

**SCHEDULING STATUS : Not Schedules**

**PROPRIETARY NAME AND DOSAGE FORM:**

M-RUB GREEN

**COMPOSITION:**

**Each 1 g contains:**

Methyl Sulphonyl Methane(MSM) 100 mg  
Glucosamine sulfate sodium 2 mg  
*Eucalyptus globulus* (Eucalyptus oil) 100 mg  
*Arnica montana* (Arnica extract) 30 mg  
*Salix alba* (Willow bark extract) 10 mg  
*Zingiber officinale* (Ginger Root extract) 50 mg  
*Aloe barbadensis* (Aloe vera) 50 mg  
*Panax ginseng* (Ginseng Root Extract) 50 mg  
Menthol 50 mg  
Echinacea 50 mg  
Tea Tree oil 5 mg  
Capsaicin 1 mg  
Methylsalicylate 0,5 mg

**PHARMACOLOGICAL CLASSIFICATION:**

D.17.0 Muscular System.

**PHARMACOLOGICAL ACTION (PHARMACOKINETICS, PHARMODYNAMICS AND SUMMARY OF CLINICAL STUDIES WHERE APPLICABLE):**

*MSM (Methylsulphonylmethane)* is an organic form of sulphur which is readily assimilated by the body. Sulphur is a vital element, often in short supply, which is needed to manufacture synovial fluid, cartilage and connective tissue. MSM has similar therapeutic benefits as a mineral hot springs, as both are rich in sulfur that relieves arthritis, chronic back pain, tendonitis and neck pain.

One of the most significant uses of MSM as a supplement is its demonstrated ability to relieve pain and inflammation. When rigid fibrous tissue cells swell and become inflamed, pressure and pain result. Since MSM can restore flexibility and permeability to cell walls, fluids can pass through the tissues more easily. This helps equalize pressure and reduce or eliminate the cause of pain. Harmful substances such as lactic acid and toxins are allowed to flow out, while nutrients are permitted to flow in. This prevents the pressure buildup in cells that causes inflammation.

*Arnica* – is a fragrant, bitter, and astringent herb that relieves pain and inflammation and clears fungal and bacterial infections. It contains the anti-inflammatory sesquiterpene lactone helanalin, as well as flavones, flavonols, triterpenoids, phenolic acid, polysaccharides and an essential oil containing thymol, thymolmethylether and azulene that soothe muscle aches, reduce inflammation, and heal wounds. It is often used for injuries such as sprains and bruises.

A pain relief composition, with an effective amount of a nerve inhibiting or pain relief component capsaicin, which numbs or inhibits the nerve endings that signal pain, in combination with an effective amount of an inflammation control component which is designed to reduce or relief inflammation, swelling, redness, fever and/or pain in the joints and muscles associated with inflammation. Other pain relief agents which may be used in combination with capsaicin include, Aloe vera, menthol and emu oil.

Menthol is included as a cooling component. This component also decreases the discomfort and burning associated with capsaicin and pain perception.

Ginseng is a circulation-Increasing component that is included to effectuate increased oxygen uptake, and better penetration of the actives to the skin and nerves, included are. It is designed to increase circulation in the capillaries of the skin resulting in increased oxygen update and better delivery and penetration of the pain relieving ingredients to the nerves and skin. Other circulation increasing agents, which are included, are MSM and ginger.

The present invention further provides a joint and/or muscle soothing and anti-inflammatory complex comprising: Glucosamine, Ginger Root extract, MSM, Aloe barbadensis and Salix alba (white willow) bark extract.

Glucosamine is found naturally in the body and a building block of healthy cartilage, and is an amino sugar, which is a key building block to the synthesis of glycosaminoglycans, hyaluronic acid and proteoglycans. This agent encourages joints to become more elastic and resilient. MSM works synergistically with Glucosamine to reduce muscle and joint pain, swelling and inflammation.

Ginger root extract is a natural herbal alternative to COX-2 inhibitors, and inhibits COX-2 enzymes that cause painful joints and muscles, thus reducing inflammation and pain

Aloe barbadensis leaf juice extract helps to reduce joint and muscle pain associated with arthritis, as well as pain related to tendonitis and injuries. It further provides anti-inflammatory and pain-relieving benefits.

Salix alba (white willow) bark extract is rich in tannins and salicylic acid-like materials. The freshly prepared extract has been reported to have analgesic, antiseptic, astringent, anti-pyretic and anti-inflammatory properties.

Echinacea has antiseptic properties on the skin.

Eucalyptus stimulates circulation, warms the body.

Tea Tree Oil is known for its powerful antiseptic qualities

**INDICATIONS:**

**M-RUB GREEN** provides natural relief from sore muscles and joints and arthritis symptoms.

**CONTRA-INDICATIONS:**

Known sensitivity to the product or its components.

**M-RUB GREEN** contains arnica that includes a compound that acts in the same way as oxytocin, which is used to induce labor and for this reason pregnant mothers should not use arnica in any form or way.

**WARNINGS :**

Arnica is an extremely potent herb, which may cause dermatitis when used externally over a prolonged period (See SIDE-EFFECTS AND SPECIAL PRECAUTIONS)

**INTERACTIONS:**

When taken orally the antiplatelet properties of willow bark extracts may increase the risk of uncontrolled bleeding if it is taken at the same time as medicine or herbals that also decrease the blood's ability to clot e.g. aspirin or warfarin.

**SAFETY IN PREGNANCY AND LACTATION:**

**M-RUB GREEN** was not tested in pregnant and lactating mothers.

**DOSAGE AND DIRECTIONS FOR USE**

EXTERNAL USE ONLY.

Massage **M-RUB GREEN** gently into skin of affected areas until it disappears as often as required, about 2 to 3 times a day in acute cases.

**SIDE EFFECTS AND SPECIAL PRECAUTIONS FOR USE:**

None known. **M-RUB GREEN** contains arnica and prolonged use may irritate the skin, causing eczema, peeling, blisters, or other skin conditions. Arnica should not be used on broken skin, such as leg ulcers. Also, people who are hypersensitive or allergic to the herbs should avoid it.

**INTERACTIONS:**

Do not mix **M-RUB GREEN** together with other products it will reduce the effectiveness of the product.

**KNOWN SIGNS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**

None known. Treatment is symptomatic and supportive.

**IDENTIFICATION:**

White to light cream crystalline ointment. It has a characteristic odour of natural herbs.

**PRESENTATION**

**M-RUB GREEN** is packed in white plastic tubes with a white tube containing 80 g ointment or white plastic jars with white lid containing 150 g ointment.

**STORAGE INSTRUCTIONS:**

Store below 25 °C. Avoid direct sunlight and moisture. KEEP OUT OF REACH OF CHILDREN.

**REGISTRATION NUMBER ( OR REFERENCE NUMBER):**

Registry number : 031702

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:**

DRA Pharmaceuticals cc, 15 Victoria Link, Route 21 Corporate Park, Irene X 31.

**DATE OF NOTIFICATION OF APPROVAL OF THIS SCIENTIFIC PACKAGE INSERT:**

To be allocated