

PROFESSIONAL INFORMATION

SCHEDULING STATUS

S1

1. NAME OF THE MEDICINE

REMICAINE JELLY (2 g per 100 g gel base), TOPICAL JELLY

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 g gel base contains:

Lignocaine hydrochloride (as monohydrate) 2 g

Preservatives: Methyl hydroxybenzoate 0,06 % *m/m*

Propyl hydroxybenzoate 0,03 % *m/m*

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Topical jelly.

A clear, translucent, colourless, semi-viscous jelly.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

REMICAINE JELLY may be used for surface anaesthesia of mucous membranes. It is particularly useful for anaesthesia of the urethra prior to catheterisation or examination.

4.2 Posology and method of administration

For urethral anaesthesia:

Males: Apply 10 to 15 ml

Females: Apply 5 to 7 ml

For topical application:

To broken skin and mucous membranes do not apply more than 10 ml at any one time.

Do not exceed the recommended dose.

4.3 Contraindications

Known hypersensitivity to lignocaine hydrochloride or to any other excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Not to be applied to the eyes.

Care should be exercised when applying the gel to the urethra that trauma has not or does not occur. This might give rise to rapid absorption of the lignocaine hydrochloride causing serious adverse effects and systemic overdose.

REMICAINE JELLY may not be used in children under the age of 2 years.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Safety and efficacy in pregnancy and lactation have not been established.

4.7 Effects on ability to drive and use machines

The effect on the ability to drive and use machines are not known.

4.8 Undesirable effects

Side effects are rare if the dose does not exceed 20 ml. Repeated application to the skin may give rise to allergic skin reactions.

REMICAINE JELLY may cause methaemoglobinaemia.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of REMICAINE JELLY is important. It allows continued monitoring of the benefit/risk balance of REMICAINE JELLY. Health care providers are asked to report any suspected adverse reactions via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>

4.9 Overdose

Bio-availability is low after oral ingestion, and the physical nature of the product makes oral administration unlikely.

Overdosage is more likely if large amounts of the gel are applied to mucous membranes or damaged skin. Symptoms of overdosage are excitation of the central nervous system manifested by yawning, restlessness, excitement, nervousness, dizziness, tinnitus, nystagmus, blurred vision, nausea and vomiting, muscle twitching, tremors and convulsions. Excitation may be followed by depression with drowsiness, respiratory failure and coma.

In the case of overdosage steps should be taken to maintain circulation and respiration and to control convulsions. Convulsions may be controlled by intravenous injection of diazepam or a short-acting barbiturate.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 13.3 Surface anaesthetics.

Lignocaine is a local anaesthetic of the amide group and may be used for local application to mucous membranes.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl hydroxybenzoate (preservative)

Methyl hydroxyethyl cellulose

Propyl hydroxybenzoate (preservative)

Sodium hydroxide

Purified water

Hydrochloric acid solution (For pH-adjustment)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Keep container well-closed. Store at or below 25 °C.

6.5 Nature and contents of container

A sterilised aluminium tube containing 20 ml.

For urethral application an applicator is supplied.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Limited

1 New Road,

Erand Gardens,

Midrand, 1685

Customer Care: 0860 ADCOCK / 232625

8. REGISTRATION NUMBER

G1349 (Act 101 of 1965)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

13 January 1989

10. DATE OF REVISION OF THE TEXT

12 April 2021

Namibia: NS1 03 1002169 (Act No. 13 of 2003)

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S1

REMICAINE JELLY (2 g per 100 g gel base), TOPICAL JELLY

Lignocaine hydrochloride (as monohydrate)

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

REMICAINE JELLY is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use REMICAINE JELLY carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share REMICAINE JELLY with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if the symptoms worsen or do not improve

What is in this leaflet

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

1. What REMICAINE JELLY is and what it is used for

Lignocaine is a local anaesthetic of the amide group and may be used for local application to mucous membranes (moist body surfaces).

REMICAINE JELLY may be used to numb the feeling on the surface of mucous membranes (moist body surfaces). It is particularly useful to numb the feeling in the urethra (tube that leads from the bladder to the outside <of the body>) prior to a catheter being inserted or an examination.

