SCHEDULING STATUS

S2

ALLERGEX MEPYRAMINE CREAM

Active substance is:

Mepyramine maleate 2 g

Preservative:

Methyl hydroxybenzoate 0,123 % *m/m*

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

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

- Keep this leaflet. You may need to read it again.
- Do not share ALLERGEX MEPYRAMINE CREAM with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve within a few days.

What is in this leaflet

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

Date: 17 March 2022

1. WHAT ALLERGEX MEPYRAMINE CREAM IS AND WHAT IT IS USED FOR

ALLERGEX MEPYRAMINE CREAM contains a medicine called mepyramine maleate.

ALLERGEX MEPYRAMINE CREAM is an anti-allergy medicine. It works by blocking a natural substance (histamine) that your body makes during an allergic reaction.

The active substance is: Mepyramine maleate 2 g

ALLERGEX MEPYRAMINE CREAM is used to relieve:

- Dry, itchy and inflamed skin, skin rashes arising from allergies, itching and inflammation caused by insect stings, bites and nettle rash.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ALLERGEX MEPYRAMINE CREAM

Do not use ALLERGEX MEPYRAMINE CREAM

- If you are hypersensitive (allergic) to mepyramine maleate or any of the other ingredients of ALLERGEX MEPYRAMINE CREAM (listed in Section 6).
- Should not be used for acute skin conditions where fluid-filled blisters form.
- Should not be used in premature infants or neonates.
- Should not be used with an air and water tight trauma medical dressing (occlusive dressings).
- Should not be used on broken skin.

Warnings and precautions

Take special care with ALLERGEX MEPYRAMINE CREAM:

- Do not apply **ALLERGEX MEPYRAMINE CREAM** repeatedly for periods longer than a few days and discontinue treatment immediately if an allergic response to a medicine after skin contact (skin sensitisation) occurs.

Other medicines and ALLERGEX MEPYRAMINE CREAM:

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

- No significant interactions described

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 taking this medicine

The safety of ALLERGEX MEPYRAMINE CREAM in pregnancy, breastfeeding and fertility has not been established.

Driving and using machinery

You may feel drowsy or sleepy if this medicine is applied to large areas. If this happens, do not drive or use any tools or machines.

It is not always possible to predict to what extent ALLERGEX MEPYRAMINE CREAM 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 ALLERGEX MEPYRAMINE CREAM affects them

3. HOW TO USE ALLERGEX MEPYRAMINE CREAM

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

The recommended dose is:

Apply to the affected area two to three times a day for up to three days

For external use only

For topical use

Do not share this medicine with any other person.

If you use more ALLERGEX MEPYRAMINE CREAM than you should

If you use more ALLERGEX MEPYRAMINE CREAM than you were told to, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to use ALLERGEX MEPYRAMINE CREAM

Do not double amount of cream to make up for forgotten application.

4. POSSIBLE SIDE EFFECTS

ALLERGEX MEPYRAMINE CREAM can have side effects.

Not all side effects reported for ALLERGEX MEPYRAMINE CREAM are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using this ALLERGEX MEPYRAMINE CREAM, please consult your doctor, pharmacist or other health care professional for advice.

- An increase in skin redness, swelling and itching in area where you have used the cream. This might be due to mild allergic reaction.
- Drowsiness and state of mental confusion

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 **ALLERGEX MEPYRAMINE CREAM.**

May also report to Adcock Ingram Limited using the following email: Adcock.AEReports@adcock.com

5. HOW TO STORE ALLERGEX MEPYRAMINE CREAM

Store at or below 25 ºC. Protect from light. Keep tightly closed

Do not store in a bathroom

Do not use after the expiry date stated on the label/tube.

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 ALLERGEX MEPYRAMINE CREAM contains:

Each 100 g contains*:*

The active substance is: Mepyramine maleate 2 g

Other Ingredients are: Emulsifying wax, Liquid paraffin, Purified water and Methyl Hydroxybenzoate.

What ALLERGEX MEPYRAMINE CREAM looks like and contents of the pack:

ALLERGEX MEPYRAMINE CREAM a smooth, white cream with a characteristic odour.

It is packaged in aluminum tubes containing 25 gram and jars containing 500 grams.

Not all pack sizes are marketed.

