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Review Article

An Overview on Pharmacological Activities of Silybum Marianum (Milk Thistle)

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ABSTRACT

This review on S. marianum, a plant widely used in traditional European medicine, provides an account of its botany, the chemistry of silymarin, and its main constituent silybin, and other compounds; analytical methods for silymarin and its isomers; pharmacology of silymarin and silybin. For many years, milk thistle (Silybum marianum) has been used as a herbal cure for a variety of illnesses. A complex blend of flavonolignans, including silibinin (silybin), silychristin, and silydianin, makes up the main active ingredient silymarin. In recent years, milk thistle leaves extract has been widely used in medicine. Silybum marianum is a flowering plant belonging to the Asteraceae family. Milk thistle appears to be safe and have multiple health benefits, known for its liver-protective, anti-inflammatory, anti- hypertensive activity, anti-viral, cardio protective anti-oxidant, properties. It is widely used in traditional medicine for its therapeutic properties. Each part of the milk thistle has some medicinal property. The purpose of this review of milk thistle is to provide a comprehensive overview of its health benefits, traditional uses, Pharmacological activity and toxicology and adverse effect.

INTRODUCTION

In ancient time people depend on medical plant for curing their complaint [1]. Medicinal property of plants are coming in highlight during ancient period. During Ancient times for rescue of diseases, people depend on nature. At that time, they are not aware about medicinal nature of plants [30]. Herbal plants are used as medicines in folk and traditional medicinal practice based on the use of plants and plant extracts. Milk thistle is a spiny herb belonging to the *Asteraceae* family [3]. Milk thistle has been used for medicinal purposes for over 2000 years [4,5]. Milk thistle needs to grow in a warm atmosphere and dry soil, and will grow

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up to 3 m high and 1 m across. However, it most commonly reaches 0.9–1.8 m in height [6]**.** The "milky white" veins on the leaves, which release a milky sap when split apart, are the source of the common name "milk thistle." Three isomeric flavonolignans—silibinin (silybin), silychristin, and silydianin collectively known as SILYMARIN extracted from dried milk thistle seeds are the medicinally active ingredients of milk thistle seeds. The most physiologically active is silybin. In addition to proteins, fixed oil, silybonol, apigenin, betaine, and free fatty acids, the seeds also include additional flavonolignans that may enhance the health benefits of milk thistle seed. [7,8] The flower has a large white flower head. Although milk thistle is one of the oldest and thoroughly researched medicinal plants. S. marianum has been used for the past two decades for treatment of different diseases such as liver disease (cirrhosis and hepatitis) and gallbladder disorders, ocular surface disease, cataracts, glaucoma, and uveitis, also protecting the liver against snake bite and insect stings, mushroom poisoning and alcohol abuse [9]. Recent exploration has unveiled the protean reme dial eventuality of milk thistle, which offers a broad range of benefits including antioxidant, hepato-defensive, anti-atherosclerotic, anti-hypertensive, anti-obesity, anti-diabetic, anti-inflammatory, anti-carcinogenic, anti-viral, and anti-fibrotic parcels. The remedial goods of milk thistle are nearly connected to the presence of a flavonoid complex called silymarin, composed of a mixture of silybin A and B, isosilybin A and B, silychristin, and silydianin [10,11].

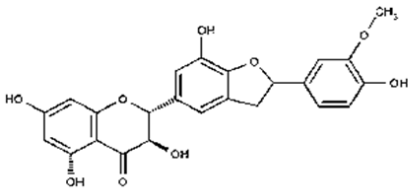
Nomenclature:

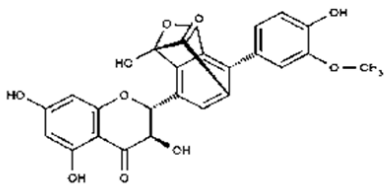
Plant Name	***Silybum marianum***
Family	Asreraceae
Genus:	Silybum
Kingdom	Plantae
Phylum	Magnoliophyta
Class	Magnoliopsida
Order	Asterales
Species	S. marianum