2. What you need to know before you use REMICAINE JELLY

Do not use REMICAINE JELLY

- if you are hypersensitive (allergic) to lignocaine hydrochloride or any of the other ingredients of REMICAINE JELLY (listed in section 6).

Warnings and precautions

Take special care

- not to apply REMICAINE JELLY to your eyes
- when applying the gel to the urethra (tube that leads from the bladder to the outside <of the body>) that trauma has not or does not occur. This might cause rapid absorption of lignocaine hydrochloride causing serious adverse effects and systemic overdose.
- REMICAINE JELLY may not be used in children under the age of 2 years.

Other medicines and REMICAINE JELLY

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

Pregnancy, breastfeeding and fertility

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 REMICAINE JELLY.

Driving and using machines

It is not always possible to predict to what extent REMICAINE JELLY may interfere with your daily activities. You should ensure that you do not engage in driving or using machines until you are aware of the measure to which REMICAINE JELLY affects you.

3. How to use REMICAINE Jelly

Do not share medicines prescribed for you with any other person.

Always use REMICAINE JELLY exactly as described in this leaflet or as your doctor or pharmacist or nurse have told you. Check with your doctor or pharmacist or nurse if you are not sure.

When REMICAINE JELLY is used to numb the feeling in the urethra (tube that leads from the bladder to the outside <of the body>) prior to a catheter being inserted or for an examination you will not be expected to use it yourself. It will be applied by a person who is qualified to do so.

The usual dose to numb the feeling of urethra (the tube that leads from the bladder to the outside <of the body>) is:

Males: Apply 10 to 15 ml

Females: Apply 5 to 7 ml

For topical application:

To broken skin and mucous membranes (moist body surfaces) do not apply more than 10 ml at any one time.

Do not exceed the recommended dose.

If you use more REMICAINE JELLY than you should

Since a health care provider will apply REMICAINE JELLY when used to numb the feeling of the urethra (the tube that leads from the bladder to the outside <of the body>), he / she will control the dosage. However, in the event of overdosage your doctor will manage the overdose.

4. Possible side effects

REMICAINE JELLY can have side effects.

Not all side effects reported for REMICAINE JELLY are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using REMICAINE JELLY, please consult your health care provider for advice.

If any of the following happens, stop using **REMICAINE JELLY** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in breathing,
- rash or itching,
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to REMICAINE JELLY. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- chest pain,
- angina,
- changes in the way your heart beats, for example, if you notice it beating faster,
- difficulty breathing,

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Less frequent side effects:

Side effects are less frequent if the dose does not exceed 20 ml.

Repeated application to the skin may give rise to allergic skin reactions.

REMICAINE JELLY may cause methaemoglobinaemia (rare blood disorder).

Reporting of side effects

If you get side effects, talk to your doctor or 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 REMICAINE JELLY.

5. How to store REMICAINE JELLY

Store all medicines out of reach of children.

- Keep container well-closed.
- Store at or below 25 °C.
- 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 REMICAINE JELLY contains

The active substance is lignocaine hydrochloride 2 g per 100 g gel base

The other ingredients are: methyl hydroxybenzoate, methyl hydroxyethyl cellulose, propyl hydroxybenzoate, sodium hydroxide, purified water and hydrochloric acid solution (for pH-adjustment).

What REMICAINE JELLY looks like and contents of the pack

A clear, translucent, colourless, semi-viscous jelly.

A sterilised aluminium tube containing 20 ml.

For urethral application an applicator is supplied.

Holder of Certificate of Registration

Adcock Ingram Limited

1 New Road, Erand Gardens,

Midrand, 1685

Customer Care: 0860 ADCOCK / 232625

This leaflet was last revised in

12 April 2021

Registration number

G 1349 (Act 101 of 1965)

Namibia: NS1 03 1002169 (Act No. 13 of 2003)
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PASIËNTINLIGTINGSVOUBILJET

SKEDULERINGSSTATUS

S1

REMICAINE JELLY (2 g per 100 g jellie basis), TOPIESE JELLIE

Lignokaïenhydrochloried (as monohidraat)

Lees die hele voubiljet sorgvuldig want dit bevat belangrike inligting

REMICAINE JELLY is beskikbaar sonder 'n doktersvoorskrif vir u om 'n ligte toestand te behandel. U moet REMICAINE JELLY egter steeds omsigtig gebruik om die beste resultate daaruit te kry.