Holder of Certificate of Registration

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

Customer Care: 0860 ADCOCK/232625

Date: 17 March 2022

This leaflet was revised in

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Registration Number

G 1540 (Act 101/1965)

Botswana: S3 BOT2103685

Namibia: NS1 14/13.4/0510

SKEDULERINGSTATUS

S2

ALLERGEX MEPIRAMIEN-ROOM

Aktiewe bestanddeel is:

mepiramienmaleaat 2 g

Preserveermiddel:

Metielhidroksiebenzoaat 0,123 % *m/m*

Lees hierdie voubiljet noukeurig want dit bevat belangrike inligting.

ALLERGEX MEPIRAMIEN-ROOM is beskikbaar sonder ’n doktersvoorskrif vir u om ’n matige toestand te behandel. U moet ALLERGEX MEPIRAMIEN-ROOM nieteenstaande steeds omsigtig gebruik om die beste resultate daarvan te kry.

- Hou hierdie voubiljet. U mag dit weer moet lees.
- Moenie ALLERGEX MEPIRAMIEN-ROOM met enige ander persoon deel nie.
- Vra u gesondheidsorgverskaffer of apteker indien u meer inligting of raad nodig het.
- U moet ’n dokter raadpleeg indien u simptome vererger of nie binne ’n paar dae verbeter nie.

Wat is in hierdie voubiljet

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

1. WAT ALLERGEX MEPIRAMIEN-ROOM IS EN WAARVOOR DIT GEBRUIK WORD

ALLERGEX MEPIRAMIEN-ROOM bevat ’n medisyne genaamd mepiramienmaleaat.

ALLERGEX MEPIRAMIEN-ROOM is ’n anti-allergie medisyne. Dit werk deur ’n natuurlike stof (histamien) wat u liggaam tydens ’n allergiese reaksie produseer te blokkeer.

Die aktiewe bestanddeel is: mepiramienmaleaat 2 g

ALLERGEX MEPIRAMIEN-ROOM word gebruik om die volgende te verlig:

Droë, jeukerige en onsteekte vel, veluitslag as gevolg van allergieë, jeuking en ontsteking as gevolg van insekste en -byte en brandneteluitslag.

2. WAT U MOET WEET VOORDAT U ALLERGEX MEPIRAMIEN-ROOM GEBRUIK

Moenie ALLERGEX MEPIRAMIEN-ROOM gebruik nie

- Indien u hipersensitief (allergies) is vir mepiramienmaleaat of enige ander bestanddele van ALLERGEX MEPIRAMIEN-ROOM (in Afdeling 6 gelys).
- Moenie vir akute velkondisies, waar vloeistofgevulde blase vorm, gebruik word nie.
- Moenie vir vroeggebore babas of neonate gebruik word nie.
- Moenie saam met ’n lug- en waterdigte mediese trauma-verband (okklusiewe verbande) gebruik word nie.
- Moenie op gebroke vel gebruik word nie.

Waarskuwing en voorsorgmaatreëls

Neem spesiale sorg met ALLERGEX MEPIRAMIEN-ROOM:

- Moenie **ALLERGEX MEPIRAMIEN-ROOM** herhaaldelik aanwend vir ’n tydperk langer as ’n paar dae nie en staak behandeling onmiddellik indien ’n allergiese reaksie tot die medisyne ná kontak met die vel (velsensitisering) voorkom.

Ander medisyne en ALLERGEX MEPIRAMIEN-ROOM:

Vertel altyd vir u gesondheidsorgverskaffer indien u enige ander medisyne gebruik. (Dit sluit alle komplementêre or tradisionele medisyne in).

- Geen beduidende interaksies is beskryf nie

Swangerskap, borsvoeding en vrugbaarheid:

Indien u swanger is of borsvoed, dink u is swanger of beplan om ’n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u hierdie medisyne gebruik

Die veiligheid van ALLERGEX MEPIRAMIEN-ROOM tydens swangerskap en borsvoeding en in vrugbaarheid is nie bepaal nie.

Bestuur en gebruik van masjinerie

U mag lomerig of slaperig voel as hierdie medisyne oor groot areas aangewend word. Indien dit gebeur, moenie bestuur of enige gereedskap of masjiene gebruik nie.

