

## Proposed patient information leaflet for NICORETTE® ICY WHITE 2 mg and 4 mg

### SCHEDULING STATUS

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### PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

NICORETTE® 2 mg gum

NICORETTE® 4 mg gum

NICORETTE® MINT 2 mg gum

NICORETTE® MINT 4 mg gum

NICORETTE® ICY WHITE 2 mg gum

NICORETTE® ICY WHITE 4 mg gum

NICORETTE® FRESHFRUIT 2 mg gum

NICORETTE® FRESHFRUIT 4 mg gum

NICORETTE® FRESHMINT 2 mg gum

NICORETTE® FRESHMINT 4 mg gum

**Read all of this leaflet carefully because it contains important information for you.**

NICORETTE® chewing gum is available without a doctor's prescription, for you to help you stop smoking. Nevertheless, you still need to use NICORETTE® chewing gum carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share NICORETTE® chewing gum with any other person.
- If you have any questions or are not sure about anything, ask your doctor or pharmacist.

### WHAT NICORETTE® chewing gum CONTAINS

NICORETTE® 2 mg chewing gum

- The active substance is nicotine-resin complex 10 mg equivalent to nicotine 2 mg.

- The other ingredients are chewing gum base, sorbitol, sodium carbonate anhydrous, flavour, glycerol, sodium hydrogen carbonate.

#### NICORETTE® 4 mg chewing gum

- The active substance is nicotine-resin complex 20 mg equivalent to nicotine 4 mg.
- The other ingredients are chewing gum base, sorbitol, sodium carbonate anhydrous, flavour, glycerol, D&C yellow No. 10.

#### NICORETTE® MINT 2 mg chewing gum

- The active substance is nicotine-resin complex 10 mg equivalent to nicotine 2 mg.
- The other ingredients are chewing gum base, xylitol, sodium carbonate anhydrous, peppermint oil, levomenthol, magnesium oxide light, sodium bicarbonate.

#### NICORETTE® MINT 4 mg chewing gum

- The active substance is nicotine-resin complex 20 mg equivalent to nicotine 4 mg.
- The other ingredients are chewing gum base, xylitol, sodium carbonate anhydrous, peppermint oil, levomenthol, magnesium oxide light, quinoline yellow (E104).

#### NICORETTE® ICY WHITE 2 mg chewing gum

- The active substance is nicotine resinate 10 mg equivalent to nicotine 2 mg.
- The other ingredients are chewing gum base, xylitol, peppermint oil, sodium carbonate anhydrous, sodium hydrogen carbonate, acesulfame potassium, levomenthol, magnesium oxide light, Winterfresh, hypromellose, sucralose, polysorbate 80, starch, titanium dioxide (E171), carnauba wax.

#### NICORETTE® ICY WHITE 4 mg chewing gum

- The active substance is nicotine resinate 20 mg equivalent to nicotine 4 mg.

- The other ingredients are chewing gum base, xylitol, peppermint oil, sodium carbonate anhydrous, acesulfame potassium, levomenthol, magnesium oxide light, quinoline yellow (E104), Winterfresh, hypromellose, sucralose, polysorbate 80, starch, titanium dioxide (E171), carnauba wax.

NICORETTE® FRESHFRUIT 2 mg: each piece contains 10 mg

nicotine-resin complex 20 %, equivalent to 2 mg nicotine.

List of excipients: chewing gum base, xylitol, sodium carbonate anhydrous, sodium hydrogen carbonate, magnesium oxide light, acesulfame potassium, peppermint oil, levomenthol, acacia, tuttifrutti (QL84441), hypromellose, sucralose, polysorbate 80, titanium dioxide (E171), and carnauba wax.

NICORETTE® FRESHFRUIT 4 mg: each piece contains 20 mg

nicotine-resin complex 20 %, equivalent to 4 mg nicotine.

List of excipients: chewing gum base, xylitol, sodium carbonate anhydrous, acesulfame potassium, magnesium oxide light, peppermint oil, levomenthol, acacia, titanium dioxide (E171), quinoline yellow (E104), tuttifrutti (QL84441), hypromellose, sucralose, polysorbate 80 and carnauba wax.

NICORETTE® FRESHMINT 2 mg: each piece contains 10 mg nicotine-resin complex 20 %,

equivalent to 2 mg nicotine.

List of excipients: chewing gum base, xylitol, sodium carbonate anhydrous, sodium hydrogen carbonate, magnesium oxide light, acesulfame potassium, peppermint oil, levomenthol, acacia, titanium dioxide (E171), carnauba wax.

NICORETTE® FRESHMINT 4 mg: each piece contains 20 mg nicotine-resin complex 20 %,

equivalent to 4 mg nicotine.

List of excipients: chewing gum base, xylitol, sodium carbonate anhydrous, magnesium oxide light, acesulfame potassium, peppermint oil, levomenthol, acacia, titanium dioxide (E171), quinoline yellow (E104), carnauba wax.

### **WHAT NICORETTE® chewing gum IS USED FOR**

NICORETTE® chewing gum helps you to give up smoking by relieving nicotine craving, as well as the unpleasant withdrawal effects that smokers experience when they stop smoking.

NICORETTE® chewing gum is most effective if you use it while you participate in a behaviour modification programme to help you stop smoking. If you use NICORETTE® for longer than three months you may not experience any additional benefits.

### **BEFORE YOU TAKE NICORETTE® chewing gum**

#### **Do not use NICORETTE® chewing gum if:**

- You are hypersensitive (allergic) to nicotine or any of the other ingredients of NICORETTE® chewing gums.
- You are under the age of 18 years.
- You are not a smoker.
- You have just suffered a heart attack.
- You have a severe heart condition that effects your heart rate or rhythm.
- You have severe chest pain (angina pectoris)
- You have a disease of the jaw joint.
- You are pregnant or breastfeeding your baby (see **Pregnancy and Breastfeeding**).

