MEXIENA

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:
S2

MEXIENA, 200 mg film-coated tablets.
Cimetidine
Sugar free

Read all of this leaflet carefully because it contains important information for you
MEXIENA is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use MEXIENA carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share MEXIENA 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 after 14 days.

What is in this leaflet
1. What MEXIENA is and what it is used for
2. What you need to know before you take MEXIENA
3. How to take MEXIENA
4. Possible side effects
5. How to store MEXIENA
6. Contents of the pack and other information

1. What MEXIENA is and what it is used for
MEXIENA is an antacid and is used for the short-term symptomatic relief of heartburn, indigestion and associated discomfort.

2. What you need to know before you take MEXIENA
Do not take MEXIENA
- If you are hypersensitive (allergic) to cimetidine or any of the other ingredients of MEXIENA (listed in section 6).
- If you are pregnant or breastfeeding your baby (see Pregnancy and breastfeeding).

Warnings and precautions
Tell your doctor if any of the following applies to you:
- If you have reduced renal function.
- If you are a middle-aged or elderly person, with new or recently changed indigestion symptoms (e.g. stomach pain or discomfort, heartburn).
- If you have a history of peptic ulcer, or if you are taking a non steroidal anti-inflammatory medicine (NSAID) e.g. aspirin, ibuprofen, naproxen, diclofenac.
- If you are taking medicines, or you have an illness, that could cause a fall in blood cell count.

Children and adolescents
The use of MEXIENA in children cannot be recommended as safety and/or efficacy has not been established.

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

Tell your doctor if you are taking any of the following medicines:
- Immunodepressants (e.g. ciclosporin).
- Heart medicines (e.g. nifedipine, diltiazem, lignocaine (lidocaine), metoprolol, procainamide).
- Anticonvulsants, to prevent fits (e.g. phenytoin).
- Suxamethonium (used for relaxing the muscle).
- Bronchodilators for breathing difficulties (e.g. theophylline).
- Antidepressants (e.g. amitriptyline).
- Antidiabetics (lowers glucose levels in the blood) (e.g. glipizide or metformin).
- Antifungals (used to treat fungal infections) (e.g. ketoconazole, itraconazole or posaconazole).
- Anti-cancer medicines (treatment of cancer or tumour) (e.g. carmustine, fluorouracil, epirubicin, or therapies such as radiation).
- Strong pain killers (e.g. morphine).
- Tacrolimus for the prevention of rejection following organ transplant.
- Antiretroviral medicines (used to treat HIV/AIDS) (e.g. atazanavir).
- Anticoagulants to thin your blood (e.g. warfarin).

When administered with MEXIENA, a reduction in the dosage of these medicines may be needed. If concurrent administration of warfarin and MEXIENA is necessary, your doctor will closely monitor the prothrombin time (the time taken for blood clotting to occur).

MEXIENA with food and drink alcohol
The daytime doses should be taken with food.

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 taking MEXIENA.
Safety in pregnancy and breastfeeding has not been established.
You should not take MEXIENA if you are pregnant or breastfeeding your baby.

Driving and using machines
Confusion, headache and dizziness have been reported with MEXIENA. You should not drive or use machines until you know how MEXIENA affects your ability to do so safely.

MEXIENA contains sodium
MEXIENA contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially sodium-free.

3. How to take MEXIENA
Do not share medicines prescribed for you with any other person.
Always take MEXIENA 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.
The usual dose is 1 tablet (200 mg of cimetidine) 3 to 4 times daily by mouth, with meals. Do not take more than 4 tablets (800 mg of cimetidine) daily. Treatment with MEXIENA should not exceed 2 weeks.

Your doctor will tell you how long your treatment with MEXIENA will last.

If you have the impression that the effect of MEXIENA is too strong or too weak, tell your doctor or pharmacist.

If you take more MEXIENA than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take MEXIENA
If you have forgotten to take a dose, leave out that dose completely if it is almost time for your next dose. Take your next dose at the normal time. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects
MEXIENA can have side effects.
Not all side effects reported for MEXIENA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MEXIENA, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop taking MEXIENA and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting or slowing and or irregular heartbeat.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to MEXIENA. 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:
- a rare type of anaemia in which the red and white blood cells and platelets are all reduced in number (symptoms might include tiredness, being short of breath, looking pale, frequent infections, bruising more easily or nose bleeds).
- inflammation of the pancreas (sudden onset of abdominal pain, nausea and vomiting).
- liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine.
- kidney problems (symptoms may include changes in the amount of urine passed and its colour, nausea, vomiting, confusion, fever and rash),

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

Tell your doctor if you notice any of the following:
Frequent side effects:
- aching muscles and/or joints,
- tiredness,
- diarrhoea,
- headache,
- dizziness.

