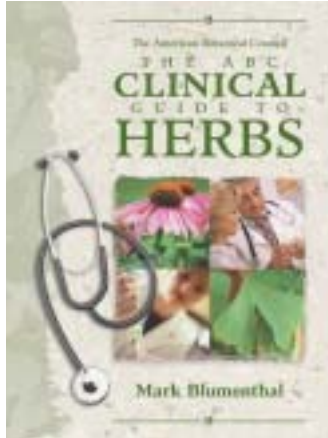


The ABC Clinical Guide to Herbs

HerbalGram is proud to present a sample chapter from the American Botanical Council's latest book, *The ABC Clinical Guide to Herbs*. Each of the 29 in-depth monographs includes an overview, description, clinical uses, dosage, duration of administration, actions, contraindications, side effects, herb-drug interactions, safety ratings, regulatory status, and a detailed chart that reviews the clinical studies conducted to date and brand names of products used in the clinical studies. A separate chapter covers proprietary herbal products that have undergone clinical studies.



The sample here is identical to what is published in *The Guide*, except that *HerbalGram* took the liberty of restoring the color to the photographs. The book itself is printed in black and white.

CE Credit for Healthcare Professionals

The ABC Clinical Guide to Herbs is accredited for Continuing Education credit in the United States for physicians, naturopathic physicians, physician assistants, pharmacists, nurses, and dietitians. This activity has been planned and implemented in accordance with the Essential Areas and Policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of the Texas Medical Association and ABC. The other accredited providers are the Oregon Board

of Naturopathic Examiners, Commission on Dietetic Registration (CDR) of the American Dietetic Association through Southwest Texas University, the American Council on Pharmaceutical Education through the Texas Pharmacy Association, and the American Nurses Credentialing Center's Commission on Accreditation through the Texas Nurses Association. Upon completion of this module, participants should be able to meet the following learning objectives:

1. Identify the 29 most popular medicinal herbs available to consumers in the U.S. market.
2. Explain the common therapeutic indications of the leading herbs.
3. Provide an overview of the clinical study research of the leading herbs.
4. Identify potential drug interactions and side effects.
5. Evaluate the safety issues and contraindications.
6. Interpret product labels for indications of clinical efficacy.
7. Distinguish different types of brands on the marketplace which are backed by clinical research.
8. Understand the implications of government regulations on the clinical use of herbs.

Citation:

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Chamomile, German

Matricaria recutita L. (syn. *Chamomilla recutita* [L.] Rauschert;
M. chamomilla L.; *M. suaveolens* L.)
 [Fam. Asteraceae]

OVERVIEW

Chamomile is one of the most widely used ingredients in herbal teas worldwide. The amount of chamomile imported into the U.S. each year is between 750,000 and one million pounds, with an estimated 90% used in teas. In the U.S. and Europe, chamomile is also a popular ingredient for external use in health and beauty aids. In commerce, chamomile is often called German chamomile or Hungarian chamomile, which should not be confused with the rarer, and more costly, Roman or English chamomile (*Anthemis nobilis* syn. *Chamaemelum nobile*).



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PRIMARY USES

Internal

- Gastrointestinal spasms
- Inflammatory diseases of the gastrointestinal tract
- Indigestion, flatulence, and/or excess gas production, bloating

External

- Inflammatory dermatosis
- Neurodermatitis
- Wound treatment after dermabrasion for tattoo removal
- Ano-genital inflammation (baths and irrigation)

OTHER POTENTIAL USES

- Diarrhea in children
- Common cold symptoms
- Alleviation of mucositis induced by radiation and chemotherapy

PHARMACOLOGICAL ACTIONS

Anti-inflammatory; muscle relaxant; antispasmodic; promotes wound-healing; deodorant; antibacterial and bacteriostatic; stimulates skin metabolism; mild sedative; carminative.

DOSAGE AND

ADMINISTRATION

Internal and External

Caution patients to report any acute complaints that last more than one week, or recur periodically.

Internal

DRIED FLOWER HEADS: 2–4 g, 3 times daily; 5 g single dose.

INFUSION: The German Commission E dosage: 150 ml boiling water poured over approximately 3 g dried flower and steeped, covered, for 5–10 minutes, 3–4 times daily between meals for gastrointestinal complaints. The official Swiss tea infusion dosage for the same indication is 900 mg, 3–5 times daily.

FLUID EXTRACT: 1:1 (*g/ml*), 38–53% ethanol (*v/v*), containing minimum 0.3% (*m/m*) blue volatile oil, 1–4 ml, 3 times daily.

TINCTURE: 1:5 (*g/ml*), 45% ethanol, 3–10 ml, 3 times daily. The Kamillosan® Konzentrat product has an approximately 1:4.0–4.5 (*w/v*) ratio in 42.8% ethanol; each 100 ml contains 150–300 mg essential oil, 150–300 mg apigenin-7-glucoside, and 50 mg (-)- α -bisabolol. Adults: 5 ml in 100 ml warm water, 4 times daily. Children: 2.5 ml, 4 times daily.

