

**PACKAGE LEAFLET**

## **Package leaflet: Information for the user**

### **Nicorama Fruitmint 2 mg medicated chewing-gum Nicorama Fruitmint 4 mg medicated chewing-gum**

nicotine

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- Contact healthcare professionals if you are still using Nicorama Fruitmint after 6 months.

#### **What is in this leaflet**

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

#### **1. What Nicorama Fruitmint is and what it is used for**

Nicorama Fruitmint belongs to a group of medicines that is used to help you stop smoking.

The nicotine in Nicorama Fruitmint relieves nicotine cravings and withdrawal problems when you stop smoking, thereby preventing relapse to smoking in smokers who are motivated to stop. Permanent cessation of tobacco use is the aim of the treatment.

When the body is suddenly no longer supplied with nicotine from tobacco, you can experience various discomforts which are known as withdrawal problems. Using Nicorama Fruitmint chewing-gum can prevent or relieve such discomfort and smoke cravings by continuing to supply a small amount of nicotine to your body during a transitional period. When you chew Nicorama Fruitmint, nicotine is released slowly and absorbed into the oral cavity. Unlike cigarettes, Nicorama Fruitmint does not contain harmful tar and carbon monoxide.

Nicorama Fruitmint should preferably be used together with a smoking cessation program. Counselling and support usually increase the chances of success to stop smoking.

#### **2. What you need to know before you take Nicorama Fruitmint**

##### **Do not take Nicorama Fruitmint:**

- if you are allergic to nicotine or any of the other ingredients of this medicine (listed in section 6).
- if you are under the age of 12
- if you are a non-smoker

##### **Warnings and precautions**

Talk to your doctor, pharmacist or nurse if you have any of the following conditions:

- recently (within 3 months) have had a **heart attack** or **stroke**

- **chest pain** (unstable angina) or angina at rest
- **heart disease** that affects the heart rate or heart rhythm
- **high blood pressure** that is not controlled by medicine
- severe or moderate **liver disease**
- severe or moderate **kidney disease**
- **diabetes**
- **epilepsy**
- overactive **thyroid gland**
- tumour of the **adrenal gland** (pheochromocytoma)
- **stomach ulcer** or **duodenal ulcer**
- **inflammation of the esophagus**

However, the risk of continued smoking always poses a greater danger than using Nicorama Fruitmint.

The chewing-gum can get stuck in dentures and dental bridges and in some cases cause damage to them.

### **Children and adolescents**

The correct dose for adults may cause severe poisoning or be lethal for children. It is therefore important that you always handle and store Nicorama Fruitmint out of the sight and reach of children.

Adolescents between 12 and 17 years of age must only use Nicorama Fruitmint that has been prescribed by healthcare professionals. Nicorama Fruitmint must not be used by children below 12 years of age.

### **Other medicines and Nicorama Fruitmint**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. If you stop smoking and if you are using other medicines, your doctor may want to adjust the dose.

No information is available on interactions between Nicorama Fruitmint and other medicines. However, apart from nicotine, other substances in cigarettes may have an effect on certain medicine.

Stopping smoking can affect the action of certain medicines e.g.:

- **theophylline** used to treat asthma
- **tacrine** used to treat Alzheimer's disease
- **olanzapine and clozapine** used to treat schizophrenia
- **insulin** used to treat diabetes. The insulin dose may need to be adjusted.

### **Nicorama Fruitmint with food and drink**

You should not eat or drink with the chewing-gum in your mouth. Drinking coffee, juices or soda together with the chewing-gum can reduce the effect of Nicorama Fruitmint. These drinks should be avoided 15 minutes before using the chewing-gum.

### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### Pregnancy

It is very important to stop smoking during pregnancy because it can result in poor growth of your baby. It can also lead to premature births or stillbirths. The best is if you can stop smoking without using nicotine-containing medicines. If you are unable to do so, Nicorama Fruitmint must only be used after consulting with the healthcare professional who is managing your pregnancy, your family doctor or a doctor who is specialized in smoking cessation.

### Breast-feeding

Nicorama Fruitmint chewing-gum should be avoided during breast-feeding as nicotine passes into breast milk and can affect your baby. If your doctor has advised you to use Nicorama Fruitmint, take the chewing-gum immediately after breast-feeding.

### Fertility

Smoking increases the risk of infertility in women and men. The effects of nicotine on fertility are unknown.