Less frequent side effects:
- anaphylaxis,
- increase in heartrate,
- slow or irregular heartbeat,
- hair loss (temporary),
- redness of the skin because of contact with irritating substance,
- joint pain,
- fever,
- confusion,
- trouble getting or keeping an erection (impotence),
- breast enlargement in men,
- nipple discharge,
- feelings of sadness, depression,
- hallucinations – seeing/feeling/hearing things that are not there,

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the **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 MEXIENA.

5. How to store MEXIENA
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Store at or below 25 °C, protected from light.
- Do not store in bathrooms.
- Do not use after the expiry date stated on the label and carton.
- Take any expired medicine or medicine not used to your closest pharmacy for destruction.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information
What MEXIENA contains
The active substance is cimetidine. Each film-coated tablet contains 200 mg cimetidine.
The other ingredients are colloidal silicone dioxide, magnesium stearate, microcrystalline cellulose, macrogol/polyethylene glycol, povidone K25, sodium lauryl sulphate, sodium starch glycolate, corn starch, purified talcum, titanium dioxide, hypromellose.

What MEXIENA looks like and contents of the pack
MEXIENA tablets are white, round shaped biconvex film-coated tablets.

MEXIENA tablets are available in:
Blister strips (10 or 14 tablets per strip) with clear, colourless polyvinylchloride PVDC (polyvinylidene chloride) coated PVC (polyvinylchloride) foil moulded to accept one tablet per pocket and sealed with soft, matte, silver, printed aluminium blister pack foil. Strips are packed into cartons with a professional information.
MEXIENA pack sizes: 10, 14, 20, 28, 30, 40, 42, 50 and 56 tablets.
Not all pack sizes may be marketed.

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MEXIENA

PASIËNT INLIGTINGSPAMFLET

SKEDULERINGSTATUS:
S2

MEXIENA, 200 mg filmbedekte tablette.
Simetidien
Suikervry

Lees die hele pamflet noukeurig deur, want dit bevat belangrike inligting vir jou
MEXIENA is beskikbaar sonder 'n dokter se voorskrif, vir jou om 'n ligte siekte te behandel. Nietemin moet jy MEXIENA steeds versigtig gebruik om die beste resultate daaruit te kry.
- Bewaar hierdie pamflet. Jy sal dit dalk weer moet lees.
- Moenie MEXIENA met enige ander persoon deel nie.
- Vra jou gesondheidsorgverskaffer of apteker as jy meer inligting of advies benodig.
- Jy moet 'n dokter sien as jou simptome vererger of nie na 14 dae verbeter nie.

Wat is in hierdie pamflet
1. Wat MEXIENA is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy MEXIENA neem
3. Hoe om MEXIENA te neem
4. Moontlike newe-effekte
5. Hoe om MEXIENA te bewaar
6. Inhoud van die pakkie en ander inligting

1. Wat MEXIENA is en waarvoor dit gebruik word
MEXIENA is 'n teensuurmiddel en word gebruik vir die korttermyn simptomatiese verligting van sooibrand, spysvertering en gepaardgaande ongemak.

2. Wat jy moet weet voordat jy MEXIENA neem
Moenie MEXIENA neem:
- As jy hipersensitief (allergies) is vir simetidien of enige van die ander bestanddele van MEXIENA (gelys in afdeling 6).
- As jy swanger is of jou baba borsvoed (sien Swangerskap en borsvoeding).

Waarskuwings en voorsorgmaatreëls
Vertel jou dokter as enige van die volgende op jou van toepassing is:
- As jy verminderde nierfunksie het.
- As jy 'n middeljarige of bejaarde persoon is, met nuwe of onlangs veranderde spysverteringsimptome (bv. maagpyn of ongemak, sooibrand).
- As jy 'n geskiedenis van peptiese ulkus het, of as jy 'n niesteroïdale anti-inflammatoriese medisyne (NSAID) neem, bv. aspirien, ibuprofen, naproxen, diklofenak.
- As jy medisyne gebruik, of jy het 'n siekte, wat 'n daling in bloedseltelling kan veroorsaak.

