsaturated iron-binding capacity [Akdogan 2004b].

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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	Online Series, 2019
ANGELICAE RADIX	Angelica Root	Supplement 2009
ANISI FRUCTUS	Aniseed	Online Series, 2014
ARNICAE FLOS	Arnica Flower	Second Edition, 2003
ARCTII RADIX	Burdock Root	Online Series, 2016
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 AETHEROLEUM	Caraway Oil	Online Series, 2019
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	Online Series, 2019
ECHINACEAE PALLIDAE RADIX	Pale Coneflower Root	Online Series, 2018
ECHINACEAE PURPUREAE HERBA	Purple Coneflower Herb	Supplement 2009
ECHINACEAE PURPUREAE RADIX	Purple Coneflower Root	Supplement 2009
ELEUTHEROCOCCI RADIX	Eleutherococcus	Supplement 2009
EQUISETI HERBA	Equisetum stem	Online Series, 2018
EUCALYPTI AETHEROLEUM	Eucalyptus Oil	Second Edition, 2003
FILIPENDULAE ULMARIAE HERBA	Meadowsweet	Online Series, 2015
FOENICULI AETHEROLEUM	Fennel Oil	Online Series, 2019
FOENICULI FRUCTUS	Fennel Fruit	Online Series, 2019
FRANGULAE CORTEX	Frangula Bark	Online Series, 2017
FUMARIAE HERBA	Fumitory	Online Series, 2018
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	Online Series, 2016
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	Online Series, 2018
JUNIPERI PSEUDO-FRUCTUS	Juniper	Second Edition, 2003

LAVANDULAE FLOS/AETHEROLEUM	Lavender Flower/Oil	Supplement 2009
LEONURI CARDIACAE HERBA	Motherwort	Online Series, 2019
LICHEN ISLANDICUS	Iceland Moss	Second Edition, 2003
LINI SEMEN	Linseed	Online Series, 2017
LIQUIRITIAE RADIX	Liquorice Root	Second Edition, 2003
LUPULI FLOS	Hop Strobile	Second Edition, 2003
MALVAE FLOS	Mallow Flower	Online Series, 2016
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	Online Series, 2019
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	Online Series, 2016
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	Online Series, 2017
RATANHIAE RADIX	Rhatany Root	Online Series, 2017
RHAMNI PURSHIANI CORTEX	Cascara	Online Series, 2015
RHEI RADIX	Rhubarb	Online Series, 2019
RIBIS NIGRI FOLIUM	Blackcurrant Leaf	Online Series, 2017
ROSAE PSEUDO-FRUCTUS	Dog Rose Hip	Supplement 2009
ROSMARINI FOLIUM	Rosemary Leaf	Second Edition, 2003
RUSCI RHIZOMA	Butcher's Broom	Online Series, 2017
SALICIS CORTEX	Willow Bark	Online Series, 2017
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	Tinnevely 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	Online Series, 2018
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
UNCARIAE TOMENTOSAE CORTEX	Cat's Claw Bark	Online Series, 2018
URTICAE FOLIUM/HERBA	Nettle Leaf/Herb	Online Series, 2018
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

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SERIES

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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.

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