Cyclizine hydrochloride 50 mg

This leaflet answers some common questions about NAUSICALM. It does not contain all the information available on this medicine

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you taking NAUSICALM against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

## What NAUSICALM is used for

NAUSICALM is used to prevent and treat nausea and vomiting associated with motion sickness

Your doctor or pharmacist may prescribe NAUSICALM for another purpose. Ask your doctor or pharmacist if you have any questions about why NAUSICALM has been prescribed for you.

## Before you take NAUSICALM

#### When you must not take it

#### Do not take NAUSICALM if:

You have an allergy to cyclizine or another piperazine derivative, or any of the tablet ingredients listed at the end of this leaflet. (If unsure, ask your doctor to check your records)

NAUSICALM is not recommended for use in individuals under 12 years of age.

NAUSICALM is not recommended for use during pregnancy.

## Before you start to take NAUSICALM

Tell your doctor or pharmacist if:

- You are allergic to any other medicines, especially other antihistamines, or any
- You are pregnant, might become pregnant or are breast-feeding.
- You have epilepsy (fits/seizures/ convulsions), kidney or liver conditions, heart disease or any other medical conditions
- You suffer from asthma, bronchitis or a persistent cough
- You suffer from prostate problems
- You have any stomach or bladder diseases
- You have any eye disease

# Taking other medicines

Do not take NAUSICALM if you are taking or being given:

- central nervous system (CNS) depressants (including alcohol, barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives and
- atropine, monoamine oxidase inhibitors (MAOIs) and tricyclic antidepressants (TCAs)

# How to use NAUSICALM

# How much to take

Be sure to take NAUSICALM exactly as your doctor or pharmacist has told you to. If you do not follow their instructions, you may not get relief from your symptoms.

# Dosage:

2

Travel sickness

Adults and Children over 12 years: Take one tablet 1 to 2 hours before departure. Then take one tablet every 6 to 8 hours if needed (up to a maximum of 3 tablets in 24 hours).

The score line only serves to facilitate breaking for ease of swallowing and does not divide the tablet into equal half-doses.

#### NOT RECOMMENDED FOR USE IN CHILDREN **UNDER 12 YEARS.**

Do not use for more than 48 hours

# While you are taking NAUSICALM **IMPORTANT:**

NAUSICALM can cause drowsiness and/or sedation and can also increase the effects of alcohol. If you are drowsy, dizzy, disorientated or confused, do not drive a vehicle, or operate machinery.

Tell all doctors, dentists and

pharmacists who are treating you that you are taking NAUSICALM before you start any new medicine.

Tell your doctor or pharmacist if you become pregnant while you are taking NAUSICALM.

If you are going to have any blood tests, tell your doctor that you are taking NAUSICALM.

If you are going to have surgery, tell the surgeon and anaesthetist that you are taking NAUSICALM.

NAUSICALM may make your skin more sensitive to the sun - you should protect your skin from exposure to bright sunlight.

10 mm

Do not give NAUSICALM to anyone else, even if his or her symptoms seem similar to yours

Do not take NAUSICALM to treat any other complaints unless your doctor tells you to.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking NAUSICALM.

NAUSICALM helps most people with nausea, but it may have unwanted side effects in a few people. These effects are usually mild and last only for a short time.

All medicines can have some unwanted effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the serious side effects.

If you think you are having an allergic reaction to NAUSICALM, tell your doctor immediately or go to the Accident and Emergency Department at your nearest hospital, if you experience some or all of the following:

- · Swelling of the face, lips, tongue, or
- other parts of the body Skin rash, itching or hives
- · Wheezing or difficulty breathing or swallowing
- Fever/chills
- Hot flushes
- Low blood pressure (feeling faint or dizzy)
- · Liver problems (changes in urine and stoolcolour, feeling weak and tired)

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Dry mouth, nose and throat
- Blurred vision
- A fast heart beat
- · Difficulty passing urine and/or passing dark urine
- Constipation
- Restlessness/nervousness
- Difficulty sleeping Seeing and hearing things that are not real
- Unusual skin eruptions /reactions Muscle twitching
- Nausea, vomiting and loss of appetite Ageneral feeling of unwellness

The list of side effects mentioned above is not complete. If you should suffer from any of these side effects or any other undesired effect please tell your doctor or pharmacist.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

If you have concerns, tell your doctor or pharmacist and follow their advice.

# Interactions with Other Medicines

The following interactions with cyclizine have been

- · Cyclizine may have additive effects with alcohol and other central nervous system depressants e.g. hypnotics, tranquillisers
- · Cyclizine enhances the soporific effect of
- Because of its anticholinergic activity cyclizine may enhance the side-effects of other anticholinergic drugs

# Overdose

Symptoms of acute toxicity from cyclizine arise from peripheral anticholinergic effects and effects on the central nervous system.

Peripheral anticholinergic symptoms include, dry mouth, nose and throat, blurred vision, tachycardia and urinary retention. Central nervous system effects include drowsiness, dizziness, incoordination, ataxia, weakness, hyper-excitability, disorientation, impaired judgement, hallucinations, hyperkinesia, extrapyramidal motor disturbances, convulsions, hyperpyrexia and

		Pranita Graphics					
Sigma Laboratories Pvt.Ltd.							
Product Name	Nausicalm Tablets	Pharma code: 30256					
Pack Size	NA						
Туре	Pack Insert						
Dimensions	360 (L) x 140 (W)mm						
Colours	Black						
Artwork Code No	PM000648-00	Superseded Artwork No. : Nil					
Date	09/09/2019	Country : Singapore					

Packaging Development Department		Site QA	Regulatory Affairs (Contract Giver)
Prepared by	Approved by		
Reason for chang	ge: New Artwork		



### respiratory depression.

An oral dose of 5 mg/kg is likely to be associated with at least one of the clinical symptoms stated above. Younger children are more susceptible to convulsions. The incidence of convulsions, in children less than 5 years, is about 60% when the oral dose ingested exceeds 40 mg/kg.

Do not take more tablets than your doctor or pharmacist tells you.

Immediately contact your doctor, pharmacist or go to the Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken any NAUSICALM by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the pack of NAUSICALM with you if you can.

## Storage

Store below 30°C. Protect from light.

Do not store NAUSICALM or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

**Keep it where children cannot reach it.** A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not take this medicine after the expiry date shown on the pack or if the packaging shows signs of tampering.

Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the blister pack they may not keep well.

## Presentation and Storage

Nausicalm tablets are white, circular, biconvex, uncoated tablets with a score line on one side, plain on the other. They are supplied in a blister pack of 6, 50 and 100 tablets.

#### Other ingredients

NAUSICALM tablets contain 50 mg cyclizine hydrochloride as the active ingredient. Each tablet also contains potato starch, lactose monohydrate, gum acacia and magnesium stearate.

#### If you want to know more

Should you have any questions regarding this product, please contact your doctor or pharmacist.

## **Product Owner:**

AFT Pharmaceuticals Ltd Level 1, 129 Hurstmere Road Takapuna, Auckland, New Zealand

## Manufacturer:

Sigma Laboratories Pvt. Ltd . 6, 7, & 8 Tivim Industrial Estate, Mapusa, Goa 403526 India

This leaflet was prepared on 6 April 2017



# Pranita Graphics

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