Kinders en adolessente
Die gebruik van MEXIENA by kinders kan nie aanbeveel word nie aangesien veiligheid en/of doeltreffendheid nie vasgestel is nie.

Ander medisyne en MEXIENA
Vertel altyd jou gesondheidsorgverskaffer as jy enige ander medisyne gebruik. (Dit sluit alle komplementêre of tradisionele medisyne in.)

Vertel jou dokter as jy enige van die volgende medisyne gebruik:
- Immuunonderdrukkers (bv. siklosporien).
- Hartmedisyne (bv. nifedipien, diltiazem, lignokaïen (lidokaïen), metoprolol, prokaïenamied).
- Antikonvulsiewe middels, om aanvalle te voorkom (bv. fenitoïen).
- Suksametonium (gebruik om spiere te ontspan).
- Brongodilators vir asemhalingsprobleme (bv. teofillien).
- Antidepressante (bv. amitriptilien).
- Antidiabetika (verlaag glukosevlakke in die bloed) (bv. glipisied of metformien).
- Antifungus middels (gebruik om swaminfeksies te behandel) (bv. ketokonasool, itrakonasool of posakonasool).
- Anti-kanker medisyne (behandeling van kanker of gewas) (bv. karmustien, fluorouracil, epirubisien, of terapieë soos bestraling).
- Sterk pynstillers (bv. morfien).
- Takrolimus vir die voorkoming van verwerping na orgaanoorplanting.
- Antiretrovirale medisyne (gebruik om MIV/VIGS te behandel) (bv. atazanavir).
- Antistolmiddels om jou bloed te verdun (bv. warfarin).

Wanneer dit saam met MEXIENA toegedien word, kan 'n vermindering in die dosis van hierdie medisyne nodig wees. As gelyktydige toediening van warfarin en MEXIENA nodig is, sal jou dokter die protrombientyd (die tyd wat dit neem vir bloedstolling) noukeurig monitor.

MEXIENA saam met kos en alkohol
Die dagdoserings moet saam met kos geneem word.

Swangerskap en borsvoeding
As jy swanger is of borsvoed, dink jy is dalk swanger of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy MEXIENA neem.
Veiligheid tydens swangerskap en borsvoeding is nie vasgestel nie.
Jy moet nie MEXIENA neem as jy swanger is of jou baba borsvoed nie.

Bestuur en gebruik van masjiene
Verwarring, hoofpyn en duiseligheid is aangemeld met MEXIENA. Jy moet nie bestuur of masjiene gebruik totdat jy weet hoe MEXIENA jou vermoë om dit veilig te doen, beïnvloed nie.

MEXIENA bevat natrium
MEXIENA bevat minder as 1 mmol natrium (23 mg) per dosis-eenheid, dit wil sê in wese natriumvry.

3. Hoe om MEXIENA te neem
Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem MEXIENA altyd presies soos beskryf in hierdie pamflet of soos jou dokter of apteker of verpleegster vir jou gesê het. Gaan praat met jou dokter of apteker of verpleegster as jy nie seker is nie.
Die gewone dosis is 1 tablet (200 mg simetidien) 3 tot 4 keer per dag per mond, met etes. Moenie meer as 4 tablette (800 mg simetidien) daagliks neem nie. Behandeling met MEXIENA behoort nie 2 weke te oorskry nie.

Jou dokter sal jou vertel hoe lank jou behandeling met MEXIENA sal duur.

As jy die indruk het dat die effek van MEXIENA te sterk of te swak is, vertel jou dokter of apteker.

As jy meer MEXIENA neem as wat jy moet
In die geval van oordosis, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

As jy vergeet om MEXIENA te neem
As jy vergeet het om 'n dosis te neem, laat daardie dosis heeltemal uit as dit amper tyd is vir jou volgende dosis. Neem jou volgende dosis op die normale tyd. Moenie 'n dubbeldosis neem om vergete individuele dosisse in te haal nie.

