

PATIENT INFORMATION LEAFLET

Scheduling status: To be allocated by Council upon registration

MPH UniSpray Topical spray

D33.6 Complementary Medicine: Discipline Specific; Western Herbal Medicine.

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety and intended use.

Read all of this leaflet carefully because it contains important information for you.

MPH UniSpray Topical spray is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use MPH UniSpray carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share MPH UniSpray with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What MPH UniSpray is and what it is used for
2. What you need to know before you use MPH UniSpray
3. How to use MPH UniSpray
4. Possible side effects
5. How to store MPH UniSpray
6. Contents of the pack and other information

1. What MPH UniSpray is and what it is used for

MPH UniSpray Topical spray is a light, non-sticky spray for easy topical application without having to touch the product with bare hands. When applied topically, the cooling sensation and soothing action:

- Provides temporary relief of muscular cramps and rheumatic pain (i.e. joint pain, back pain, tennis – and golfer's elbow, frozen shoulders, sprains and strains)
- Improves blood circulation in micro-vessels
- Decrease the sensation of "heavy legs"
- Provides temporary relief of pain and itching associated with sunburn, insect bites and other minor skin irritations.
- Provides temporary relief of mild nasal congestion and chest congestion.

2. What you need to know before you use MPH UniSpray

MPH UniSpray is for external use only.

Do not use MPH UniSpray:

- If you are hypersensitive (allergic) to any of the ingredients in MPH UniSpray. Talk to your doctor if this applies to you.
- If you have epilepsy, asthma, persistent or chronic cough, or other chronic lung conditions.
- With other products containing camphor, menthol and/or eucalyptus.
- On the face or near the nose or mouth.
- If you are pregnant or breastfeeding.
- Do not apply this product to broken, irritated or sensitive skins.

Warnings and precautions

WARNING: Contains CAMPHOR. Harmful if swallowed. For external use only. Keep out of reach of children.

CAUTION Flammable Gas

Take special care :

- If accidental ingestion occurs, seek urgent medical attention or contact a Poison Information Centre
- If symptoms persist or worsen, reoccur or are accompanied by a fever, rash or persistent headache, discontinue use and consult a relevant health care provider.
- Do not use topically on broken, irritated or very sensitive skins.
- Do not inhale the spray
- Avoid direct contact with eyes, mucous membranes, genitals and nose & mouth.
- Avoid exposure of applied area to the sun.
- Do not use with other products containing camphor, menthol and/or eucalyptus.
- If you experience pain, swelling or blistering, stop use and get medical help right away.
- Keep out of reach of children
- For external use only.
- Use exclusively for the intended purpose.

Children and adolescents

Do not use MPH UniSpray for children under 2 years. For children (2-12yrs) MPH UniSpray should be applied by adults only. Do not spray near the face and do not inhale the spray.

Other medicines and MPH UniSpray

Always tell your health care provider if you are taking any other medication. (This includes all complementary or traditional medicine)

- Do not use with other products containing camphor, menthol and/or eucalyptus.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using this medicine. Do not use if pregnant.

Driving and using machinery

MPH UniSpray is not expected to have an influence on the ability to drive and use machines. It is not always possible to predict to what extent it may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which MPH UniSpray affects them.

3. How to use MPH UniSpray

Always use MPH UniSpray exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Shake well before use. Hold can upright, 10 – 15 cm from the skin and apply evenly to the affected areas, up to three (3) times per day. Allow the area to dry until absorbed into the skin. Do not exceed the recommended dosage.

If the product came into contact with your hands, avoid touching your eyes after application and wash your hands thoroughly.

If you use more MPH UniSpray than you should

You may experience the following signs and symptoms:

- Rashes
- Intense burning discomfort
- Nausea
- Dizziness and/or headaches

In the event of overdose, discontinue use, rinse the area with water and consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take MPH UniSpray

Do not apply a double dose to make up for the forgotten individual dosage.

If you stop taking MPH UniSpray

There are no known withdrawal effects.

4. Possible side effects

MPH UniSpray can have side effects. (Also see **If you use more MPH UniSpray than you should**) Not all side effects reported for MPH UniSpray are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking it, please consult your health care provider for advice. Tell your doctor if you notice any of the following:

Side effects:

- Skin rash
- Intense burning discomfort
- Nausea

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of MPH UniSpray.

5. How to store MPH UniSpray

Store all medicines out of reach of children.

Extremely flammable aerosol. Pressurised container; may explode if heated. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Do not pierce or burn, even after use. Avoid direct sunlight. Do not expose container to temperatures exceeding 50 °C, even when empty.

Store at or below 25°C, in a dry place in the original container.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MPH UniSpray contains

The active substances per 100 g spray are Menthol 3,0 g, Camphor 2,0 g, Peppermint oil 1.25 g, Eucalyptus 1,0 g and Clove oil 0,25 g. The other ingredients are denatured alcohol, butane and propane.

What MPH UniSpray looks like and contents of the pack

MPH UniSpray is a colourless spray with the odour of menthol, camphor eucalyptus and clove.

MPH UniSpray is presented in an aluminium spray can of 120 ml with a blue lid.