- Hou hierdie voubiljet. U mag dit weer moet lees.
- Moenie REMICAINE JELLY met enige ander persoon deel nie.
- Vra u gesondheidsorgverskaffer of apteker as u meer inligting of raad benodig.
- U moet 'n dokter raadpleeg as die simptome vererger of nie verbeter nie.

Wat in hierdie voubiljet is

1. Wat REMICAINE JELLY is en waarvoor dit gebruik word.
2. Wat u moet weet voordat u REMICAINE JELLY gebruik.
3. Hoe om REMICAINE JELLY te gebruik
4. Moontlike newe-effekte
5. Hoe om REMICAINE JELLY te bêre
6. Inhoud van pak en ander inligting

1. Wat REMICAINE JELLY is en waarvoor dit gebruik word.

Lignokaïen is 'n topiese verdoofmiddel van die amied-groep en kan gebruik word vir plaaslike aanwending aan slymvliese (klam liggaamsoppervlakke).

REMICAINE JELLY kan gebruik word om die gevoel van die slymvliese (klam liggaamsoppervlakke) te verdoof. Dit is veral nuttig om die gevoel in die uretra (buis wat van die blaas na buite <die liggaam> lei voordat 'n kateter ingesit word of voor 'n ondersoek gedoen word.

2. Wat u moet weet voordat u REMICAINE JELLY gebruik

Moenie REMICAINE JELLY gebruik nie

- as u hipersensitief (allergies) is vir lignokaïenhydrochloried of enige van die ander bestanddele van REMICAINE JELLY (in afdeling 6 gelys).

Waarskuwings en voorsorgmaatreëls

Neem spesiale sorg

- om nie REMICAINE JELLY in u oë aan te wend nie.
- dat wanneer die jellie aan die uretra (buis wat van die blaas na buite <die liggaam> lei aangewend word, trauma nie voorkom of voorgekom het nie. Dit mag veroorsaak dat lignokaïenhydrochloried vinnig opgeneem word wat ernstige ongewenste uitwerking en sistemiese oordosis kan veroorsaak.
- REMICAINE JELLY moenie vir kinders onder die ouderdom van 2 jaar oud gebruik word nie.

Ander medisyne en REMICAINE JELLY

Vertel altyd u gesondheidsorgverskaffer as u enige medisyne gebruik. (Dit sluit alle aanvullende of tradisionele medisynes in.)

Swangerskap, borsvoeding en vrugbaarheid

Raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer as u swanger is of borsvoed, dink u mag dalk swanger wees of beplan om 'n baba te hê voordat u REMICAINE JELLY gebruik.

Bestuur en die bedryf van masjinerie

Dit is nie altyd moontlik om te voorspel tot watter mate REMICAINE JELLY by u daaglikse bedrywighede mag inmeng nie. U moet verseker dat u nie bestuur of masjinerie bedryf voordat u bewus is van die mate waartoe REMICAINE JELLY u beïnvloed nie.

3. Hoe om REMICAINE JELLY te gebruik

Moenie medisyne wat aan u voorgeskryf is met enige ander persoon deel nie.

Gebruik REMICAINE JELLY altyd presies soos in hierdie voubiljet of deur u dokter of apteker voorgeskryf is.

Bevestig met u dokter of apteker of verpleegster as u onseker is.

Wanneer REMICAINE JELLY gebruik word om die gevoel in die uretra (die buis wat van die blaas na buite <die liggaam> lei te verdoof voordat 'n kateter ingesit word of 'n ondersoek gedoen word, word daar nie van u verwag om dit self te gebruik nie. Dit sal deur 'n persoon wat daarvoor gekwalifiseer is gedoen word.

