

مصرف الممن فرا ورده مای طبیعی



تعاریف:

(نقشه راه فر آورده های طبیعی و داروهای طب سنتی ایران در افق ۱۴۰۴ سازمان غذا و داروی وزارت بهداشت، درمان و آموزش پزشکی)

• گیاه دارویی:

گیاهی که به طور مستقیم یا غیرمستقیم تمام یا اجزایی از آن به صورت تازه یا خشک شده و یا مواد مؤثره استخراجی از آن به منظور اثرات بهداشتی، پیشگیری و درمانی در بدن انسان، حیوانات و دیگر گیاهان به کار میرود.

• داروی گیاهی:

هرگونه فرآورده دارویی که منحصرا، از نظر اجزاء متشکله فعال، شامل یک یا چند ماده گیاهی فرآوری نشده و یا ترکیبی از هردو با فرمولاسیون گوناگون برای عرضه در بازار دارویی جهت تشخیص، پیشگیری، کمک به اعمال فیزیولوژیک، درمان و حفظ بهداشت بدن انسان، حیوانات و سایر گیاهان به کار میرود.

Dr. A.Raeesdana



• فرآوردههای گیاهی:

مواد گیاهی که به صورت خام و یا فراوری شده به منظور کاربرد در پزشکی، دامپزشکی و گیاه پزشکی و نیز کاربردهای تجاری، صنعتی، غذایی و بهداشتی استفاده می شوند و شامل داروهای گیاهی، فرآوردههای طبیعی و مکمل با منشأ گیاهی، افزودنیهای غذایی و طعم دهندهها، رنگ دهندهها، عرقیات و عصارهها و اسانسها، فرآوردههای آرایشی و بهداشتی و کنترل کننده آفات و بیماریهای گیاهی میباشد، فرآوردههای گیاهی گفته می شود.



• فرآوردههای طبیعی:

به فراوردههایی که از مواد طبیعی حاصل از گیاهان، جانوران، میکروارگانیسم ها و معادن استخراج می شوند، از قبیل داروهای طبیعی (جامد، نیمه جامد و مایع)، مواد اولیه طبیعی (عصاره و اسانس)، فرآوردههای گیاهی دارویی، فرآوردههای فرآوردههای تشخیص فرآورده طبیعی و فرآوردههای تشخیص حساسیت، داروهای مشابه درمانی گفته می شود.

فرآوردههای طبیعی در ایران





آیین نامه مربوط به ساخت داروهای گیاهی

اطلاعاتی که بر اساس پرسشنامه تقاضای ساخت و تولید داروهای گیاهی به منظور بررسی و صدور پروانه ساخت مورد نیاز می باشند شامل:

- اطلاعات و مشخصات گیاهان به کار رفته در فرمولاسیون شامل جنس و گونه گیاهان و ارسال نمونه های هرباریومی که به تایید یکی از موزه های گیاهی مورد تایید وزارت بهداشت، درمان و آموزش پزشکی رسیده باشد.
- ارائه فرمولاسیون کامل فرآورده با ذکر کلیه مواد متشکله (اصلی و کمکی). ضمنا در مورد فرآورده هایی که نمونه خارجی دارند ارائه فرمولاسیون نمونه خارجی الزامی است.
 - روش ساخت فرآورده به طور کامل
 - ارسال روشهای کنترل کمی و کیفی و تعیین مشخصات فیزیکی محصول نهایی
 - ارسال روشهای کنترل میکروبی و نتایج آن
 - شکل و روش مصرف دارو
 - موارد و میزان مصرف، منع مصرف و عوارض جانبی
 - کنترل پایداری فرآورده و تعیین تاریخ انقضای مصرف
 - شرایط نگهداری
 - ارسال فرآورده قابل عرضه به بازار
 - یک نمونه از بروشور

آیین نامه مربوط به ساخت داروهای گیاهی

- طرحی از مطالب و عناوین روی بسته بندی شامل:

نام دارو، نام و نشانی سازنده، قیمت برای مصرف کننده،تاریخ انقضای مدت مصرف، شکل دارویی و موارد مصرف، ترکیب دارو (شامل نام و مواد به کار رفته)، نام و مقدار ماده موثره، مقدار دارو در هر بسته، شماره پروانه ساخت (IRC)، شماره سری ساخت و تاریخ ساخت، مطالب مهم (شامل: هشدارها، احتیاط ها و ممنوعیتها) با تایید اداره کل نظارت بر امور دارو و مواد مخدر به طور واضح روی بسته بندی داروها، جعبه، برچسب و... در یک کادر قرمز رنگ نوشته شود.

_شرایط نگهداری

آیین نامه مربوط به ساخت داروهای گیاهی

- در مورد داروهای گیاهی جدید لازم است موارد زیر نیز اضافه گردد:

الف_ مدارک و نتایج آزمایشات فارماکولوژی، سم شناسی، حیوانی (Animal test) و بالینی (Clinical Trial) که در یکی از مراکز معتبر و مورد قبول وزارت بهداشت، درمان و آموزش پزشکی انجام پذیرفته است.

ب_ تعیین مقدار مصرف بر اساس آزمایشات بالینی انجام شده

Botanical safety?????



Are botanical safe?

Many people believe that products labeled "natural" are safe and good for them.

This **is not necessarily true** because the <u>safety of a</u> <u>botanical depends on many things</u>, such as its <u>chemical makeup</u>, how it works in the body, how it is prepared, and the dose used.

Inadequate reporting makes it difficult to determine whether a herb-drug interaction has occurred.

The action of botanicals range from mild to powerful (potent).

A botanical with <u>mild action</u> may have subtle effects.

Chamomile and peppermint, both mild botanicals, are usually taken as teas to aid digestion and are generally considered safe for self-administration.

• Some mild botanicals may have to be taken for weeks or months before their full effects are achieved.

Valerian: may be effective as a sleep aid after 14 days of use but it is rarely effective after just one dose.

In contrast a powerful botanical produces a fast result.

Kava: have an immediate and powerful action affecting anxiety and muscle relaxation.

The dose and form of a botanical preparation also <u>play</u> <u>important roles in its safety.</u>

Teas, tinctures, and extracts have different strengths.

The same amount of a botanical may be contained in a cup of tea, a few teaspoons of tincture, or an even smaller quantity of an extract. Also, different preparations vary in the relative amounts and concentrations of chemical removed from the whole botanical.

Peppermint tea is generally considered safe to drink but peppermint oil is much more concentrated and can be <u>toxic</u> if used incorrectly.

It is important to follow the manufacturer's suggested directions for using a botanical and not exceed the recommended dose without the advice of a healthcare provider.

What should we do?

- Ask patients about their disease, age, pregnancy, nursing, Drug History such as: medicines, OTC, Herbal, home remedies and ...
- Be sure if patients use dangerous drugs such as Digoxin, Warfarin, Carbamazepine, Cyclosporine didn't use herbal medicine.
- Tell them all natural remedies are not safe.