External

BATH ADDITIVE: 50 g dried flower added to 10 liters (about 2.5 gallons) water, as a bath for ano-genital inflammation.

GARGLE: 100 ml boiling water poured over 3–10 g dried flower and steeped, covered, for 5–10 minutes. The tea infusion used as a wash or gargle for inflammation of the mucous membranes of the mouth and throat. Or, 5 ml tincture poured into 100 ml warm water and gargled 3 or more times daily.

INHALATION: 100 ml boiling water poured over 3–10 g dried flower and steeped, covered, for 5–10 minutes. Or, 15 ml tincture poured into 0.5 liter boiled water, 1–3 times daily. Steam vapor inhaled for inflammation of the upper respiratory tract.

POULTICE: Semisolid paste or plaster containing 3–10% (*m/m*) of flower heads.

RINSE: Hot aqueous rinse containing 3–10% infusion.

NOTE: Do not apply the infusion near the eyes.

CONTRAINDICATIONS

Known hypersensitivity to plants of the *Asteraceae* (*Compositae*) family such as arnica flower (*Arnica* spp.), chamomile flower (*Matricaria* spp.), marigold flower (*Calendula officinalis*), and yarrow flower (*Achillea* spp.); ragweed (*Ambrosia* spp.); asters (*Aster tataricus*); and chrysanthemums (*Chrysanthemum* spp.).

PREGNANCY AND LACTATION: No known restrictions.

ADVERSE EFFECTS

Minor side effects have been recorded. In rare cases, a contact allergy may occur. Washing the eyes with chamomile tea may cause allergic conjunctivitis in rare cases. The highly concentrated hot tea has been reported to act as an emetic. The unprocessed, crude flower is free from any toxic effects. Rarely, anaphylactic reactions can occur. Case reports have documented contact dermatitis and urticaria as well as one fatal anaphylaxis after a chamomile-containing enema was given during labor.

DRUG INTERACTIONS

No known interactions. Fluid extract may prevent ethyl alcohol-induced ulcer formation. Potential interactions with warfarin have been cautioned.

CLINICAL REVIEW

Of 10 clinical studies on German chamomile extract (8,668 total participants), all but 1 demonstrated positive effects for indications including dermatological, neurological, and respiratory conditions. Three studies focused on the use of chamomile as a mouthwash for stomatitis and for its astringent and cooling effects. One stomatitis study did not notice significant improvement. Dermatological studies included a controlled, bilateral, comparative study investigating a chamomile cream against inflammatory dermatoses, and a double-blind (DB) study on use of a chamomile extract to promote wound-healing after dermabrasion. Other studies demonstrating positive results included inhalation of the steam vapor of chamomile extract to treat respiratory tract conditions related to the common cold, inhalation of the volatile oil to determine the effect of olfactory stimulation on mood, and oral ingestion of the aqueous infusion to investigate cardiac effects after ventricular catheterization. In a study of 8,058 mothers in childbirth conducted over a period of eight years, two essential oils, clary sage (*Salvia sclarea*) and chamomile, were shown to be effective in alleviating pain during labor. A recent DB, placebo-controlled study investigated the use of a chamomile fluid extract and apple pectin combination product for treating young children with acute, non-complicated diarrhea.



Chamomile, German

Matricaria recutita L. (syn. *Chamomilla recutita* [L.] Rauschert; *M. chamomilla* L.; *M. suaveolens* L.)
[Fam. Asteraceae]

OVERVIEW

In the U.S., chamomile is one of the most widely used herbal ingredients in teas as well as in cosmetic, health, and beauty aid products. The amount of chamomile imported into the U.S. each year is between 750,000 and one million pounds, with an estimated 90% used in teas. In commerce, chamomile is often called German chamomile or Hungarian chamomile, which should not be confused with the rare, and more costly, Roman or English chamomile (*Anthemis nobilis* syn. *Chamaemelum nobile*).

USES

Internal

Indigestion; flatulence (gas); bloating; gastrointestinal spasms; inflammatory diseases of the gastrointestinal tract.

External

Inflammatory skin conditions; scaly patches of skin resulting from an itch that is irritated when scratched; wound treatment after dermabrasion for tattoo removal; inflamed anal and genital areas (baths and irrigation).

DOSAGE

For acute complaints that last more than one week, or recur periodically, consult your healthcare provider.

Internal

FLUID EXTRACT: 1–4 ml, 3 times daily.

TINCTURE: Adults: 5 ml in 100 ml warm water, 4 times daily. Children: 2.5 ml, 4 times daily.

External

BATH ADDITIVE: Add 50 g dried flower per 10 liters (approximately 2.5 gallons) water. Bathe in the infusion for ano-genital inflammation.

GARGLE: Pour 100 ml boiling water over 3–10 g dried flower and steep, covered, for 5–10 minutes. Use the tea infusion as a wash or gargle for inflammation of the mucous membranes of the mouth and throat, or pour 5 ml tincture into 100 ml warm water, and gargle 3 or more times daily.