Die gewone dosis om die gevoel van die uretra (die buis wat van die blaas na buite <die liggaam> lei te verdoof is:

Mans: Wend 10 tot 15 ml aan

Vroue: Wend 5 tot 7 ml aan

Vir topiese aanwending:

Moenie meer as 10 ml aan gebroke vel en slymvliese (klam liggaamsoppervlakke) ter enige enkele tyd aanwend nie.

Moenie die aanbevole dosis oorskry nie.

As u meer REMICAINE JELLY gebruik as wat u moet

Aangesien 'n gesondheidsorgverskaffer REMICAINE JELLY sal aanwend wanneer dit gebruik word om die uretra (die buis wat van die blaas na buite <die liggaam> lei te verdoof aangewend word, sal hy/sy die dosis beheer. In die geval van oordosering sal u dokter egter die oordosis bestuur.

4. Moontlike newe-effekte

REMICAINE JELLY kan newe-effekte hê.

Nie alle newe-effekte wat vir REMICAINE JELLY aangemeld is word in hierdie voubiljet ingesluit nie. As u algemene gesondheid versleg of as u enige ongewenste gevolge ervaar tydens gebruik van REMICAINE JELLY, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Staak gebruik van **REMICAINE JELLY** as enige van die volgende gebeur, vertel dadelik u dokter of gaan na die ongevalle afdeling by u naaste hospitaal:

- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat asemnood kan veroorsaak,
- uitslag of jeuking,
- floute.

Hierdie is ernstige newe-effekte. As u dit het mag u 'n ernstige reaksie teen REMICAINE JELLY ervaar. U mag dringende mediese aandag of hospitalisasie benodig.

Vertel u dokter onmiddellik of gaan na die ongevalle afdeling by u naaste hospitaal as u enige van volgende opmerk:

- borspyn,
- angina,
- veranderinge in die manier hoe u hart klop, byvoorbeeld as u opmerk dat dit vinniger klop,
- asemnood,

Hierdie is almal ernstige newe-effekte. U mag dringende mediese aandag benodig.

Vertel u dokter as u enige van die volgende opmerk:

Minder algemene newe-effekte:

Newe-effekte is minder gereeld as die dosis nie 20 ml oorskry nie.

Herhaalde aanwending op die vel kan allergiese velreaksies veroorsaak.

REMICAINE JELLY kan methemoglobinemie (’n skaars bloedversteuring) veroorsaak.

Aanmelding van newe-effekte

As u newe-effekte ervaar, praat met u dokter of apteker. U kan newe-effekte ook by SAHPRA aanmeld via die “**6.04 Adverse Drug Reaction Reporting Form**”, aanlyn gevind onder SAHPRA se publikasies:

<https://www.sahpra.org.za/Publications/Index/8>. Deur newe-effekte aan te meld kan u help om meer inligting oor die veiligheid van REMICAINE JELLY te bekom.

5. Hoe om REMICAINE JELLY te bêre

Bêre alle medisyne buite bereik van kinders

- Hou die houer dig toe.
- Bêre teen of laer as 25 °C.
- Gee alle ongebruikte medisyne aan u apteker terug.
- Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) afspoel nie.

6. Inhoud van pak en ander inligting

Wat REMICAINE JELLY bevat

Die aktiewe bestanddeel is lignokaïenhydrochloried 2 g per 100 g jellie basis

Die ander bestanddele is: metielhidroksiebensoaat, metielhidroksie-etiëlsellulose, propielhidroksiebensoaat, natriumhidroksied, gesuiwerde water en soutsuur-oplossing (vir pH-aanpassing).

Hoe REMICAINE JELLY lyk en inhoud van pak

’n Helder, deurskynende, kleurlose semi-viskose jellie.

’n Gesteriliseerde aluminiumbuis wat 20 ml bevat.

’n Toediener word vir uretrale toediening verskaf.

Houer van Registrasiesertifikaat

Adcock Ingram Beperk

New Road 1, Erand Gardens,

Midrand, 1685

Klantediens: 0860 ADCOCK / 232625

Laaste hersieningsdatum

12 April 2021

Registrasienuommer

G 1349 (Wet 101 of 1965)

Namibië: NS1 03 1002169 (Wet Nr. 13 van 2003)

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