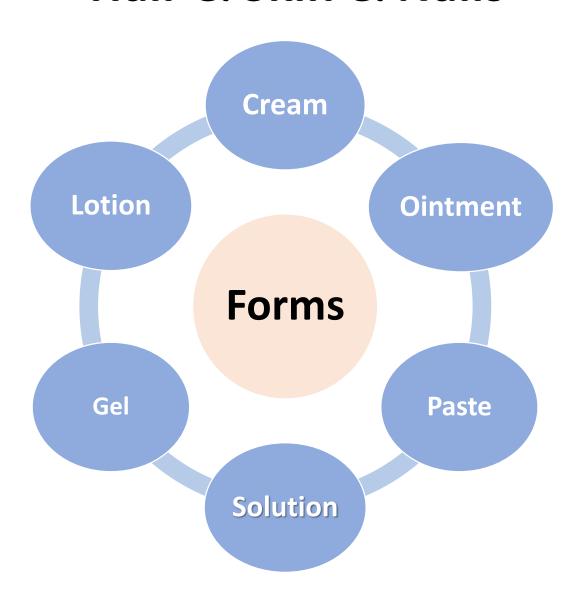


- فهرست فرآورده های طبیعی / گیاهی دارای مجوز (به منظور اجرای مفاد تبصره ۲ بند پ ماده ۷۲ قانون برنامه ششم توسعه اقتصادی، اجتماعی و فرهنگی جمهوری اسلامی ایران) دانلود فایل
 - تاریخ آخرین بروز رسانی چهارشنبه ۳۰ آبان ۱۳۹۷: ۱۰۸۷ مورد

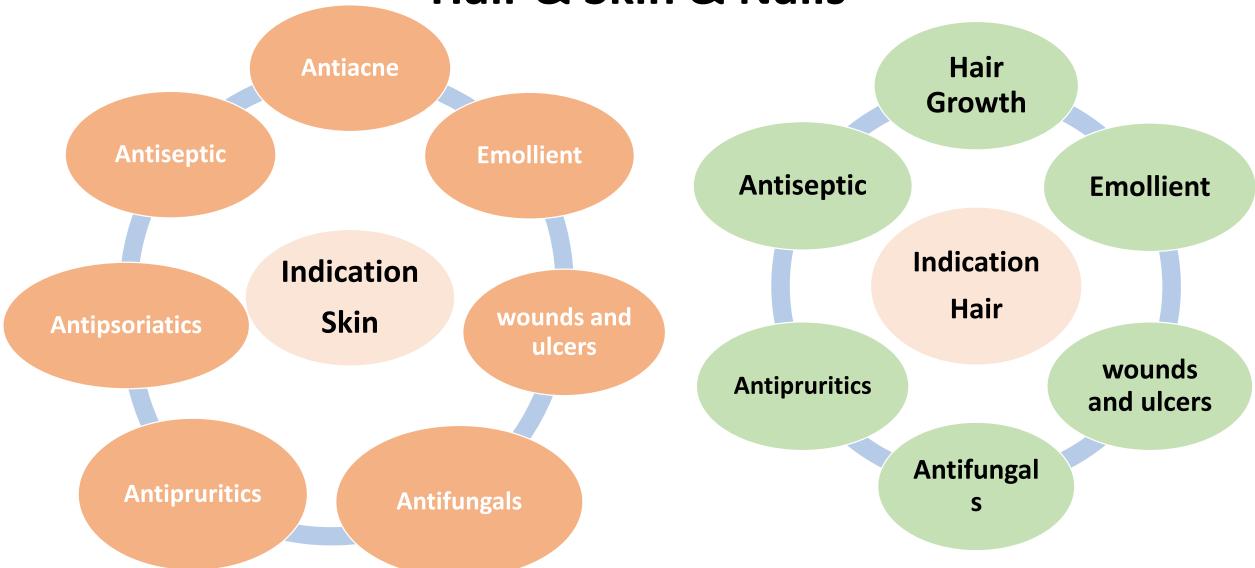
Α	В	С	D	E	F	G	Н	1	J	K
- II =	English 🔻	Form	ATC N 🔻	ATC Eng 🔻	ATC Farsi	Ingredient 🔻	Lab ▼	√ لابراتوار	√ نام دارو	√ شکال دارویی
1	AFS	Drop	A03	Drugs for functional gastrointestina I disorders	داروهاي موثر در مشکلات عملکرد دستگاه گوارش	ninorita	Giah Essence	گیاه اسانس	آ اف اس	قطره
2	Atheromod-B	Tablet	A05	Bile and Liver Therapy	درمان مشکلات کبدی و صفراوی		Barij Essence	باريج اسانس	آترومد-بی	قرص
3	Atsez	Topical Solution	D11	Other dermatological preparations	ساير فراورده هاي پوستي	aculeatus, Arct	Shahdara kaspian	شهد آرا کاسپین	آتستر	محلول موضعي
4	Arthrocen	Capsule	M01	Antiinflammat ory and antirheumatic products	فراورده های ضدالتهاب و ضدروماتیسم	gratissima, Gly	Arvin Arman Gostar	آروین آرمان گستر	آرتروسن	كپسول
5	Arthrofeed	Capsule	M01	Antiinflammat ory and antirheumatic products	فراورده های ضدالتهاب و ضدروماتیسم	gratissima, Gly	Bahar paya	بهار پایا	آرتروفيد	كپسول
6	Arthroherb	F.C.Tablet	M09	Other drugs for disorders of the musculo-		Harpagophytu m procumbens	Amin	امين	آرتروهرب	قرص روکشدار