INHALATION: Pour 100 ml boiling water over 3–10 g dried flower and steep, covered, for 5–10 minutes, or pour 15 ml tincture into approximately 2 cups boiled water, 1–3 times daily. Inhale steam vapor for inflammation of the upper respiratory tract.

Comments

When using a dietary supplement, purchase it from a reliable source. For best results, use the same brand of product throughout the period of use. As with all medications and dietary supplements, please inform your healthcare provider of all herbs and medications you are taking. Interactions may occur between medications and herbs or even among different herbs when taken at the same time. Treat your herbal supplement with care by taking it as directed, storing it as advised on the label, and keeping it out of the reach of children and pets. Consult your healthcare provider with any questions.



Illustration © 2003 Peggy Duke

CONTRAINDICATIONS

Individuals allergic to plants in the same family (including arnica, marigold, yarrow, chrysanthemum, and ragweed, for example) may experience a similar reaction to chamomile.

PREGNANCY AND LACTATION: There are no known restrictions for usage during pregnancy or while breast-feeding.

ADVERSE EFFECTS

Rare cases of allergic reactions to chamomile used as an eyewash have been reported. A fatal, possibly allergic, reaction occurred during labor after a chamomile enema was used. Highly concentrated hot tea may cause vomiting. Other adverse effects include dermatitis and urticaria.

DRUG INTERACTIONS

The fluid extract may prevent ulcers caused by alcohol consumption. Potential interactions with the anticoagulating drug warfarin have been speculated.



The information contained on this sheet has been excerpted from *The ABC Clinical Guide to Herbs* © 2003 by the American Botanical Council (ABC). ABC is an independent member-based educational organization focusing on the medicinal use of herbs. For more detailed information about this herb please consult the healthcare provider who gave you this sheet. To order *The ABC Clinical Guide to Herbs* or become a member of ABC, visit their website at www.herbalgram.org.

Chamomile, German

Matricaria recutita L. (syn. *Chamomilla recutita* [L.] Rauschert;
M. chamomilla L.; *M. suaveolens* L.)
[Fam. *Asteraceae*]

OVERVIEW

Chamomile is one of the most widely used ingredients in herbal teas worldwide. The amount of chamomile imported into the U.S. each year is between 750,000 and one million pounds, with an estimated 90% used in teas (Keating, 2001). In the U.S. and Europe, chamomile is also a popular ingredient for external use in health and beauty aids. In commerce, chamomile is often called German chamomile or Hungarian chamomile, which should not be confused with the rarer, and more costly, Roman or English chamomile (*Anthemis nobilis* syn. *Chamaemelum nobile*).



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DESCRIPTION

Chamomile preparations consist of the fresh or dried flower heads of *Matricaria recutita* L. (syn. *Chamomilla recutita* [L.] Rauschert; *M. chamomilla* L.; *M. suaveolens* L.) [Fam. *Asteraceae*]. Pharmacopeial grade chamomile must contain no less than 0.4% of blue volatile oil, and no less than 0.3% of apigenin-7-glucoside (USP, 2002). Pharmacopeial grade chamomile fluid extract contains not less than 0.3% of blue residual oil with an ethanol content of 38%–53% (v/v) (Ph.Eur., 2001).

PRIMARY USES

Internal

- Gastrointestinal spasms, inflammatory diseases of the gastrointestinal tract (Morant and Ruppner, 2001; Blumenthal *et al.*, 1998; Bradley, 1992; Braun *et al.*, 1996)
- Indigestion, flatulence and/or excess gas production, bloating (Health Canada, 1996)

External

Dermatology

- Inflammatory dermatosis and neurodermatitis (Aertgeerts *et al.*, 1985)
- Wound treatment after dermabrasion for tattoo removal (Glowania *et al.*, 1987)
- Ano-genital inflammation (baths and irrigation) (Blumenthal *et al.*, 1998; Braun *et al.*, 1996)

OTHER POTENTIAL USES

- Diarrhea in children (de la Motte *et al.*, 1997)
- Common cold symptoms (Saller *et al.*, 1990)

Oncology

- Alleviation of radiation and chemotherapy induced mucositis (Carl and Emrich, 1991)

DOSAGE

Internal

Crude Preparations

DRIED FLOWER HEADS: 2–4 g, 3 times daily (Bradley, 1992), 5 g single dose (CCRUM, 1992).

INFUSION: The German Commission E dosage is 150 ml boiling water poured over approximately 3 g dried flower and steeped, covered, for 5–10 minutes, 3–4 times daily between meals for gastrointestinal complaints (Blumenthal *et al.*, 1998; Braun *et al.*, 1996). The official Swiss tea infusion dosage for the same indication is 900 mg, 3–5 times daily (Morant and Ruppner, 2001).

FLUID EXTRACT: 1:1 (g/ml), 38–53% ethanol (v/v), containing minimum 0.3% (w/w) blue volatile oil, 1–4 ml, 3 times daily (Bradley, 1992).

TINCTURE: 1:5 (g/ml), 45% ethanol, 3–10 ml, 3 times daily (Bradley, 1992).