### **Driving and using machines**

No effects on the ability to drive a car or operate machinery have been observed.

### **Nicorama Fruitmint contains xylitol, butylated hydroxytoluene, butylated hydroxyanisole and sodium**

Nicorama Fruitmint contains xylitol which can have a laxative effect.

Calorific value: 2.4 kcal/g xylitol, which corresponds to 0.8 kcal per chewing-gum (Nicorama Fruitmint 2 mg and 4 mg).

Nicorama Fruitmint contains butylated hydroxytoluene and butylated hydroxyanisole which can cause local skin reactions (e.g. contact dermatitis) or can be irritating to the eyes and mucous membranes.

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

## **3. How to take Nicorama Fruitmint**

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

### **Treatment with Nicorama Fruitmint chewing-gum**

Chewing-gum strength should be chosen based on your nicotine dependence. If you smoke more than 20 cigarettes per day or if you have previously failed with Nicorama Fruitmint 2 mg, 4 mg should be chosen. In other cases, 2 mg should be used.

Nicorama Fruitmint chewing-gums should be taken when you would normally have smoked cigarettes, or if smoking cravings arise. At the beginning of treatment, 1 chewing-gum can be taken every 1 to 2 hours. Sufficient amount of chewing-gums should be taken every day. The dosage is individual based on your nicotine dependence. In most cases, 8 to 12 chewing-gums per day is sufficient. To maximize the chances of success, it is important not to underdose.

Maximum daily dose:

Nicorama Fruitmint 2 mg: 24 gums per day, corresponding to nicotine 48 mg/day.

Nicorama Fruitmint 4 mg: 16 gums per day, corresponding to nicotine 64 mg/day.

The treatment time is individual. Normally, treatment should last for at least 3 months. The nicotine dose is thereafter gradually reduced. The treatment should be terminated when the dose is reduced to 1 to 2 chewing-gums per day.

Regular use of Nicorama Fruitmint chewing-gums longer than 6 months is normally not recommended. In some cases, longer treatment times may be necessary to avoid relapse to smoking. Any remaining chewing-gums should be saved, as smoking cravings may suddenly arise. Counselling and support can improve the chances of success.

### **Chewing technique**

Correct chewing technique is important. Chew Nicorama Fruitmint slowly, with pauses, otherwise you may be at risk of getting heartburn and hiccups:

- Chew until the taste becomes strong or a slight burning sensation is felt, then stop chewing.

- Let the chewing-gum rest between the cheek and the gums until the taste and burning sensation has ceased.
- Then slowly chew again until the taste becomes strong again or you experience a slight burning sensation.
- Repeat the chewing procedure for about 30 minutes.

The nicotine effects only occur after a few minutes. The same quick satisfaction as in smoking can therefore not be expected.

#### **If you take more Nicorama Fruitmint than you should**

If you have taken too much medicine or if, for example, a child has taken the medicine by mistake, contact a doctor or hospital for assessment of the risk and counselling.

Nicotine overdose can occur if you smoke while using Nicorama Fruitmint chewing-gums. Nicotine doses that are tolerated by adult smokers during treatment can cause severe poisoning symptoms in children and can have fatal outcome.

Symptoms of overdose are nausea, vomiting, increased salivation, abdominal pain, diarrhoea, sweating, headache, dizziness, disturbed hearing and pronounced weakness. At high doses, these symptoms may be followed by low blood pressure, weak and irregular heart rate, breathing difficulties, extreme fatigue, circulatory collapse and generalized convulsions.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Nicorama Fruitmint can give the same side effects as nicotine administered in another way. The side effects depend on how high dose you take.

Irritation of the mouth and throat can be experienced, but most users adapt to this with continuous use.

**Stop taking Nicorama Fruitmint and immediately contact a doctor if you experience any of the following symptoms of a serious allergic reaction** (angioedema or anaphylactic reaction), rarely occurring:

- swollen face, tongue or throat
- difficulty to swallow
- hives, rash and difficulty breathing

#### **Other side effects that may occur:**

**Very common side effects** (may affect more than 1 in 10 users):

- Headache
- Cough, throat irritation
- Hiccups, nausea

**Common side effects** (may affect up to 1 in 10 users):

- Local effects such as burning sensation, inflammation in the mouth, altered taste sensation
- Dry mouth or increased salivation
- Stomach problems or abdominal pain
- Vomiting, gas or diarrhoea
- Fatigue
- Hypersensitivity (allergy)
- Tingling sensation