Dr. A.Raeesdana

Local Herbal medicines Hair & Skin & Nails



Local Herbal medicines Hair & Skin & Nails



Allium cepa (Wounds treatment)

Aloe Sp. (Wounds treatment ,Emollients, Antipruritics, Antipsoriatics)

Arctostaphylos uva-ursi (Hair Growth)

Arnebia euchroma (Antiacne)

Calendula officinalis (Antipruritics)

Cinnamomum camphora (Wounds treatment)

Coriandrum sativum (Wounds treatment)

Curcuma longa (Wounds treatment)

Ferula gummosa (Antiacne, Wounds treatment)

Glycyrrhiza glabra (Emollients, Antipsoriatics)

Lavandula stoechas (Antiacne)

Lawsonia inermis (Wounds treatment)

Melilotus officinalis (Wounds treatment)

Myrtus communis (Hair Growth)

Olea europaea (Wounds treatment)

Rosa canina (Wounds treatment)

Rosmarinus officinalis (Emollients, Wounds treatment, Hair Growth)

Rosmarinus officinalis (Hair Growth)

Ruscus aculeatus (Hair Growth)

Urtica dioica (Hair Growth)

Allium cepa L. (Onion)

Medicinal Parts:

The medicinal part is the bulb.



INDICATIONS AND USAGE Approved by Commission E:

- Loss of appetite
- Arteriosclerosis
- Dyspeptic complaints
- Fevers and colds
- Cough/bronchitis
- Hypertension
- Tendency to infection
- Inflammation of the mouth and pharynx
- Common cold

Unproven Uses: Wounds treatment





No health hazards or side effects are known in conjunction with the proper administration of designated therapeutic dosages.

Frequent contact with the drug leads on rare occasion to allergic reactions (hand eczema).



Aloe barbadensis/capensis/vera (Aloe)

Medicinal Parts:

The medicinal part of the plant is dried juice of the leaves.



INDICATIONS AND USAGE Approved by Commission E:

Constipation

Unproven Uses:

Wounds treatment
Emollients
Antipruritics
Antipsoriatics



PRECAUTIONS AND ADVERSE REACTIONS:

Hypersensitivity, manifested by generalized nummular eczematous and papular dermatitis, have been reported after long-term use of topical Aloe preparations



Arctostaphylos uva-ursi L. (Uva-Ursi)

Medicinal Parts:

The medicinal parts of the plant are the dried leaves and preparations of the fresh leaves.



INDICATIONS AND USAGE Approved by Commission E:

• Infections of the urinary tract Uva-Ursi is used for inflammatory disorders of the efferent urinary tract.



Hair Growth



PRECAUTIONS AND ADVERSE REACTIONS:

General: No health hazards are known in conjunction with the proper administration of designated therapeutic dosages.

Pregnancy: The drug is contraindicated during pregnancy.

Nursing Mothers: The drug is contraindicated in nursing mothers.