TINCTURE: 1:4.0–4.5 (w/v) ratio in 42.8% ethanol. Adults: 5 ml in 100 ml warm water, 4 times daily. Children: 2.5 ml, 4 times daily (Asta Medica, 1998; Gelbe Liste Pharmindex, 2000).

External

Crude Preparations

BATH ADDITIVE: 50g dried flower added per 10 liters (ca. 2.5 gallons) water as a bath for ano-genital inflammation (Blumenthal *et al.*, 1998; Braun *et al.*, 1996).

GARGLE: 100 ml boiling water poured over 3–10 g dried flower and steeped, covered, for 5–10 minutes (Braun *et al.*, 1996). The tea infusion is used as a wash or gargle for inflammation of the mucous membranes of the mouth and throat (Blumenthal *et al.*, 1998; Braun *et al.*, 1996). Or 5 ml tincture poured into 100 ml warm water and gargled 3 or more times daily (Asta Medica, 1998).

INHALATION: 100 ml boiling water poured over 3–10 g dried

flower and steeped, covered, for 5–10 min. (Braun *et al.*, 1996). Or 15 ml tincture poured into 0.5 liter boiled water, 1–3 times daily (Asta Medica, 1998). Steam vapor inhaled for inflammation of the upper respiratory tract.

POULTICE: Semisolid paste or plaster containing 3–10% (*m/m*) of flower heads (Blumenthal *et al.*, 1998).

RINSE: Hot aqueous rinse containing 3–10% infusion (Blumenthal *et al.*, 1998).

NOTE: Do not apply infusion near eyes (Braun *et al.*, 1996).

DURATION OF ADMINISTRATION

Internal and external

For acute complaints that last more than one week, or recur periodically, consult a healthcare provider (Braun *et al.*, 1996).

CHEMISTRY

Chamomile contains from 6–8% flavonoids (Hänsel *et al.*, 1999; Bruneton, 1999; Dölle *et al.*, 1985), composed of flavone glycosides including apigenin 7-glucoside and its 6'-acetylated derivative and flavonols including luteolin glucosides, quercetin glycosides, and isorhamnetin (Bruneton, 1999); up to 10% mucilage polysaccharides (Carle and Isaac, 1985; Meyer-Buchtela, 1999); 0.4–2.0% volatile oil, composed of bisabolane sesquiterpenes (up to 50%) and chamazulene (1–15%); sesquiterpene lactones (matricin and matricarin) (Bruneton, 1999; Carle and Isaac, 1985); and up to 0.3% choline (Schilcher, 1987).

PHARMACOLOGICAL ACTIONS

According to the German Commission E, chamomile is anti-inflammatory; muscle relaxant; antispasmodic; promotes wound-healing; deodorant; antibacterial; bacteriostatic; stimulates skin metabolism (Blumenthal *et al.*, 1998).

Internal

Human

Sedative (Bradley, 1992; Gould *et al.*, 1973; Mann and Staba, 1986); carminative (CCRUM, 1992).

Animal

Inhibits ulceration (Szelenyi *et al.*, 1979); relaxes smooth muscle (Carle and Gomaa, 1991,92); depresses central nervous system (CNS) (Della Loggia *et al.*, 1982). Apigenin binds to central benzodiazepine receptors, producing anxiolytic effects in mice but without any sedative or myorelaxant effects (Viola *et al.*, 1995). A subsequent study reports, in contrast, that apigenin has sedative action without anxiolytic and/or myorelaxant effect. The study links the sedative action of chamomile extracts not to an activation of GABA_A receptors by apigenin, but to other compounds with benzodiazepine-like activity (Avallone *et al.*, 2000).

In vitro

Antipeptic (reduces proteolytic activity of pepsin by 50%) (Thierner *et al.*, 1972; Isaac and Thierner, 1975); prevents and relieves inflammation (Ammon and Sabieraj, 1996).

External

Human

Anti-inflammatory (Aertgeerts *et al.*, 1985); astringent; cooling (Nasemann, 1975); promotes wound-healing (Glowania *et al.*, 1987).

Animal

Anti-inflammatory (Carle and Gomaa, 1991,92; Tubaro *et al.*, 1984; WHO, 1999).

MECHANISM OF ACTION

- Whole plant extracts of chamomile have demonstrated antispasmodic action, though the mechanism of action was unclear (Forster *et al.*, 1980). Antispasmodic effects are due mainly to chamomile's water-soluble constituents (Carle and Gomaa, 1991,92) such as the flavonoids apigenin and apigenin-7-O-glucoside and the volatile oil (–)- α -bisabolol, which act similarly to papaverine (Bruneton, 1999; WHO, 1999).
- Sedative effects are attributed to the flavonoids, including apigenin, which acts as a ligand for the central benzodiazepine receptors. Apigenin competitively inhibits the binding of flunitrazepam, thus providing a molecular basis for possible weak CNS-depressing activity of water-based preparations (e.g., teas) (Viola *et al.*, 1995).
- Apigenin may be an anti-inflammatory constituent (Hadley and Petry, 1999), due to the water-soluble and lipophilic components. The flavones block the arachidonic acid pathway by inhibiting phospholipase A, cyclo-oxygenase, and lipoxygenase pathways. The volatile oil components, chamazulene and α -bisabolol, have also demonstrated anti-inflammatory action by interfering with 5-lipoxygenase and cyclo-oxygenase production (Carle and Gomaa, 1991,92).
- The azulene components of the volatile oil have anti-allergenic and anti-inflammatory actions, though the mechanism of action was unclear (Farnsworth and Morgan, 1972).
- Azulene may prevent histamine discharge from tissue by activating the pituitary-adrenal system, causing the release of cortisone (Stern and Milin, 1956); or azulene may prevent allergic seizures caused by histamine release, activating cellular resistance and speeding the process of healing (Meer and Meer, 1960).
- Chamomile extract accelerates wound-healing, reportedly by reducing inflammation and promoting tissue granulation and regeneration on topical application (Carle and Isaac, 1987).