Dit is nie altyd moontlike om te voorspel tot watter mate die gebruik van ALLERGEX MEPIRAMIEN-ROOM met die daaglikse aktiwiteite van ’n pasiënt kan inmeng nie. Pasiënte moet seker maak dat hulle nie aan enige van die bogenoemde aktiwiteite deelneem totdat hulle bewus is van die mate waartoe ALLERGEX MEPIRAMIEN-ROOM hulle beïnvloed nie

3. HOE OM ALLERGEX MEPIRAMIEN-ROOM TE GEBRUIK

Gebruik hierdie medisyne altyd presies soos in hierdie voubiljet of deur u dokter of apteker voorgeskryf is. Bevestig met u dokter of apteker indien u nie seker is nie.

Die aanbevole dosis is:

Wend drie keer per dag op die aangetaste area aan vir tot drie dae

Slegs vir eksterne gebruik

Vir topiese gebruik

Moenie hierdie medisyne met enige ander persoon deel nie

Indien u meer ALLERGEX MEPIRAMIEN-ROOM gebruik as wat u moet

Indien u meer ALLERGEX MEPIRAMIEN-ROOM gebruik as wat u moet, taadpleeg u dokter of apteker. Indien nie een van hulle beskikbaar is nie, soek hulp by die naaste hospitaal of gifsentrum.

Indien u vergeet om ALLERGEX MEPIRAMIEN-ROOM te gebruik

Moenie 'n dubbel hoeveelheid room aanwend om op te maak vir vergete aanwendings nie

4. MOONTLIKE NEWE-EFFEKTE

ALLERGEX MEPIRAMIEN-ROOM mag newe-effekte hê.

Nie alle newe-effekte wat vir ALLERGEX MEPIRAMIEN-ROOM aangemeld is word in hierdie voubiljet ingesluit nie. Raadpleeg asseblief u dokter, apteker of gesondheidsorgwerker vir advies indien u algemene gesondheid versleg of as u onaangename gevolge tydens gebruik van ALLERGEX MEPIRAMIEN-ROOM ervaar.

- 'n Toename in rooiheid van die vel, swelling en gejeuk in die area waar u die room aangewend het. Dit mag as gevolg van 'n ligte allergiese reaksie wees.

- Lomerigheid of 'n toestand van geestelike verwarring

Aanmelding van newe-effekte

Praat met u dokter, apteker of verpleegster indien u newe-effekte ervaar. U kan newe-effekte ook direk 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 met meer inligting oor die veiligheid van **ALLERGEX MEPIRAMIEN-ROOM.**

U kan dit ook by Adcock Ingram Beperk aanmeld deur die volgende e-pos te gebruik:

Adcock.AEReports@adcock.com

5. HOE OM ALLERGEX MEPIRAMIEN-ROOM TE BÊRE

Bêre teen of onder 25 ºC. Beskerm teen lig. Hou stewig toe

Moenie in ’n badkamer bêre nie

Moenie na die vervaldatum soos op die etiket/buis genoem, gebruik nie

Gee alle ongebruikte medisyne aan u apterker terug

Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) afspoel nie.

6. INHOUD VAN PAK EN ANDER INLIGTING

Wat ALLERGEX MEPIRAMIEN-ROOM bevat:

Elke 100 g bevat*:*

Die aktiewe bestanddeel is: mepiramienmaleaat 2 g

Ander bestanddele is: Emulsifiserende was, Vloeibare paraffien, Gesuiwerde water en Metielhidroksiebenzoaat.

Hoe ALLERGEX MEPIRAMIEN-ROOM lyk en inhoud van die pak:

ALLERGEX MEPIRAMIEN-ROOM is ’n gladde, wit room met ’n kenmerkende reuk.

Dit kom in aluminium buise wat 25 gram bevat en potte wat 500 gram bevat.

Nie alle pakgroottes word bemark nie.

Houer van Registrasiesertifikaat

Adcock Ingram Beperk

New Road 1

Erand Gardens

Midrand, 1685

Klantediens: 0860 ADCOCK/232625

Laaste hersiening van voubiljet

10 Maart 2022

Registrasienommer

G 1540 (Act 101/1965)

Botswana: S3 BOT2103685
Namibië: NS1 14/13.4/0510