Arnebia euchroma I.M.Johnst. (Arnebia root)

Medicinal Parts: Root

INDICATIONS AND USAGE Approved by

Commission E: -

Unproven Uses:

Antiacne

PRECAUTIONS AND ADVERSE REACTIONS: -



Glycyrrhiza glabra L.

(Licorice)

Medicinal Parts: unpeeled, dried roots and the runners, the peeled dried roots, and the rhizome with the roots

INDICATIONS AND USAGE Approved by Commission E:

- Cough/bronchitis
- Gastritis

Unproven use: Emollients, Antipsoriatics



Calendula officinalis L. (Marigold)

Medicinal Parts:

The medicinal part is the flower.



INDICATIONS AND USAGE Approved by Commission E:

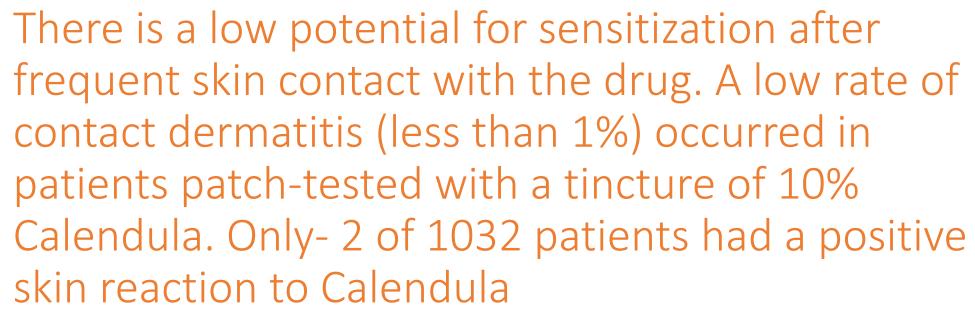
- Inflammation of the mouth and pharynx
- Wounds and burns

Externally, Marigold is used for inflammation of the oral and pharyngeal mucosa, poorly healing wounds, leg ulcers, to clean wounds, and for acute and chronic skin inflammation.



PRECAUTIONS AND ADVERSE REACTIONS:

No health hazards or side effects are known in conjunction with the proper administration of designated therapeutic dosages.





Curcuma longa L.

(Tuemeric)

Medicinal Parts: Stewed and dried rhizome INDICATIONS AND USAGE Approved by Commission E:

- Dyspeptic complaints
- Loss of appetite

Unproven Use: Wounds treatment





No health hazards or side effects are known in conjunction with the proper administration of designated therapeutic dosages.

Cinnamomum camphora (L.) T.Nees & C.H.Eberm.

(Comphor tree)

Medicinal Parts:

The medicinal part is camphor oil extracted from the tree.



INDICATIONS AND USAGE Approved by Commission E:

- Arrhythmia
- Cough/bronchitis
- Hypotension
- Nervous heart complaints
- Rheumatism

Unproven Uses: Wounds treatment



Local administration can lead to skin irritation, as well as to resorbent and/or airborne poisonings. Contact eczema occasionally appears following the application of oily salves containing camphor. The drug is sometimes used as a hashish substitute because 6 to 10 g leads to intoxication.



Pediatric Use: Camphor salves should not be administered to infants.



Coriandrum sativum L.

(Coriander)

Medicinal Parts:

The medicinal parts are the coriander oil and dried ripe fruit.



INDICATIONS AND USAGE Approved by Commission E:

- Dyspeptic complaints
- Loss of appetite

Unproven Uses: Wounds treatment



Health risks or side effects following the proper administration of designated therapeutic dosages are not recorded. The drug possesses a weak potential for sensitization.



Ferula gummosa Boiss.

(Galbanum)

Medicinal Parts:

The medicinal part is the oily gumresin.



INDICATIONS AND USAGE Approved by Commission E:

Unproven Uses:

Internally, Galbanum is used for digestive disorders and flatulence; externally it is used in the treatment of wounds.



Health risks or side effects following the proper administration of designated therapeutic dosages are not recorded.