CONTRAINDICATIONS

Known hypersensitivity to plants of the *Asteraceae* (*Compositae*) family such as arnica flower (*Arnica* spp.), chamomile flower (*Matricaria* spp.), marigold flower (*Calendula officinalis* L.), and yarrow flower (*Achillea* spp.) (Braun *et al.*, 1996); ragweed (*Ambrosia* spp.); asters (*Aster tataricus* L. f.); and chrysanthemums (*Chrysanthemum* spp.) (WHO, 1999).

PREGNANCY AND LACTATION: No known restrictions in pregnancy or lactation (De Smet *et al.*, 1992; McGuffin *et al.*, 1997). No adverse teratogenic effects have been reported *in vivo* (WHO, 1999).

ADVERSE EFFECTS

Minor side effects are recorded by several references (McGuffin *et al.*, 1997). There is empirical evidence of extremely rare contact allergy (Bradley, 1992; Brinker, 2001). Eye washing

with chamomile tea may induce allergic conjunctivitis in rare cases (Subiza *et al.*, 1990). Highly concentrated hot tea has been reported to act as an emetic (Chadha, 1952–1988). The unprocessed crude flower is free from any toxic effects (CCRUM, 1992). Case reports describing contact dermatitis and urticaria have been documented (Foti *et al.*, 2000; Giordano-Labadie, 2000; Rodriguez-Serna *et al.*, 1998; Pereira, 1997; McGeorge and Steele, 1991; van Ketel, 1982). A case report regarding a fatal outcome of anaphylaxis when a chamomile-containing enema was given during labor has been documented (Jensen-Jarolim *et al.*, 1998). Rarely, anaphylactic reactions can occur (Casterline, 1980; Subiza *et al.*, 1989).

There have been several reports in the literature of suspected anaphylaxis associated with the use of chamomile. One authoritative source, reviewing the available literature from over almost 100 years, concluded, “This rather remote possibility may have been greatly overemphasized in the nonmedical literature. Only five cases of allergy specifically attributed to German chamomile were identified worldwide between 1887 and 1982; however, a recent report indicates that a German chamomile ether extract used in allergic patch testing from 1985 to 1990 in 3,851 tested individuals produced an allergic reaction in sixty-six patients or 1.7%.” (Robbers and Tyler, 1999). One of the reports receiving widespread attention in the medical press was based on a misinterpretation of the taxonomic identity of the so-called “chamomile” (Anon., 1979). This article warned readers to avoid teas made from the Composite family, including chamomile, goldenrod (*Solidago virgaurea*), marigold, and yarrow. The article cited a paper titled “Anaphylactic reaction to chamomile tea” (Benner and Lee, 1973), which does not specify the genus or species of the purported chamomile material implicated in the single case described, a 35-year old woman who suffered from ragweed hay fever and who developed anaphylaxis following ingestion of one cup of the purported “chamomile tea” (Awang, 1990). The incident was incorrectly inferred to be the popular German or Hungarian chamomile (*M. recutita*). The actual case was based on ingestion of dog fennel (*Anthemis cotula*), a plant not widely used in commercial products, and generally unavailable in the U.S. Dog fennel is a member of the genus *Anthemis*, the same as Roman or English chamomile (*A. nobilis*, syn. *Chamaemelum nobile*) — hence the erroneous appellation “chamomile” by the authors of the case reports (Lewis, 1992). Dog fennel contains a higher level of anthecotulid, a sesquiterpene lactone that has demonstrated activity in primary irritant contact dermatitis (Hausen *et al.*, 1984).

However, there have been some recent reports of anaphylaxis to German chamomile (*M. recutita*). In one study, 10 out of 14 patients with a history of allergy to chamomile, spices, or “weeds” tested positive to chamomile in a skin prick/RAST test (Reider *et al.*, 2000). Curiously, chamazulene in German chamomile has anti-allergenic and anti-inflammatory activity, and another constituent, an EN-IN-dicycloether, has demonstrated anti-inflammatory, anti-anaphylactic, spasmolytic, and bacteriostatic activity (Farnsworth and Morgan, 1972).

