

Arnigel®

GEL

SCHEDULING STATUS:

Unscheduled

PROPRIETARY NAME AND DOSAGE FORM:

ARNIGEL®, Gel

COMPOSITION:

Each 100g of gel contains:

Arnica montana mother tincture..... 7 g

Excipients: Carbomer, 10 % sodium hydroxide solution, ethyl alcohol (96 % V/V) purified water

PHARMACOLOGICAL CLASSIFICATION:

Homeopathic medicine A32-2 Other

PHARMACOLOGICAL ACTION:

Acts homeopathically and locally in the treatment of minor injury.

INDICATIONS:

Homeopathic medicinal product used in adults and children over 1 year of age as topical supportive treatment for minor injury (bruises, muscle fatigue, etc...) in which the skin remains unbroken.

CONTRA-INDICATIONS:

Children under 1 year of age.

Hypersensitivity to the active substance Arnica or to any of the excipients included in this homeopathic medicinal product.

Do not use on mucous membranes, eyes, oozing dermatosis, infected lesions or wounds.

WARNINGS:

For external use only. Do not apply to open wounds. If symptoms do not improve or worsen, treatment should be reassessed.

In case of doubt, ask your practitioner.

INTERACTIONS:

Not recommended in combination with Antivitamin K.

Ask your practitioner or pharmacist if you are using, have recently used or might use any other medicines.

PREGNANCY AND LACTATION:

Ask your practitioner for advice during pregnancy. Do not use on the breasts while breastfeeding.

DOSAGE AND DIRECTIONS FOR USE:

Cutaneous use.

Apply a thin layer of Arnigel® to the painful region as soon as possible, lightly massaging until the gel has been completely absorbed. Renew the application once or twice a day.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

Dermatosis risk for hypersensitive person to Arnica. Allergic reaction: stop using the treatment.

Due to the presence of alcohol, frequent applications on skin may provoke irritation and skin dryness.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

None known

IDENTIFICATION:

Clear gel in an aluminium tube.

PRESENTATION:

Gel in a sealed 75 g aluminium tube with epoxy-phenol inner varnish. One cardboard box contains one 75 g aluminium tube and a package insert.

STORAGE INSTRUCTIONS:

Store at or below 30°C. Keep out of sight and reach of children.

Do not use after the expiry date stated on the cardboard box.

Keep the tube closed.

REGISTRY NUMBER:

142508

NAME AND BUSINESS ADDRESS OF THE APPLICANT:

VJ Bartlett, 1st Floor Convention Tower,
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Cape Town, 8001

ENQUIRIES: Tel (021) 403 - 6390

Website: www.lebron.co.za

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INSERT:

28 April 2010

Arnigel®

GEL

SKEDULERINGSSTATUS:

Ongeskeduleerd

EIENDOMSNAAM:

ARNIGEL Gel

SAMESTELLING:

100 g gel bevat:

Arnica montana MT7 g

Onaktiewe bestanddele: Carbomer, 10 % natriumhidroksied oplossing, etielalkohol (96 % v/v) gesuiwerde water

FARMAKOLOGIESE KLASSEKATEGORIE:

Homeopatiese medisyne A32.2 Ander

FARMAKOLOGIESE WERKING:

Hierdie produk werk plaaslik op 'n homeopatiese wyse in behandeling van geringe beserings.

INDIKASIES:

Homeopatiese geneesmiddel wat gebruik word in volwassenes en kinders ouer as 1 jaar as plaaslike ondersteunende behandeling vir geringe beserings (kneusings en vermoeide spiere) waar die vel nie gebroke is nie.

KONTRA-INDIKASIES:

Kinders onder die ouderdom van 1 jaar.
Hipersensitiwiteit teenoor die aktiewe bestanddeel of enige van die onaktiewe bestanddele.
Moet nie op slymvliese , oë, druipe dermatoses, besmette letsels of wonde gebruik word nie.

WAARSKUWINGS:

Slegs vir uitwendige gebruik . Moet nie aan oop wonde toedien nie.
Indien simptome nie verbeter nie of vererger, moet behandeling heroorweeg word.
In geval van twyfel, raadpleeg u praktisyn.

INTERAKSIES:

Nie aanbeveel in kombinasie met Antivitamien K.
Raadpleeg u praktisyn of apteker indien u onlangs, tans, of beplan om enige ander medisyne te gebruik.

SWANGERSKAP EN BORSVOEDING:

Adviseer u praktisyn tydens swangerskap. Moet nie op die borste tydens borsvoeding gebruik nie.

DOSIS EN GEBRUIKSAANWYSINGS:

Kutane gebruik.

Wend 'n dun laag ArniGel aan op die pynlike area so gou as moontlik , terwyl dit liggies masseer word totdat die gel heeltemal geabsorbeer is . Herhaal die prosedure een of twee keer per dag.

NEWE-EFFEKTE EN SPESIALE

VOORSORGMATREELS:

Dermatitis risiko in hipersensitiwiteit vir arnica mag voorkom.

Allergiese reaksie : Staak die behandeling.

As gevolg van die teenwoordigheid van alkohol, mag gereelde aanwendings op vel irritasie en vel droogheid veroorsaak.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

Geen bekend nie.

IDENTIFIKASIE:

Deurskynende gel in 'n aluminium buis.

AANBIEDING:

Gel in 'n verseëlde 75 g aluminium buis met epoxy-fenol innerlike vernis. Een kartondoos wat 'n 75 g aluminium buis en 'n voubiljet bevat .

BERGINGSANWYSINGS:

Bewaar teen of benede 30° C. Hou buite bereik en sig van kinders.

Moenie na die vervaldatum wat op die kartondoos vermeld is gebruik nie.
Hou die buis toegesluit.

REGISTERNOMMER:

142508

NAAM EN BESIGHEIDSAFDRAGER VAN APPLIKANT:

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Webtuiste: www.lebron.co.za

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