Glycyrrhiza glabra L. (Licorice)

Medicinal Parts: unpeeled, dried roots and the runners, the peeled dried roots, and the rhizome with the roots





INDICATIONS AND USAGE Approved by Commission E:

- Cough/bronchitis
- Gastritis

Unproven uses: Emollients, Antipsoriatics



No health hazards or side effects are known in conjunction with the proper administration of designated therapeutic dosages.

Lavandula angustifolia L.

(English lavender)

Medicinal Parts:

The medicinal parts are the essential oil extracted from the fresh flowers and/or the inflorescences, the flowers collected just before opening and dried, the fresh flowers and the dried flowers.



INDICATIONS AND USAGE Approved by Commission E:

- Loss of appetite
- Nervousness and insomnia
- Circulatory disorders
- Dyspeptic compaints

Unproven Uses:

Externally, it is used for rheumatic conditions (the drug as an extract in liniments), as a sedative in cases of tension, exhaustion; also for poorly healing wounds (lavender baths) and for sleep as aroma therapy (herb pillow).



No health hazards or side effects are known in conjunction with the proper administration of designated therapeutic dosages. The volatile oil possesses a weak potential for sensitization.



Lawsonia inermis L.

(Henna)

Medicinal Parts:

The medicinal parts are the pulverized leaves, the fruit and the bark.



Unproven Uses: The drug is used externally for eczema. scabies, fungal infections and ulcers. It is also used for amebic dysentery and gastrointestinal ulcers. In African folk medicine, it is used as an abortifacient. The drug is also contained in facial and hair lotions and is used to treat dandruff.





Health risks or side effects following the proper administration of designated therapeutic dosages are not recorded.

Melilotus officinalis L.

(Sweet clover)

Medicinal Parts:

The medicinal part is the flowering herb.



INDICATIONS AND USAGE Approved by Commission E:

- Blunt injuries
- Hemorrhoids
- Venous conditions

Unproven Uses: Wounds treatment



No health hazards or side effects are known in conjunction with the proper administration of designated therapeutic dosages.



Myrtus communis L. (Myrtle)

Medicinal Parts:

The medicinal parts are the leaves (dried and as a source of oil), twigs and the fresh, flowering branches.



Unproven Uses:

Among external uses are ear infections, tired limbs, fatigue and leukorrhea. External applications include ear infections, tired limbs, and leukorrhea.

Hair Growth



General: No health hazards or side effects are known in conjunction with the proper administration of designated therapeutic dosages.



Olea europea L. (Olive)

Medicinal Parts:

Olive oil and Olive leaves are available from numerous manufacturers. The leaves are sometimes marketed as Olive Leaf-Powder.



Unproven Uses:

Externally, it has been used for psoriasis, eczema, sunburn, mild burns and rheumatism. Its use as a lubricant for constipation and dry skin conditions appears plausible because of trie oily characteristics.



No health hazards or side effects are known in conjunction with the proper administration of designated therapeutic dosages.

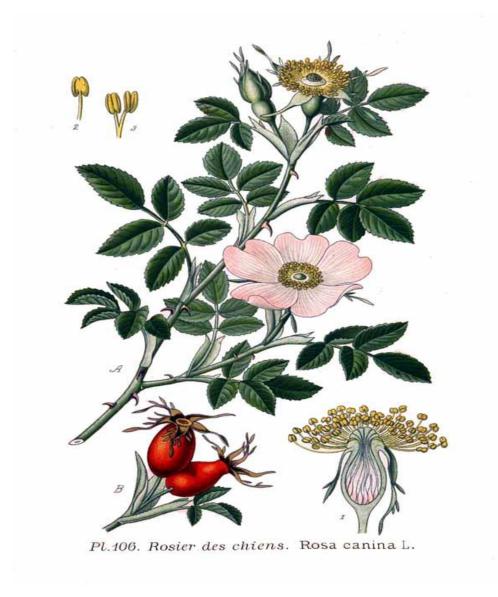


Rosa canina L.