DRUG INTERACTIONS

According to the German Commission E, no interactions are known (Blumenthal *et al.*, 1998). The fluid extract may prevent ethyl alcohol-induced ulcer formation (Brinker, 2001). *In vitro* studies of the inhibitory effect of ethanolic herbal extracts and tinctures on the cytochrome P450 3A4 (CYP3A4) system

revealed a median inhibitory concentration (IC50) of a chamomile extract ranging from 1–2%. This might have implications for predicting the likelihood of potential herb-drug interactions (Budzinski *et al.*, 2000), although such reactions have not been reported. Potential interactions with warfarin have been reported, and caution regarding their concomitant use has been suggested (Heck *et al.*, 2000), although this remains speculative.

AMERICAN HERBAL PRODUCTS ASSOCIATION (AHPA) SAFETY RATING

CLASS 1: Herbs that can be safely consumed when used appropriately (McGuffin *et al.*, 1997).

REGULATORY STATUS

AUSTRIA: Official in the *Austrian Pharmacopoeia* (ÖAB) (Wichtl, 1997).

BELGIUM: Herbal medicine for oral or external use for specific indication (Bradley, 1992; Van Hellemont, 1986; WHO, 1998).

CANADA: Permitted as a Traditional Herbal Medicine (THM) or homeopathic drug for oral use. Requires premarket authorization and assignment of a Drug Identification Number (DIN) if labeled as a THM or homeopathic drug (Health Canada, 1996). Food, if no claim statement is made.

COUNCIL OF EUROPE: Dried flower, essential oil and fluid extract official in *European Pharmacopoeia*, 3rd edition (Ph.Eur., 2001).

FRANCE: Traditional Herbal Medicine (THM) for oral and external use for specific indications (Bradley, 1992; Bruneton, 1999). Official in the *French Pharmacopoeia*, 10th edition (Ph.Fr.X) (WHO, 1999).

GERMANY: Approved nonprescription drug of the German Commission E for oral and external use (Blumenthal *et al.*, 1998). Tea infusion form is an approved nonprescription drug in the *German Standard License* monographs (Braun *et al.*, 1996). The alcoholic fluid extract and the volatile oil forms are official in the *German Pharmacopoeia* (DAB, 1999).

INDIA: Licensed single drug in Unani system of medicine (CCRUM, 1992). Also listed in compound formulations official in the *National Formulary of Unani Medicine* (NFUM I) with standards approved by the Unani Pharmacopoeia Committee (UPC) (NFUM, 1983).

ITALY: Listed in the *Italian Pharmacopoeia* (Newall *et al.*, 1996).

RUSSIAN FEDERATION: Official in the USSR X (Bradley, 1992; Newall *et al.*, 1996).

SWEDEN: Natural remedy for self-medication. Requires marketing authorization by the Medical Products Agency (WHO, 1998).

SWITZERLAND: Official in the *Swiss Pharmacopoeia* (Ph.Helv.) (Wichtl, 1997). Creams, fluid extracts, powders, sprays, and tea infusions are Category D non-prescription drugs with sale limited to pharmacies and drugstores (Morant and Ruppanner, 2001; Asta Medica, 2000; WHO, 1998).

U.K.: Herbal medicine specified in the *General Sale List*, Schedule 1 (medicinal products requiring a full product license), Table A (internal or external use) (GSL, 1990).

U.S.: Generally recognized as safe (GRAS) (US FDA, 1998). Food or dietary supplement, depending on the claim statement (USC, 1994). Listed in the Official Monographs of the U.S.

National Formulary, 19th edition (USP, 2002). Tincture of the whole flower plant, 1:10 (*w/v*) in 45% alcohol (*v/v*), is a Class C over-the-counter (OTC) drug of the *Homeopathic Pharmacopoeia of the United States* (HPUS, 1990).

CLINICAL REVIEW

Ten studies are outlined in the following table, "Clinical Studies on German Chamomile," including a total of 8,668 participants. All but one of the studies (Fidler *et al.*, 1996) demonstrated positive effects for indications including dermatological, neurological, and respiratory conditions. Three studies (Fidler *et al.*, 1996; Carl and Emrich, 1991; Nasemann, 1975) focused on the use of chamomile as a mouthwash for its astringent and cooling effects, stomatitis, and mucositis (Fidler *et al.*, 1996; Carl and Emrich, 1991; Nasemann, 1975). One stomatitis study did not notice significant improvement (Fidler *et al.*, 1996). Other dermatological studies included one controlled, bilateral, comparative study investigating a chamomile cream against inflammatory dermatoses (Aertgeerts *et al.*, 1985), and a DB study on using a chamomile extract to promote wound-healing after dermabrasion (Glowania *et al.*, 1987). Other studies demonstrating positive results included inhalation of the steam vapor of chamomile extract to treat respiratory tract conditions related to the common cold (Saller *et al.*, 1990); inhalation of volatile oil to determine the effect of olfactory stimulation on mood (Roberts and Williams, 1992); and oral ingestion of the aqueous infusion to investigate cardiac effects after ventricular catheterization (Gould *et al.*, 1973). In a study of 8,058 mothers in childbirth conducted over a period of eight years, two essential oils, clary sage (*Salvia sclarea* L.) and chamomile were shown to be effective in alleviating pain during labor (Burns *et al.*, 2000). A recent DB,PC study investigated the use of a chamomile fluid extract and apple pectin combination product for treating young children with acute, non-complicated diarrhea (de la Motte *et al.*, 1997).