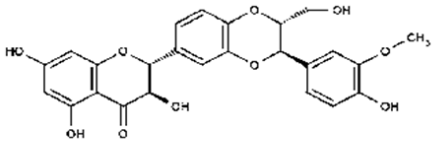
Img1: ***Silybum Marianum***

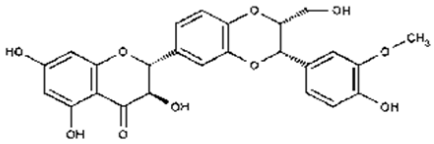
Chemical components:

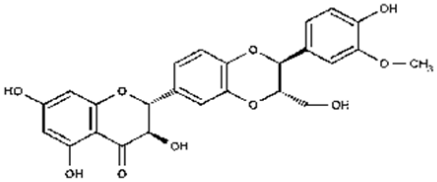
The main silymarin compounds reported in the scientific literature are taxifolin, silybin A and B, silychristin, isosilychristin, silydianin, and silychristin. Naturally occurring iso- and trans-di-stereoisomers of silibinin (silybin A and silybin B) and isosilybin (isosilybin A and isosilybin B). **[12]**

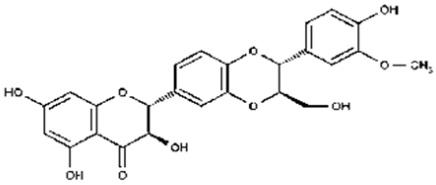

Silychristin

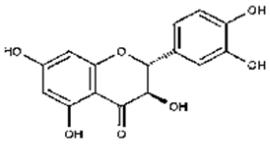

Silydianin


Silybin A


Silybin B


Isosilybin A


Isosilybin B


Taxifolin

Therapeutic uses:

1. Hepatitis, cirrhosis, and jaundice
2. Diabetes management
3. Indigestion
4. Acne
5. Allergic rhinitis
6. Cancer treatment
7. Bone health
8. High cholesterol
9. Mushroom poisoning
10. Alzheimer disease

Toxicology and adverse effects: Silymarin acceptability is good and just a gentle gastrointestinal disturbance and mild allergic reactions, urticaria, nausea, headache, joint pain, itching and mild laxative symptoms have been reported. In animal studies, silymarin has been reported to be nontoxic and symptom free with the maximum oral doses of 2500 and 5000 mg/kg. It has been also illustrated that silymarin is not teratogen and had no post-mortem toxicity. As there was not significant toxicity of silymarin reported in human studies, this substance can be used with anti-tuberculosis drugs as a supplement added to the diet. [13]

1. Acute Toxicity:

In animals, silymarin was set up to have no significant side effect when administered at high doses. Because of the stimulatory goods of the plant on the liver and gallbladder, some experts believe that a mild laxative effect may occur during earlier days of consumption. In controlled trial the side effects of this herb hardly dominated the placebo. In a study of several thousand cases, very low incidences of adverse effects were found,

which mainly were limited to mild gastrointestinal disorders. [14]

2. Chronic Toxicity:

Long-term use of this plant extract is safe with number of abnormality. Silybin, silydianin, and silychristin were not cytotoxic and genotoxic at concentration of 100 µm. Silymarin is safe in humans at therapeutic doses and is well tolerated even at a high dose of 700 mg three times a day for 24 weeks. Some gastrointestinal discomforts occurred like nausea and diarrhoea. One clinical trial showed silymarin is safe in pregnancy, and there were no anomalies. [15]

Pharmacological activity:

- **Hepatoprotective activity:** Silymarin has its liver-protective properties. It stabilizes cell membranes, inhibit liver cell damage, and promote the regeneration of new liver cells. It is used as a complementary treatment for liver diseases such as hepatitis and cirrhosis. [16]

- Stimulation of DNA polymerase by silymarin results in increase in the conflation of ribosomal RNA and reconstruction of liver cells. Increase of cellular glutamine attention stabilizes superoxide dismutase and glutathione peroxidase. Silymarin decreases the enlarged liver by inhibiting 5-lipoxygenase cycle and free revolutionary in Kupffer cells of liver.[17] Moreover, silybin in the mouse's hepatocyte cells inhibits production of peroxidation lipid and cellular damage**.** [18] Actually, the effect of silymarin on cellular permeability is associated with differences of membrane lipids including cholesterol and phospholipids. Silymarin also act on other lipid compartments in the liver that may influence the uptake and secretion of lipoproteins. [19]