(Dog rose)

Medicinal Parts:

The medicinal parts are the petals, the Rose hips with and without seeds and die seeds.



Unproven Uses:

Wounds treatment



No health hazards or side effects are known in conjunction with the proper administration of designated therapeutic dosages.



Rosmarinus officinalis L.

(Rosemary)

Medicinal Parts:

The medicinal parts are the oil extracted from the leaves and the leafy stems, the flowering, dried twig tips, the dried leaves, the fresh leaves, the fresh aerial parts collected during flowering and the flowering branches.



Approved by Commission E:

- Blood pressure problems
- Dyspeptic complaints
- Loss of appetite
- Rheumatism

Unproven Uses:

It is used externally as a poultice for poorly healing wounds, for eczema, as an analgesic for injuries of the mouth and throat, topically for myalgias, intercostal neuralgia and sciatica.



No health hazards or side effects are known in conjunction with the proper administration of designated therapeutic dosages. Contact allergies have been observed on occasion.



Ruscus aculeatus L.

(Butcher's Broom)

Medicinal Parts:

The medicinal parts are the herb and the rhizome.



Approved by Commission E:

- Hemorrhoids
- Venous conditions

Unproven Uses:

Hair Growth



No health hazards or side effects are known in conjunction with the proper administration of designated therapeutic dosages.



Urtica dioica L.

(Stinging Nettle)

Medicinal Parts:

The medicinal parts are the fresh and dried flowering plant and the roots.



Approved by Commission E:

- Infections of the urinary tract
- Kidney and bladder stones
- Rheumatism



Externally, the drug is used as a hair and scalp remedy against oily hair and dandruff.



PRECAUTIONS AND ADVERSE REACTIONS:

No health hazards or side effects are known in conjunction with the proper administration of designated therapeutic dosages. Possible allergic reactions (skin afflictions, edema) have been observed in rare cases following intake of the drug. Contact urticaria frequently occurs when skin is exposed to the plant. The urticaria is accompanied by a stinging sensation that may last as long as 12 hours post exposure.



Ziziphus jujuba L. (Jujube)

Medicinal Parts:

The medicinal part is the fruit.

The Jujube berry is classed with raisins, dates and figs, and can be eaten fresh or dried.



Unproven Uses: Jujube is used as a also used as a prophylactic against liver



ulcers.

nutrient and tonic. It is

disease and stress



No health hazards or side effects are known in conjunction with the proper administration of designated therapeutic dosages.



Refrences:

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- 2. Stockleys Herbal Medicine Interaction.2nd edition
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- 7. https://medlineplus.gov/
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Fenugreek *Trigonella foenum-graecum* L.

Medicinal parts:

The ripe, dried seeds

Approved by Commission E:

Inflammation of the skin



Precaution and adverse reactions:

General: Health risks or side effects following the proper administration of designated therapeutic dosages are not recorded. Sensitization is possible through repeated external administration of the drug.



Feverfew

Tanacetum parthenium (L.) Sch.Bip.

Medicinal parts:

The herb of the plant

Medicinal usage approved by Commission E:

Feverfew is used mainly for migraine, arthritis, rheumatic diseases and allergies.



Precaution and adverse reactions:

General: No health hazards or side effects are known in conjunction with the proper administration of designated therapeutic dosages.

The drug has a high potential for sensitization via skin contact.

A post-Feverfew syndrome has been reported in about 10% of migraine patients who abruptly stopped taking Feverfew. Rebound headaches, insomnia, muscle stiffness, joint pain, fatigue, nervousness and tension have occurred (Miller, 1998).



Precaution and adverse reactions:

Skin:

There are reports of allergic dermatitis on exposure to

the leaves and petals of Feverfew.

Eczema was reported in greenhouse workers exposed to various members of the Compositae family, including Feverfew.



Flax Linum usitatissimum L.