BRANDED PRODUCTS

Diarrhoesan® Chamomile fluidextract: Dr. Loges & Co. GmbH / Postfach 1262 / Schützenstrasse 5 / 21423 Winsen / Germany / Tel.: +49-041-71-7070 / Fax: +49-041-71-7071-00 / Email: info@loges.com. Each 100 ml of solution contains 2.5 ml of chamomile fluidextract (1:1), eluent: ethanol 55% and 3.2 g of apple pectin.

Kamillosan® Creme: VIATRIS GmbH & Co. KG / Weismüllerstrasse., 45 / D-60314 Frankfurt/Main / Germany / Tel.: +49-69-4001 2811 / Fax: +49-69-4001 2951 / Email: info@viatris.com / www.viatris.com (formerly known as ASTA Medica AG). One gram cream contains 20 mg ethanolic dry extract (2.75:1) in a fatty ointment base. The extract contains no less than 0.2 mg volatile oil and a minimum of 0.07 mg (-)- α -bisabolol.

Kamillosan® Konzentrat: VIATRIS GmbH & Co. KG. Hydroalcoholic tincture extracted with 38.5% (*m/m*) ethanol; drug-to-extract ratio of approximately 1:4.0–4.5 (*w/v*), in 42.8% ethanol. Each 100 ml of tincture contains 150–300 mg essential oil; 150–300 mg apigenin-7-glucoside and 50 mg (-)- α -bisabolol.

Kamillosan® Liquidum: VIATRIS GmbH & Co. KG. Standardized hydroalcoholic fluid extract; 150 mg of essential oil

per 100 ml fluid extract containing a minimum of 3 mg chamazulene and 50 mg α -bisabolol.

Kneipp® Kamillen-Konzentrat: Kneipp Werke /105-107 Stonehurst Court / Northvale, NJ 07647 / U.S.A. / Tel: (201) 750-0600 / Fax: (201) 750-2070 / www.kneipp.com. Hydroalcoholic fluid extract.

American equivalents, if any, are found in the Product Table beginning on page 398.

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Clinical Studies on Chamomile (*Matricaria recutita* L.)

Oral/Gastrointestinal

Author/Year	Subject	Design	Duration	Dosage	Preparation	Results/Conclusion
Fidler <i>et al.</i> , 1996	Stomatitis	Phase III, DB, PC, R n=164	2 weeks	30 drops extract in 100 ml water as mouthwash 3x/day vs. placebo	Kamillosan® Konzentrat, diluted in water	Chamomile mouthwash administered in addition to cryotherapy did not significantly alleviate 5 fluorouracil (5-FU)-induced stomatitis (p=0.32). However, subset analysis based on gender did reveal unexpected differential effects, suggesting that chamomile might be beneficial for males but detrimental for females. This could not be explained by reasons other than chance.
Carl and Emrich, 1991	Stomatitis and mucositis	U n=98	Varying durations for different treatment groups	Oral rinse during repeated cycles	Kamillosan® Liquidum	Chamomile oral rinse decreased stomatitis and was found to be beneficial in the treatment of mucositis resulting from radiation and cancer chemotherapeutic agents. The resolution of mucositis appeared to be accelerated by the chamomile rinse. Prophylactic oral care appeared to modify oral environment favorably and maintain tissue integrity.
Nasemann, 1975	Astringent and cooling effect	DB n=36	18 months	Mouth wash, 5–6x/day	Kamillosan®	With exception of patients with glossodynia, extract showed astringent and cooling action.

Dermatological

Author/Year	Subject	Design	Duration	Dosage	Preparation	Results/Conclusion
Glowania <i>et al.</i> , 1987	Dermabrasion	R, PC, DB n=14 healthy males with abrasions of tattoos on the arms with Derma III equipment (1.5 mm depth)	14 days	Chamomile extract compresses for 1 hour, 3x/day until wounds are completely dry	Chamomile extract standardized to 3 mg chamazulene and 50 mg levomenol	Objective parameters were used to evaluate epithelial and drying effect of chamomile preparation applied topically to weeping wound area after dermabrasion from tattoo removal. Chamomile extract significantly decreased weeping wound size, and sped up healing time by enhancing drying of oozing wounds.
Aertgeerts <i>et al.</i> , 1985	Inflammatory dermatoses	Cn, Cm, MC n=161	3–4 weeks	Chamomile cream vs. 0.25% hydrocortisone, 0.75% fluocortin butyl ester, 5% bufexamac	Kamillosan® Crème	Chamomile cream showed more or less equally effective therapeutic results as hydrocortisone for treatment of inflammatory dermatoses. It proved superior to the nonsteroidal, anti-inflammatory agent 5% bufexamac as well as to 0.75% fluocortin butyl ester. For treatment of neurodermatitis, chamomile cream was therapeutically comparable to hydrocortisone and superior to other tested products.

