

PATIENT INFORMATION LEAFLET

Scheduling status: To be allocated by Council upon registration

MPH UniRub liposomal gel

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

- Keep this leaflet. You may need to read it again.
- Do not share MPH UniRub 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 UniRub is and what it is used for
2. What you need to know before you use MPH UniRub
3. How to use MPH UniRub
4. Possible side effects
5. How to store MPH UniRub
6. Contents of the pack and other information

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

MPH UniRub liposomal gel is a light, non-sticky, smooth gel with a deep penetrating formula. 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 UniRub

MPH UniRub is for external use only.

Do not use MPH UniRub:

- If you are hypersensitive (allergic) to any of the ingredients in MPH UniRub. 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.

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.
- Avoid direct contact with eyes, mucous membranes, genitals and nose and 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.

Children and adolescents

Do not use MPH UniRub for children under 2 years. For children (2-12yrs) MPH UniRub should be applied by adults only.

Other medicines and MPH UniRub

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 UniRub 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 UniRub affects them.

3. How to use MPH UniRub

Always use MPH UniRub 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.

Apply thinly and evenly to the affected areas, up to three (3) times per day. Massage the area gently with MPH UniRub, until absorbed into the skin Do not exceed the recommended dosage.

For sore muscles: Massage MPH UniRub into muscles after exercise to relieve muscle soreness or stiffness

Avoid touching your eyes after application and wash your hands thoroughly after use.

If you apply more MPH UniRub 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 UniRub

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

If you stop taking MPH UniRub

There are no known withdrawal effects.

4. Possible side effects

MPH UniRub can have side effects. (Also see **If you apply more MPH UniRub than you should**) Not all side effects reported for MPH UniRub 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 UniRub.

5. How to store MPH UniRub

Store all medicines out of reach of children. Store at or below 25°C, in a dry place in the original container. Avoid direct sunlight. 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 UniRub contains

The active substances per 100 g gel 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 polysorbate, carbopol ultrez, euxyl, methylene blue, purified water and sodium hydroxide

What MPH UniRub looks like and contents of the pack

MPH UniRub is a white to light-blue cream-gel with the odour of menthol, camphor and eucalyptus.

MPH UniRub is presented in a white plastic jar with a white plastic dome lid in sizes of 250 g and 125 g.

Holder of certificate of registration

MPharm Herbaceuticals
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Lytelton, 0140
Tel No: 079 870 1407

This leaflet was last revised in

April 2023

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 UniRub liposomale gel

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

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

Wat is in die voubiljet

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

1. Wat MPH UniRub is en waarvoor dit gebruik word

MPH UniRub liposomale gel is 'n ligte, nie-klewerige, gladde gel met 'n goed geabsorbeerde formule. Wanneer dit aan die vel gesmeer word sal die strelende gevoel en die verkoelende werking die volgende voordele inhou:

- Verskaf tydelike verligting van spierkrampe en rummatak pyn (bv. Gewrigspyn, ruggyn, tennis – en gholfspelers elmboog, seer skouers, swikke en verstuitings)
- Bevorder bloedsirkulasie in mikro-bloedvate
- Verminder die gevoel van "moeie 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 UniRub neem

Moet nie MPH UniRub gebruik:

- Indien u sensitief (allergies) is vir enige van die bestanddele in MPH UniRub nie (in afdeling 6 gelys). Raadpleeg u dokter as dit op u van toepassing is.
- Indien u epilepsie, asma, knaende of chroniese hoes, 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.

Neem spesiale sorg:

- Indien MPH UniRub 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.
- 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.

Kinders en adolessente

Moenie MPH UniRub vir kinders onder 2 jaar aanwend nie. Vir kinders (2-12 jaar) moet MPH UniRub slegs deur volwassenes aangewend word.

Ander medikasie en MPH UniRub

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 UniRub 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 UniRub hulle beïnvloed nie.

3. Hoe om MPH UniRub te gebruik

Neem altyd MPH UniRub 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.

Wend 'n dun, egalige laag MPH UniRub aan die geïrriteerde area aan tot drie (3) keer per dag. Die area kan gemasseer word totdat die MPH UniRub, geabsorbeer is deur die vel. Moenie die aanbevele dosering oorskry nie.

Vir seer spiere: Masseer spiere met MPH UniRub na oefening om styfheid en seer spiere te verlig.

Vermoed die oe en was hande deeglik na gebruik.

Indien jy meer MPH UniRub 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 UniRub aan te wend

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

As u stop om MPH UniRub te gebruik

Daar is geen bekende onttrekkingsimptome nie.

4. Moontlike nuwe-effekte

MPH UniRub kan nuwe-effekte hê (Sien ook **Indien jy meer MPH UniRub gebruik as wat jy moet**). Nie alle nuwe-effekte wat vir MPH UniRub 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:

Nowe-effekte:

- Vel uitslag
- Intense branderige ongemak
- Naarheid

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 UniRub te verskaf.

5. Hoe om MPH UniRub te berg

Berg alle medikasie buite die bereik van kinders.

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 UniRub bevat

Die aktiewe bestanddele per 100 g gel is Menthol 3,0 g, Camphor 2,0 g, Peppermint olie 1,25 g Eucalyptus 1,0 g en Naeltjie olie 0,25 g.

Die ander bestanddele is polysorbaat, carbopol ultrez, euxyl, metileen blou, gesuiwerde water en natrium hidrosied.

Hoe MPH UniRub lyk en die inhoud van die houër

MPH UniRub is 'n wit tot lig-blou romerige gel met die geur van menthol, camphor, eucalyptus.

MPH UniRub word aangebied in 'n wit plastiese houër met 'n wit prop in groottes van 250 g and 125 g.

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.mpharmerbs.com om die professionele inligting te lees.