**Uncommon side effects** (may affect up to 1 in 100 users):

- Nasal congestion, sneezing
- Breathing with wheezing sound (bronchospasm), difficulty breathing (dyspnoea), throat tightness
- Redness of the skin (flushing), increased sweating
- Tingling sensation in the mouth, inflammation of the tongue, damage to the oral mucosa, voice changes, pain in mouth and throat, belching
- Heart palpitations (a different sensation of your heartbeat), increased heart rate, high blood pressure
- Rash (including hives) and/or itching
- Abnormal dreams
- Discomfort and pain in the chest
- Feeling of weakness, feeling ill
- Pain in the jaw muscle

**Rare side effects** (may affect up to 1 in 1 000 users):

- Difficulty swallowing, decreased sensitivity in the mouth
- Retching
- Abnormal heart rhythm (atrial fibrillation)

**Have been reported** (occur in an unknown number of users):

- Blurred vision, increased tear production (tear flow)
- Dryness in the throat, discomfort in the stomach, pain in the lips
- Skin redness
- Tense jaw

**Symptoms in connection with smoking cessation** (withdrawal symptoms)

Some of the side effects you experience when you stop smoking may be withdrawal symptoms that are caused by decreased nicotine intake

- Irritability, aggression, impatience or frustration
- Feeling anxious, restlessness or difficulty concentrating
- Waking up at night or sleep disturbance
- Increased appetite or weight gain
- Feeling depressed
- Craving to smoke
- Decreased heart rate
- Bleeding gums or ulcers in the mouth
- Dizziness or feeling faint
- Coughing, sore throat, stuffy or runny nose
- Constipation

### **Reporting of side effects**

If you get any 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 directly via [the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Nicorama Fruitmint**

Keep this medicine out of the sight and reach of children.

This medicine does not require any special storage conditions.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## **6. Contents of the pack and other information**

### **What Nicorama Fruitmint contains**

Nicorama Fruitmint chewing-gums are sugarfree and available in two strengths, 2 mg and 4 mg.

#### *Nicorama Fruitmint 2 mg*

- The active substance is nicotine. One chewing-gum contains 2 mg nicotine in the form of nicotine resinate.
- The other ingredients are: chewing gum base (containing butylated hydroxytoluene [E321]), xylitol (E967), silica (colloidal, hydrated), magnesium stearate, sodium carbonate (anhydrous), hypromellose, flavouring with cooling effect, mint flavour, sodium hydrogen carbonate, citrus-/fruit flavour (containing butylated hydroxyanisole [E320]), levomenthol, macrogol, glycerol, titanium dioxide (E171), talc, acesulfame potassium, sucralose, xanthan gum.

#### *Nicorama Fruitmint 4 mg*

- The active substance is nicotine. One chewing-gum contains 4 mg nicotine in the form of nicotine resinate.
- The other ingredients are: chewing gum base (containing butylated hydroxytoluene [E321]), xylitol (E967), silica (colloidal, hydrated), magnesium stearate, sodium carbonate (anhydrous), hypromellose, flavouring with cooling effect, mint flavour, sodium hydrogen carbonate, citrus-/fruit flavour (containing butylated hydroxyanisole [E320]), levomenthol, macrogol, glycerol, titanium dioxide (E171), talc, acesulfame potassium, sucralose, yellow iron oxide (E172), xanthan gum.

### **What Nicorama Fruitmint looks like and contents of the pack**

*2 mg*: White to off-white, round, biconvex, coated chewing-gums, which are smooth on both sides.

Diameter: 15 mm and thickness: 8 mm.

*4 mg*: Light yellow, round, biconvex, coated chewing-gums, which are smooth on both sides.

Diameter: 15 mm and thickness: 8 mm.

30, 96, 105 and 204 chewing-gums in blister packs.

Not all pack-sizes may be marketed

### **Marketing Authorisation Holder and Manufacturer**

#### Marketing Authorisation Holder

[To be completed nationally]

#### Manufacturer

ABF Pharmaceutical Services GmbH  
Brunner Straße 63/18-19  
1230 Wien, Austria

**This medicinal product is authorised in the Member States of the EEA under the following names:**

{Name of the Member State} {Name of the medicinal product}  
{Name of the Member State} {Name of the medicinal product}

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