KEY: C – controlled, CC – case-control, CH – cohort, CI – confidence interval, Cm – comparison, CO – crossover, CS – cross-sectional, DB – double-blind, E – epidemiological, LC – longitudinal cohort, MA – meta-analysis, MC – multi-center, n – number of patients, O – open, OB – observational, OL – open label, OR – odds ratio, P – prospective, PB – patient-blind, PC – placebo-controlled, PG – parallel group, PS – pilot study, R – randomized, RC – reference-controlled, RCS – retrospective cross-sectional, RS – retrospective, S – surveillance, SB – single-blind, SC – single-center, U – uncontrolled, UP – unpublished, VC – vehicle-controlled.

Clinical Studies on Chamomile (*Matricaria recutita* L.) (cont.)

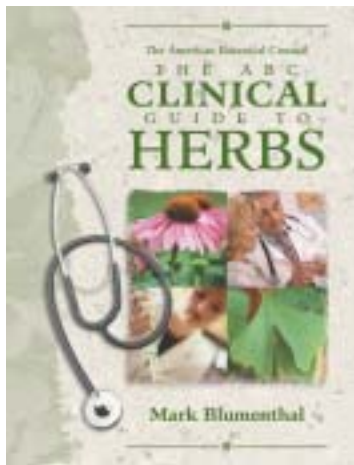
Other

Author/Year	Subject	Design	Duration	Dosage	Preparation	Results/Conclusion
de la Motte <i>et al.</i> , 1997	Acute diarrhea in children	P, DB, R, MC, PG, PC n=79 children, 6 months to 5.5 years	3 days	1st dose 10 ml, followed by 5 ml/hour, up to 60 ml/day	Diarrhoeasan® Chamomile fluid extract (0.035 mg/g chamazulene and 0.5 mg/g (-)- α -bisabolol) combined with apple pectin	After 3 days of treatment, diarrhea in the pectin/chamomile group had ended significantly ($p < 0.05$) more frequently than placebo. Pectin/chamomile reduced duration of diarrhea significantly ($p < 0.05$) by at least 5.2 hours. Parents documented subjects' well-being in a diary twice daily and, compared to placebo, a trend of continuous improvement was observed in the pectin/chamomile group.
Roberts and Williams, 1992	Neurology, psychiatry	PC n=22	1 day	1x exposure vs. placebo	Chamomile flower volatile oil	Patients were asked to visualize positive and negative phrases following olfactory stimulation by chamomile oil or placebo. Chamomile oil significantly increased latency for all images, and shifted mood ratings and frequency judgments in a more positive direction, suggesting a possible mode of action.
Saller <i>et al.</i> , 1990	Respiratory	PC, R n=60	1 day	Steam inhalation, 1x/5 hours	Kneipp® Kamillen-Konzentrat, alcoholic fluidextract diluted in boiled water	Steam inhalation, below a towel, with chamomile extract in hot water reduced the severity of common cold symptoms in a pronounced and dose-dependent manner. Onset of action occurred within 15 minutes and reached maximum effect between 30–120 minutes; then efficacy declined after 2–3 hours.
Gould <i>et al.</i> , 1973	Cardio-vascular effects	U n=12 hospitalized patients	1 day	2 tea bags in 6 ounces boiled water, 1x	Chamomile flower tea infusion (brand not stated)	Significant increase in mean brachial artery pressure from 91 to 98 mmHg ($p < 0.05$). No other significant hemodynamic changes were observed. Blood pressure and cardiac output were measured prior to drinking tea and 30 minutes later. Average cardiac index showed only slight decrease, and average stroke index was essentially unchanged. 10 of the 12 patients fell into deep sleep 10 minutes after ingestion, lasting until end of cardiac catheterization approximately 90 minutes.

Combination Product with Chamomile (Essential Oil)

Author/Year	Subject	Design	Duration	Dosage	Preparation	Results/Conclusion
Burns <i>et al.</i> , 2000	Pain during childbirth	O n=8,058	8 years	Not stated	10 essential oils, including chamomile	The study found that aromatherapy with 2 of the tested essential oils, clary sage and chamomile, reduced maternal anxiety, fear, and/or pain during labor. The use of aromatherapy was found to reduce the use of systemic opioids in the study center, from 6% in 1990 per woman to 0.4% in 1997.

KEY: C – controlled, CC – case-control, CH – cohort, CI – confidence interval, Cm – comparison, CO – crossover, CS – cross-sectional, DB – double-blind, E – epidemiological, LC – longitudinal cohort, MA – meta-analysis, MC – multi-center, n – number of patients, O – open, OB – observational, OL – open label, OR – odds ratio, P – prospective, PB – patient-blind, PC – placebo-controlled, PG – parallel group, PS – pilot study, R – randomized, RC – reference-controlled, RCS – retrospective cross-sectional, RS – retrospective, S – surveillance, SB – single-blind, SC – single-center, U – uncontrolled, UP – unpublished, VC – vehicle-controlled.



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