- **Anti- hypertensive activity:** There's a veritably very small number of studies regarding the impact of silymarin/ silibinin on hypertension. Those studies mainly assess hypertension in environment of liver complaint [20]. The vasodilated properties of silymarin have been implicated in two more studies using rat models [21, 22]. Silymarin administration (200 mg/ kg/ day for 5 weeks) significantly perfected pulmonary artery hypertension at early stage before it became a severe and unrecoverable condition. The beginning medium may involve the suppression of a chemokine/receptor axis, CXCR4/SDF-1 axis (CXCR4 is a chemokine receptor and SDF-1, stromal cell deducted factor, is its ligand), which may delay pulmonary arteriolar occlusion and pulmonary vascular remodeling, and therefore can meliorate pulmonary arterial hypertension (PAH) [23, 24, 25]. Up-to-date data about the hypotensive exertion of silibinin/silymarin are veritably scarce, and it's clear that more studies are required to unravel the underlying mechanisms of silibinin/silymarin's effect on arterial systemic hypertension.[26]

- **Antiviral activities:** Silibinin from SM showed antiviral anti-viral activity against herpes simplex virus, type 2 (HSV-2) with IC50 value of 100 µg/mL and the therapeutic index of 3.8. This compound exhibited a more potent virucidal effect with an IC50 of 5 µg/ ml and the therapeutic index of 76. [27].

1. Intravenous Silibinin in Hepatitis C Virus Infected cases: An intravenous expression of silibinin (Silibinin-C- 20, 3-dihydrogen succinate, disodium salt), retailed as Legalon SIL, has been tested in HCV-infected patients. At present, all published data on the use of Legalon SIL are uncontrolled series or case

reports in the following three different clinical scenarios.

2. Treatment of nonresponders to pegylated interferon alpha and ribavirin: The first report on the clinical use of SIL in chronic hepatitis C demonstrated a dose-dependent decline of HCV RNA over 7 days of daily intravenous infusion in subjects who were prior nonresponders to pegylated interferon alpha (PegIFN) and ribavirin (RBV) therapy. With triple SIL, PegIFN, and RBV therapy, HCV RNA further decreased and became undetectable at week 12 in seven patients who received 15 and 20 mg/kg SIL (50%). [26] Treatment with PegIFN/RBV in responders was continued for up to a further 60 weeks. A sustained virologic response was obtained in three patients. This seminal study showed that intravenous silibinin suppresses HCV infection in vivo in patients who failed conventional PegIFN þ RBV therapy.

- **Cardiovascular activity:** Silymarin increases the regenerative ability of cardiovascular tissues by activating ribosomes and increases protein synthesis. It has been shown to stabilize the cellular membrane through modifying the transporters and receptors of cell membranes. Silymarin reduces the expression of inflammatory cytokines (e.g., TNF-alpha, IL-6) and other mediators, helping to lower systemic inflammation, which is linked to atherosclerosis and other cardiovascular conditions. Specific studies suggest doses in the range of 200 mg to 400 mg daily for cardiovascular effects.[29]

- **Anticancer Activity:** Human tumor carcinoma cell lines (liver) that used in this study were obtained from the American Type Culture Collection (ATCC, Minisota, USA). The tumor cell lines were maintained at the National Cancer Institute, Cairo, Egypt, by serial sub-culturing. Samples were prepared by dissolving 1:1 Stock solution and stored at -20°C in dimethyl sulfoxide (DMSO) at 100 mM. Different concentrations of the milk thistle seeds extract (0.1, 0.5, and 1.0 µg mL-1) were used. The cytotoxicity was carried out using Sulphorhodamine-B (SRB) assay. [27] SRB is a bright pink aminoxanthrene dye with two sulphonic groups. It is a protein stain that binds to the amino groups of intracellular proteins under mildly acidic conditions to provide a sensitive index of cellular protein content. One active substance known as silymarin has strong antioxidant properties and has been shown to inhibit the growth of human prostate, breast, and cervical cancer cells in test tubes [28,29]. Further studies are needed to determine whether milk thistle is safe or effective for people with these forms of cancer.