Holder of certificate of registration

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This leaflet was last revised in

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Application number

To be allocated by Council upon registration

Access to the corresponding Professional Information

Vist www.mpharmherbs.com to read the Professional Information.

Skedulering status: Sal toegestaan word deur die Raad na registrasie.

MPH UniSpray topikale spreï

D33.6 Komplementere Medisyne: Dissipline Spesifiek; Westerse Krui Medisyne,

Hierdie ongeregistreerde medikasie is nog nie deur die SAHPRA geëvalueer vir die kwaliteit, veiligheid en bedoelde gebruik nie.

Lees die hele voubiljet aandagtig deur, want dit bevat belangrike inligting vir u.

MPH UniSpray topikale spreï is beskikbaar sonder 'n doktersvoorskrif om jou gesondheid te handhaaf. Jy moet nietemin steeds MPH UniSpray versigtig gebruik om die beste resultate daaruit te kry.

- Hou die voubiljet. Dit mag dalk nodig wees om dit weer te lees.
- Moenie MPH UniSpray met enige ander persoon deel nie.
- Vra jou apteker indien jy meer inligting of advies benodig.

Wat is in die voubiljet

1. Wat MPH UniSpray is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy MPH UniSpray gebruik
3. Hoe om MPH UniSpray te gebruik
4. Moontlike nuwe-effekte
5. Hoe om MPH UniSpray te stoor
6. Inhoud van die houër en ander inligting

1. Wat MPH UniSpray is en waarvoor dit gebruik word

MPH UniSpray Topikale spreï is a ligte, nie-klewerige spreï vir gemaklike topikale aanwending sonder om die produk met die hande aan te raak. Wanneer dit aan die vel aangewend word sal die strelende gevoel en die verkoelende werking die volgende voordele inhou:

- Verskaf tydelike verligting van spierkrampe en rummatiek pyn (bv. Gewrigspyn, ruggpyn, tennis – en golfspelers elmboog, seer skouers, swikke en verstuiings)
- Bevorder bloedsirkulasie in mikro-bloedvate
- Verminder die gevoel van "moee bene"
- Verskaf tydelike verligting van pyn en jeuk geassosieer met sonbrand, insekbyte en ander matige vel irritasies.
- Verskaf tydelike verligting van matige neus kongestie en toe bors.

2. Wat jy moet weet voordat jy MPH UniSpray neem

Moet nie MPH UniSpray gebruik:

- Indien u sensitief (allergies) is vir enige van die bestanddele in MPH UniSpray nie (in afdeling 6 gelys). Raadpleeg u dokter as dit op u van toepassing is.
- Indien u epilepsie, asma, knaende of chroniese hoës, of ander chroniese long toestande onderlede het nie.
- Tesame met ander preparate wat camphor, menthol en/of eucalyptus bevat nie.
- Op die gesig of naby die neus of mond nie.
- Indien u swanger is of borsvoed nie.
- Op gebroke, geïrriteerde of sensitiewe vel areas nie.

Waarskuwings en voorsorgmaatreëls

WAARSKUWING: Bevat CAMPHOR. Skadelik indien ingesluk. Slegs vir eksterne gebruik. Hou buite bereik van kinders.

WAARSKUWING: Vlambare Gas

Neem spesiale sorg:

- Indien MPH UniSpray per ongeluk ingeneem is moet mediese behandeling onmiddelik verkry word of kontak 'n vergiftigings sentrum
- Indien simptome bly of vererger, terugkeer of gepaardgaan met 'n koors, uitslag of knaende hoofpyn, staak gebruik en raadpleeg 'n relevante gesondheidsorg deskundige.
- Nie vir gebruik op gebroke, geïrriteerde of sensitiewe vel areas nie.
- Moenie die sproei inasem nie.
- Vermoed direkte kontak met oe, slymvliese, genitale areas, neus en mond.
- Beskerm behandelde areas teen direkte blootstelling aan die son.
- Moenie saam met ander produkte wat camphor, menthol en/of eucalyptus bevat gebruik nie.
- Indien u pyn, swelling of blase ervaar, staak gebruik en kry onmiddelik mediese hulp.
- Hou buite bereik van kinders
- Slegs vir eksterne gebruik.
- Gebruik slegs vir die aangeduide doel.

Kinders en adolessente

Moenie MPH UniSpray vir kinders onder 2 jaar aanwend nie. Vir kinders (2-12 jaar) moet MPH UniSpray slegs deur volwassenes aangewend word. Moenie naby die gesig spuit of sproei inasem nie.

Ander medikasie en MPH UniSpray

Vertel altyd jou gesondheidsorgverskaffer indien jy enige ander medikasie neem. (Dit sluit alle komplementêre en tradisionele medikasie in)

- Moenie saam met ander produkte wat camphor, menthol en/of eucalyptus bevat, gebruik nie.

Swangerskap en borsvoeding

As u swanger is of borsvoed, dink dat u swanger is of van plan is om 'n baba te kry, raadpleeg u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u hierdie medisyne gebruik. Nie vir gebruik tydens swangerskap nie.

