

## 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 nonsteroidal 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, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, macrogol/polyethylene glycol, povidone K25, sodium lauryl sulphate, sodium starch glycolate, starch, purified talcum, titanium dioxide.

### **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.

### **Holder of certificate of registration**

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