4. Moontlike newe-effekte
MEXIENA kan newe-effekte hê.
Nie alle newe-effekte wat vir MEXIENA aangemeld is, is in hierdie pamflet ingesluit nie. Indien u algemene gesondheid versleg of as u enige nadelige effekte ervaar terwyl u MEXIENA neem, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies.

As enige van die volgende gebeur, hou op om MEXIENA te neem en vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal,
- uitslag of jeuk,
- floute of verlangsaming en of onreëlmatige hartklop.

Dit is alles baie ernstige newe-effekte. As jy dit het, het jy dalk 'n ernstige allergiese reaksie op MEXIENA gehad. Jy benodig dalk dringende mediese aandag of hospitalisasie.

Vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal as jy enige van die volgende opmerk:
- 'n seldsame tipe bloedarmoede waarin die rooi- en witbloedselle en bloedplaatjies almal verminder is (simptome kan moegheid, kortasem, bleek lyk, gereelde infeksies, makliker kneusplekke of neusbloeding insluit).
- ontsteking van die pankreas (skielike aanvang van buikpyn, naarheid en braking).
- lewersiekte met naarheid, braking, verlies aan eetlus, algemeen onwel voel, koors, jeuk, vergeling van die vel en oë, en donkerkleurige urine.
- nierprobleme (simptome kan veranderinge in die hoeveelheid urine wat deurgegee word en die kleur daarvan, naarheid, braking, verwarring, koors en uitslag insluit),

Dit is alles ernstige newe-effekte. Jy benodig dalk dringende mediese hulp.

Vertel jou dokter as jy enige van die volgende opmerk:
Gereelde newe-effekte:
- seer spiere en/of gewrigte,
- moegheid,
- diarree,
- hoofpyn,
- duiseligheid.

Minder gereelde newe-effekte:
- anafilakse,
- toename in hartklop,
- stadige of onreëlmatige hartklop,
- haarverlies (tydelik),
- rooiheid van die vel as gevolg van kontak met irriterende stof,
- gewrigspyn,
- koors,
- verwarring,
- probleme om 'n ereksie te kry of te behou (impotensie),
- borsvergroting by mans,
- tepelafskeiding,
- gevoelens van hartseer, depressie,
- hallusinasies – sien/voel/hoor dinge wat nie daar is nie,

Indien u enige newe-effekte opmerk wat nie in hierdie pamflet genoem word nie, stel asseblief u dokter of apteker in kennis.

Aanmelding van newe-effekte
As jy newe-effekte kry, praat met jou dokter of apteker. Jy kan ook newe-effekte aan SAHPRA rapporteer via die **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 jy help om meer inligting oor die veiligheid van MEXIENA te verskaf.

5. Hoe om MEXIENA te bewaar
- HOU ALLE MEDISYNE BUITE BEREIK VAN KINDERS.
- Berg by of onder 25 °C, beskerm teen lig.
- Moenie in badkamers bêre nie.
- Moet nie na die vervaldatum soos op die etiket en karton gebruik nie.
- Neem enige medisyne wat verval het of medisyne wat nie gebruik is nie na jou naaste apteek vir vernietiging.
- Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pakkie en ander inligting
Wat MEXIENA bevat
Die aktiewe bestanddeel is simetidien. Elke filmbedekte tablet bevat 200 mg simetidien.
Die ander bestanddele is kolloïdale silikoondioksied, magnesiumstearaat, mikrokristallyne sellulose, makrogol/poliëtileenglikol, povidoon K25, natriumlaurielsulfaat, natriumstyselglikolaat, mieliestysel, gesuiwerde talk, titaandioksied, hipromellose.

Hoe lyk MEXIENA en inhoud van die verpakking
MEXIENA tablette is wit, ronde bikonvekse filmbedekte tablette.

MEXIENA tablette is beskikbaar in:
Blisterstroke (10 of 14 tablette per strook) met helder, kleurlose polivinielchloried PVDC (polivinielchloried) bedekte PVC (polivinielchloried) foelie gevorm om een tablet per sak te aanvaar en verseël met sagte, mat, silwer, gedrukte aluminium blisterpak foelie. Strokies word in kartonne verpak met 'n professionele inligting.
MEXIENA pakgroottes: 10, 14, 20, 28, 30, 40, 42, 50 en 56 tablette.
Nie alle pakgroottes word moontlik bemark nie.

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