Bestuur en die gebruik van masjinerie

Daar word nie verwag dat MPH UniSpray enige effek op die vermoë om te bestuur of masjinerie te gebruik sal hê nie. Dit is nie altyd moontlik om te voorspel tot watter mate dit met die daaglikse aktiwiteite van die pasiënt kan inmeng nie. Pasiënte moet toesien dat hulle nie aan die bogenoemde aktiwiteite deelneem totdat hulle bewus is van die mate waartoe MPH UniSpray hulle beïnvloed nie.

3. Hoe om MPH UniSpray te gebruik

Neem altyd MPH UniSpray presies soos wat dit aangedui word in hierdie voubiljet of soos jou dokter, apteker of verpleegster dit vir jou voorgeskryf het. Raadpleeg jou dokter, apteker of verpleegster indien u onseker is.

Skud voor gebruik. Hou kannetjie regop, 10 – 15 cm van die vel en wend 'n egalige lagie MPH UniSpray aan die geaffekteerde area aan tot drie (3) keer per dag. Laat die area toe om droog te word totdat die MPH UniSpray, geabsorbeer is deur die vel. Moenie die aanbevele dosering oorskry nie.

Indien met hande in kontak gekom het, vermy die oe en was hande deeglik.

Indien jy meer MPH UniSpray gebruik as wat jy moet:

Jy kan die volgende tekens en simptome ervaar:

- Veluitslag
- Intense branderige ongemak
- Naarheid
- Duiseligheid en/of hoofpyn

In geval van oordosering, staak gebruik, spoel area met water en kontak u dokter of apteker. Indien hulle nie beskikbaar is nie, kontak die naaste hospital of vergiftiging sentrum.

As u vergeet om MPH UniSpray te gebruik

Moenie 'n dubbele dosis aanswend om op te maak vir die vergete dosis nie.

As u stop om MPH UniSpray te gebruik

Daar is geen bekende onttrekkingsimptome nie.

4. Moontlike nuwe-effekte

MPH UniSpray kan nuwe-effekte hê (Sien ook **Indien jy meer MPH UniSpray gebruik as wat jy moet**). Nie alle nuwe-effekte wat vir MPH UniSpray aangemeld is, is in hierdie voubiljet nie. Indien jou algehele gesondheid verswak of jy enige ongewenste effekte ervaar terwyl jy dit neem, raadpleeg asseblief jou verskaffer van gesondheidsorg vir advies. Vertel jou dokter indien jy enige van die volgende waarneem:

Neuwe-effekte:

- Vel uitslag
- Intense branderige ongemak

Indien jy enige nuwe-effekte ervaar wat nie in hierdie voubiljet genoem word nie, lig asseblief jou dokter of apteker daarvan in.

Aanmelding van nuwe-effekte

As jy enige nuwe-effekte kry, praat met jou dokter, apteker of verpleegster. Jy kan ook nuwe-effekte aan SAHPRA rapporteer deur die **"6.04 Adverse Drug Reaction Reporting Form"** wat gevind kan word onder SAHPRA se publikasies: <https://www.sahpra.org.za/Publications/Index/8> te voltooi. Deur nuwe-effekte aan te meld, kan jy help om meer inligting rondom die veiligheid van MPH UniSpray te verskaf.

5. Hoe om MPH UniSpray te berg

Berg alle medikasie buite die bereik van kinders.

Vlambare gas. Houër is onder hoe druk, mag ontplof indien verhit word. Vermoed hitte, warm oppervlakte, vonke, vlamme en ander bronne van ontbranding, Rook verbode. Moenie die kannetjie probeer deurboor of brand nie, selfs na gebruik wanneer die kannetjie leeg is nie. Vermoed direkte sonlig. Moenie die kannetjie aan temperature bo 50 °C, blootstel nie, selfs nie na die kannetjie leeg is nie.

Berg benede 25 °C, in 'n droë plek in die oorspronklike verpakking.

Bring alle ongebruikte medikasie terug na jou apteker.

Moenie ongebruikte medikasie by dreine of rioolstelsels (bv. toilette) afspoel nie.

6. Inhoud van die houër en ander inligting

Wat MPH UniSpray bevat

Die aktiewe bestanddele per 100 g spreï is Menthol 3,0 g, Camphor 2,0 g, Peppermint oil 1.25 g, Eucalyptus 1,0 g and Clove oil 0,25 g, Die ander bestanddele is gedenatureerde alkohol, butaan en propaan.

Hoe MPH UniSpray lyk en die inhoud van die houër

MPH UniSpray is 'n kleurlose spreï met die geur van menthol, camphor, eucalyptus en naeltjies.

MPH UniSpray word aangebied in 'n aluminium kannetjie met 'n blou prop in 'n grootte van 120 ml.

Houër van die sertifikaat van registrasie

MPharm Herbaceuticals
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Lyttelton, 0140
Tel No: 079 870 1407

Die voubiljet was laas hersien in

April 2023

Aansoek nommer

Sal toegestaan word deur Raad tydens registrasie

Toegang tot die ooreenstemmende professionele inligting

Besoek www.mpharmherbs.com om die professionele inligting te lees.