PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S2

NOMOWAKE 25 film coated tablets

Doxylamine succinate

Contains 50 mg mannitol (sugar alcohol) per tablet.

Read all of this leaflet carefully before you start taking NOMOWAKE:

NOMOWAKE is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use NOMOWAKE carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share NOMOWAKE 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 7 days.

What is in this leaflet:

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

1. What NOMOWAKE is and what it is used for

NOMOWAKE is an antihistamine that makes you drowsy and sleepy.

NOMOWAKE is used to alleviate sleeplessness.

2. What you need to know before you take NOMOWAKE

Do not take NOMOWAKE:

- if you are hypersensitive (allergic) to doxylamine succinate or any of the other ingredients of NOMOWAKE (listed in section 6 of this leaflet)
- if you are hypersensitive (allergic) to any other antihistamines
- if you are pregnant or breastfeeding (see section “Pregnancy and breastfeeding”)
- if you suffer from epilepsy (seizures/fits)
- if you have heart problems
- if you have an acute asthma attack
- if you are taking a specific group of medicines, used for the treatment of depression, called monoamine oxidase inhibitors (MAOIs).

Warnings and precautions:

Take special care with NOMOWAKE:

- if you have liver or kidney problems
- if you are dehydrated
- if you are older than 65 years
- if you have chronic bronchitis (inflammation of the bronchi with production of mucus that leads to coughing and difficulty in breathing)
- if you have emphysema (a chronic lung disease that makes breathing difficult)
- if you have glaucoma (increased pressure inside the eye)
- if you have prostatic hypertrophy (abnormal enlargement of the prostate)
- if you have problems with your stomach
- if you have bladder problems
- if you have low potassium levels or other electrolyte abnormalities.

Your doctor may check your hearing function from time to time if you take NOMOWAKE with

certain other medicines (see section “Other medicines and NOMOWAKE”).

Children and adolescents:

Do not give NOMOWAKE to children and adolescents under the age of 12 years because it is unlikely to be safe.

Other medicines and NOMOWAKE:

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

Tell your doctor or pharmacist if you are currently taking:

- aminoglycosides, erythromycin, clarithromycin and telithromycin (used to treat bacterial infections)
- carboplatin, cisplatin (used to treat certain types of cancer)
- barbiturates, hypnotics, anxiolytic sedatives (used to treat sleeping disorders)
- antipsychotic medicines (used to treat mental health conditions)
- opioid analgesics (used to treat severe pain)
- epinephrine (adrenaline) (used to treat life-threatening emergencies)
- antidysrhythmic medicines such as amiodarone (used to treat abnormal heart rhythms)
- malaria medicines (used to treat malaria)
- antihistamines (used to treat allergies)
- antihyperlipidaemic medicines (used to treat high cholesterol)
- clonidine (used to treat high blood pressure)
- antidepressants, such as fluoxetine, fluvoxamine, paroxetine, bupropion and monoamine oxidase inhibitors (used to treat depression)
- antiviral medicines such as indinavir and ritonavir (used to treat HIV/aids)
- antifungal medicines such as fluconazole, ketoconazole, itraconazol, voriconazole and terbinafine (used to treat fungus infections).

NOMOWAKE may interfere with skin allergy tests that use allergens. You should stop taking NOMOWAKE at least three days before allergy tests.

NOMOWAKE with food, drink and alcohol:

Do not drink alcohol while taking NOMOWAKE.

There are no known interactions between NOMOWAKE and food.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care provider for advice before taking NOMOWAKE.

Do not use NOMOWAKE during pregnancy and breastfeeding.

Driving and using machines:

NOMOWAKE may cause side effects, such as drowsiness and impaired concentration and can affect your ability to drive a vehicle and use machines (see section 4). Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how NOMOWAKE affects you.

3. How to take NOMOWAKE

Do not share your medicine with any other person.

Always take NOMOWAKE exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Adults (over 12 years old):

The usual dose is 1 to 2 tablets taken orally with water at bedtime.

Duration of treatment:

Treatment duration should be as short as possible. The duration of treatment can range from a few days to a week. Do not take NOMOWAKE for more than 7 days unless otherwised advised by your

doctor.

If you take more NOMOWAKE than you should:

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre. Take this leaflet and the carton with you so the doctor will know what you have taken, whether there are any NOMOWAKE tablets left or not.
The most frequent symptoms of an overdose are confusion, disorientation, drowsiness, and dizziness.

If you forget to take NOMOWAKE:

NOMOWAKE is used for occasional sleeplessness and does not have to be taken every day. If you forget to take a dose, skip the missed dose and take NOMOWAKE the next evening if it is necessary. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

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

If any of the following happens, stop taking NOMOWAKE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to NOMOWAKE. 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:

- passing less urine than is normal for you
- bleeding and bruising more easily than normal
- convulsion (fits).

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:

- inability to sleep, lack of energy, nervousness
- dizziness, headache, drowsiness
- blurred vision
- vertigo (sensation of spinning or swaying)
- increased phlegm in the chest
- dry mouth, constipation, stomach pain
- tiredness.

Less frequent side effects:

- feeling agitated, depressed or relaxed, having nightmares
- feeling intense happiness or excitement
- tremors (involuntary trembling or shaking of hands and feet)
- double vision
- ringing in the ears
- light-headedness when getting up from a lying or sitting position
- changes in the way your heart beats (beating faster)
- difficulty breathing or tightness of the chest
- nausea (feeling sick), vomiting (being sick), diarrhoea, indigestion

- loss of body mass or increased appetite
- difficulty urinating or pain during urination
- abnormal physical weakness.

Side effects occurring with an unknown frequency:

- generally feeling unwell.

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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects 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 NOMOWAKE.

5. How to store NOMOWAKE

- Store at or below 25 °C.
- Keep the blister strips in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What NOMOWAKE contains:

The active substance is doxylamine succinate.

Each film coated tablet contains 25 mg doxylamine succinate.

The other ingredients are: Mannitol, microcrystalline cellulose, sodium carboxymethyl starch, colloidal anhydrous silica, magnesium stearate, indigo carmine, hydrated aluminium oxide and Opadry Y-1-7000 (consisting of hypromellose (E464), polyethylene glycol (macrogol 400) (E1521) and titanium dioxide (E171)).

What NOMOWAKE looks like and contents of the pack:

Blue, oval, biconvex, coated and scored tablet.

NOMOWAKE is packed in aluminium/aluminium blister strips.

Pack sizes: 14 or 28 tablets.

Holder of certificate of registration:

LeBasi Pharmaceuticals (Pty) Ltd

San Domenico Building, Ground Floor, Unit 6

10 Church Street

Durbanville

7551

087 551 3245

This leaflet was last revised:

Registration number:

54/2.2/0168

Date of registration:

8 November 2022