Medicinal parts:

The stem as a sterile linen thread, the oil extracted from the seeds, the dry ripe seeds, the linseed cakes and the fresh flowering plant.



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Approved by Commission E:

Inflammation of the skin



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Precaution and adverse reactions:

General: No health hazards or side effects are known in conjunction with the proper administration of designated therapeutic dosages. The use of large quantities of the drug as a laxative with too little fluid intake can lead to an ileus.

The cyanogenic glycosides present no danger with the intake of therapeutic dosages; the glycosides are broken down only to a limited extent in the body. An elevation in the concentration of cyanide ions and of the detoxification product thiocyanic acid in the blood could not be demonstrated.

It is recommended that if flaxseed is taken for inflammatory bowel conditions, that the flaxseed be preswollen before use (Bisset & Wichtl, 1994).

Peppermint *Mentha × piperita* L.

Medicinal parts:

oil extracted from the aerial parts of the flowering plant, the dried leaves and flowering branch tips, the fresh flowering plant and the whole plant.



Indication, usage approved by Commission E:

- PEPPERMINT LEAVES
- Liver and gallbladder complaints 9 Dyspeptic complaints
- PEPPERMINT OIL
- Common cold
- Cough/bronchitis
- Inflammation of the mouth and pharynx
- Liver and gallbladder complaints
- Dyspeptic complaints
- Tendency to infection

PRECAUTIONS AND ADVERSE REACTIONS:

PEPPERMINT LEAVES

No health hazards are known in conjunction with the proper administration of designated therapeutic dosages. Gallstone carriers could experience colic due to the cholagogic effect.

PEPPERMINT OIL

General: No health hazards are known in conjunction with the proper administration of designated therapeutic dosages. The intake can lead to gastric complaints in susceptible persons. The volatile oil possesses a weak potential for sensitization due to its menthol content. One is advised against administration of the drug in the presence of a tendency to gastroesophageal reflux.

Dr. A.raeesdana

Pediatric Use:

Preparations containing the oil should not be applied to the faces of infants or small children, particularly not in the nasal area (glottal spasm or bronchial spasm up to asthma-like attacks or even possible respiratory failure).



Pineapple

Scientific Name: Ananas comosus (L.) Merr.

Family: Bromeliaceae

Medicinal Parts:

• The fruit.

• Bromelain: a mixture of enzymes found in the pineapple plant (Fruit & Stem)

Habitat: Habitat: Hawaii, Japan, Taiwan



INDICATIONS AND USAGE

Pinapple Fruit:

Approved by Commission E:

Wounds and burns

Bromelain:

Currently, bromelain is used as a dietary supplement for nasal swelling and inflammation, osteoarthritis, cancer, poor digestion, and muscle soreness.

Topical (applied to the skin) bromelain is used for wounds and burns.

PRECAUTIONS AND ADVERSE REACTIONS

Pinapple Fruit

No health hazards are known in conjunction with the proper administration of designated therapeutic dosages.

Gastric complaints and diarrhea may occur as side effects of internal administration.

Allergic reactions following repeated administration have been observed.

PRECAUTIONS AND ADVERSE REACTIONS

Bromelain

There have been some reports of gastrointestinal problems, increased heart rate, and menstrual problems in people who have taken bromelain orally.

Allergic reactions may occur in individuals who are sensitive or allergic to pineapples or who may have other allergies.

Refrences:

- 1. PDR for Herbal medicines, 2000 H
- 2. WHO monographs on selected medicinal plants (http://www.who.int/medicinedocs/en/m/abstract/Js14213e/), Vol.1, 2, 3, 4
- 3. http://www.theplantlist.org
- 4. Herbal Medicines in pregnancy & lactation

Dr. S. Hamidi

What are some additional sources of information on botanical?

Web-based resources such as:

PubMed

FDAexternal link disclaimer

Dietary Supplements: Background Information from the Office of Dietary Supplements (ODS).

http://ods.od.nih.gov