- **Antioxidant activity:** Antioxidant activity were determined by using the DPPH (2,2-diphenyl-1-picrylhydrazil) radical method [30]. The leaves aqueous extract attained by decoction had the highest value followed by aqueous ethanol extract with DPPH inhibition percentage equal to 68.80% at concentration of 200 µg / ml. The absorbance of the reaction mixture against ultra-pure water were measured at 517 nm using a spectrophotometer. On the other hand, a control solution without sample extract was prepared and its absorbance against ultrapure water was measured at 517 nm in a spectrophotometer device. [31]

- **Gastroprotective Effects:** The gastroprotective effects of Silybum marianum (Milk Thistle) are primarily attributed to its active compound silymarin, which has shown beneficial effects on the gastrointestinal (GI)

system.[32] Protection Against Gastric Ulcers, Anti-inflammatory Effects on the Stomach, Reduction in Helicobacter pylori-Induced Gastritis, Reducing Gastric Acid and Improving pH Balance, Protection Against Non-Steroidal Anti-Inflammatory Drug (NSAID)-Induced Gastric Injury, Antioxidant Protection for the Gastrointestinal Tract, Regulation of Gut Motility, Gastroprotective Effects in Chronic Liver Disease.[33,34]

Miscellaneous properties: Silybum marianum can lower demand for insulin in diabetic patients with alcohol-related liver cirrhosis. However, there is no study about the effect of the herb on glucose metabolism change in patients without liver disease.[35] In a double-eyeless trail on 6 women cases who were chronically using psychoactive medicine the quantum of liver enzymes including alanine transaminase and aspartate transaminase were increased, including alanine transaminase and aspartate transaminase were increased. Taking 400 mg silymarin twice daily for 90 days led to decreased lipoperoxidase and liver damage when compared with the control group. [36,37] Milk thistle dropped the AUC of E- 3174 (active metabolite of losartan) and increased the AUC of losartan, reported in a clinical trial on 12 healthy men. The study reported that the drop in losartan AUC is dependent on inhibition of CYP2C9 [38] Silymarin can reduce adverse effect of chemical drugs similar as anticancer medicines including paclitaxel, cisplatin, methotrexate, fluorouracil, and blood lipid reducing drugs including clofibrate, lovastatin, pravastatin, and psychoactive drugs like haloperidol, tacrine, and some other medicines including nitrous oxide, acetaminophen, metronidazole, and cyclosporine. [39,40]

Formulations of Silybum marianum:

Silybum marianum, also known as milk thistle, is a flowering herb that is used in many marketed formulations. These formulations include tablets, capsules, tinctures gels, and herbal teas, cosmetic creams, suspensions, Nanocrystals, Nanosuspensions and Solid Dispersions solid Nano-dispersions, Soy lecithin nanoparticles. Silymarin has been formulated in liposomes and bilosomes to improve its delivery and hepatoprotective effects. A fermented formulation of Silybum marianum seeds has been developed that is more effective and safer than other market formulations in hepatoprotective activity. Silybum marianum has also been formulated into herbal tablets using lactose co-processed excipients.

CONCLUSION:

In this study, the biological activities of S. marianum in the literature were compiled. As a result of the study, it was determined that the plant has important biological activities. The review of milk thistle (Silybum marianum) highlights its health benefits, traditional uses. With established benefits for liver health, silymarin also shows promise in addressing other conditions such as diabetes, hypertension, viral and oxidative stress. .Furthermore, important research gaps exist, particularly in understanding the detailed mechanisms of action, long-term effects, and variations in response among different demographic groups. Addressing these gaps will be crucial for optimizing the therapeutic use of milk thistle. Ultimately, milk thistle represents a valuable resource in pharmaceutical chemistry, bridging traditional herbal medicine and modern therapeutic approaches. In this context, it has been determined that the plant can be a natural agent and can be used in pharmacological designs. Ongoing research and adherence to quality control standards will be essential for maximizing its

benefits and integrating it effectively into clinical practice.

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