

ASPIRIN and ARNICA CREAM AUST R59072

Composition: Aspirin B.P. and Tincture Arnica B.P.C in a 'Sorbolene Cream like' base.

Description: Aspirin and Arnica cream is a white, pleasantly perfumed, non-greasy oil in a water emulsion containing Aspirin B.P. which is a white crystalline powder, stable in dry air, but which gradually hydrolyses in contact with moisture to acetic acid and salicylic acids. Aspirin and Arnica Cream is a fairly unstable emulsion and will not handle very high or very low temperatures. It will "crack" or liquify if held below or above room temperature for any period of time. Please store at or just below room temperature (15-25 C) to ensure maximum pharmaceutical quality. The aspirin content remains relatively unaffected and the cream can still be used for some time. However, since this mainly affects the cosmetic qualities only, if this occurs during delivery or storage, please notify the manufacturer to arrange replacement stock.

Aspirin and Arnica Cream contains excipients Cetomacrogol, Paraffin Liquid, White Soft Paraffin, Propylene Glycol, Melaleuca oil, Chlorocresol (preservative only) and Water.

Pharmacology

Mechanism of Action: Aspirin and Arnica Cream is an anti-inflammatory and analgesic preparation designed for external application with rubbing. Due to a 'sorbolene cream like' base, it exerts an emollient action, as with other Non-Steroidal Anti-inflammatory Drugs (NSAIDS), its mode of action is unknown, however its ability to inhibit prostaglandin synthesis may be involved in the anti-inflammatory effect.

Pharmacodynamics Effects: In inflammation of traumatic or rheumatic origin, Aspirin and Arnica Cream has been shown to relieve pain, reduce oedema, and shorten the time to return of normal function.

Indications: Short term (up to 2 weeks) local symptomatic treatment of the following musculoskeletal inflammatory conditions:

- Acute soft tissue injuries, including sprains, tendinitis and sports injury.
- Localised forms of soft tissue rheumatism, for example tendinitis, bursitis.

Contraindications: Known hypersensitivity to Aspirin, Propylene Glycol, Isopropyl Alcohol, Melaleuca Oil or the other ingredients in the cream.

Patients in whom attacks of asthma, urticaria or acute rhinitis are precipitated by aspirin or other non-steroidal anti-inflammatory drugs. (NSAIDS)

Precautions: Aspirin and Arnica Cream should be applied only to intact, healthy skin and not to skin wounds, infections, exudative dermatoses or open injuries. It should not be allowed to come into contact with the eyes or mucous membranes, and should never be taken by mouth.

Warnings: The likelihood of systemic side effects occurring following topical Aspirin is small compared with the frequency of side effects following oral aspirin, however, when Aspirin and Arnica Cream is applied to relatively large areas of skin and over a prolonged period of time the possibility of systemic side effects cannot be excluded. In general, topical NSAIDS should be used with caution in those patients with a history of (or active) gastrointestinal ulceration or bleeding or severe renal impairment.

Use in Pregnancy: Category C. Non-steroidal anti-inflammatory drugs inhibit prostaglandin synthesis and when given during the latter part of pregnancy, may cause closure of the fetal ductus arteriosus, fetal renal impairment, inhibition of platelet aggregation, and delay labour and birth. Continuous treatment with NSAIDS during the last trimester of pregnancy should only be given on sound indications. During the last few days before expected birth, agents with an inhibitory effect on prostaglandin synthesis should be avoided.

Safety of Aspirin in pregnancy has not been established therefore Aspirin and Arnica Cream should not be used in pregnant women or those likely to become pregnant unless the expected benefits are likely to outweigh any possible risk.

Drug Interactions: No drug interactions during treatment with Aspirin and Arnica Cream have been reported. The concurrent use of NSAIDs and warfarin has been associated with severe, sometimes fatal haemorrhage. The exact mechanism of the interaction between NSAIDs and warfarin is unknown, but may involve enhanced bleeding from NSAID-induced gastrointestinal ulceration or an additive effect of anticoagulation by warfarin and inhibition of platelet function by NSAIDs. Systematic reactions are unlikely to occur when Aspirin and Arnica Cream is used as recommended.

Adverse Reactions:

- Local Reactions: Occasional allergic or non-allergic contact dermatitis (with symptom and signs such as itching, reddening, oedema or scaling of skin).
- Systemic Reactions: In isolated case, generalised skin rash, hypersensitivity reactions e.g. asthmatic attack, angioedema.

Dosage and Administration:

- Adults: Aspirin and Arnica Cream is applied locally to the skin 3 or 4 times daily, and rubbed in gently. The amount needed depends on the size of the painful site. The duration of treatment depends on the indication and the response obtained. Treatment beyond two weeks duration is not recommended and therapy should be reviewed after this time.
- Children: Dosage recommendations and indications for the use of Aspirin and Arnica Cream in children have not been established.

Pack: White, creamy non-greasy oil emulsion in a Sorbolene Cream like base. Available in 50g glass jars with plastic lid.

For more information, or any question you may have, please contact us: sales@aspirinandarnica.com.au