#### **Take special care with NICORETTE® chewing gum:**

Ask your doctor or pharmacist for advice before using NICORETTE® chewing gum if:

- You have recently had a serious cardiovascular event like a stroke or heart attack.

- You have persistent indigestion or pains in the chest.
- You have uncontrolled high blood pressure.
- You have a stomach ulcer.
- You have an overactive thyroid gland.
- You have diabetes that is controlled with insulin (you may require lower doses of insulin as a result of smoking cessation).
- You have a tumour of the adrenal glands (phaeochromocytoma) – your doctor will have told you.
- You have severe/moderate liver or severe kidney disease.

The chewing gum may stick to, and may in rare cases damage dentures.

If you are a woman, smoking can cause a delay in you falling pregnant and significantly increase your risk of not falling pregnant. If you are a man, smoking can reduce your sperm production and lower the fertilising capacity of your sperm.

### **Taking Nicorette® chewing gum with food and drink**

Do not eat or drink while chewing NICORETTE® chewing gum.

### **Pregnancy and Breastfeeding**

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using NICORETTE® chewing gum, as it may cause harm to your baby.

Take adequate precautions to avoid becoming pregnant while using NICORETTE® chewing gum.

Your doctor may wish to consider a pregnancy test before starting therapy with NICORETTE® chewing gum. If you use NICORETTE® chewing gum during pregnancy or if you become pregnant while using NICORETTE® chewing gum, you should consider the potential hazard to your unborn baby.

NICORETTE® chewing gum should be avoided during breastfeeding as nicotine is excreted in breast milk and may affect your child.

### **Driving and using machinery**

NICORETTE® can cause dizziness. Do not drive a vehicle, operate machinery, or do anything else that requires your attention until you know how NICORETTE® affects you.

### **Important information about some of the ingredients of NICORETTE® chewing gum**

Some flavours of NICORETTE® chewing gum contains xylitol, which may cause diarrhoea and flatulence when taken by mouth in large amounts.

NICORETTE® 2 mg & 4 mg chewing gum contains sorbitol, and is unsuitable for use if you have fructose intolerance that is hereditary.

### **Using other medicines with NICORETTE® chewing gum**

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

This is especially important if you take medicines containing:

- Caffeine (stimulant found in coffee and some medicines)
- Theophylline (for asthma)
- Imipramine (for depression or mood disorders)
- Pentazocine (for severe pain)
- Glutethimide (for insomnia)
- Propoxyphene (for mild to moderate pain)
- Furosemide (for water retention associated with heart failure)
- Propanolol (for high blood pressure)

### **HOW TO USE NICORETTE® chewing gum**

Do not exceed the stated dose.

Do not share medicines prescribed for you with others.

The usual dose is one piece of NICORETTE® chewing gum whenever you feel the need to smoke. Only chew one piece of NICORETTE® chewing gum at a time. The number of NICORETTE® chewing gum pieces you use per day will depend on your craving, it could be between 10 - 12 pieces per day.

You must not use more than 15 pieces of NICORETTE® chewing gum in 24 hours.

You can use NICORETTE® chewing gum for 3 months at the above-mentioned dose. Thereafter you have to start using less NICORETTE® chewing gum pieces each day until you are not using any NICORETTE® chewing gum per day.

Regular use beyond 3 months is generally not recommended. Some ex-smokers may need longer treatment to avoid returning to smoking. Keep any unused chewing gum handy in case the urge to smoke suddenly returns.

If you have the impression that the effect of NICORETTE® chewing gum is too strong or too weak, tell your doctor or pharmacist.

### **Which strength of chewing gum to use**

Use NICORETTE® 2 mg chewing gum (any flavour) if you smoke 20 cigarettes or less daily.

Use NICORETTE® 4 mg chewing gum (any flavour) if you smoke more than 20 cigarettes daily or if you have previously failed a quitting attempt using the 2 mg gum.

### **How to chew NICORETTE® chewing gum**

1. Stop smoking completely at the same time in order to increase your chances of success.
2. Chew a piece of chewing gum when you feel the need to smoke; the chewing gum is chewed to release nicotine.
3. Then stop chewing (rest) so that nicotine can be taken in through the lining of the mouth.

4. Nicotine swallowed in the saliva is not beneficial and in excess may irritate your throat or upset your stomach causing e.g. hiccups. To avoid this chew slowly until the taste becomes strong then stop and rest the chewing gum between gum and cheek.
5. When the taste fades, chew a few times until the taste gets strong, then rest the chewing gum again.
6. Keep chewing the gum for about half an hour.
7. When the chewing gum has lost its strength dispose of it carefully, such as back in the hole of the blister.
8. Do not swallow the gum.

**If you use more NICORETTE® chewing gum than you should:**

Symptoms of overdosage are those of acute nicotine poisoning and include nausea, salivation, stomach pain, diarrhoea, sweating, headache, dizziness, disturbed hearing and marked weakness. In the event of overdosage consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre. Take this leaflet and the rest of the remaining NICORETTE® chewing gum with you so the doctor will know what you have taken.

**POSSIBLE SIDE EFFECTS**

NICORETTE® chewing gum like all other medicines may cause unwanted side effects in some people.

NICORETTE® chewing gum can have side effects.

Not all side effects reported for NICORETTE® chewing gum are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NICORETTE® chewing gum, please consult your doctor, pharmacist or other healthcare professional for advice.

NICORETTE® chewing gum may cause side effects similar to those associated with nicotine from smoking or other tobacco use.



These are mainly dose-dependent. Most of the possible side effects occur during the first weeks after start of treatment.

If any of the following happens, stop taking NICORETTE® chewing gum 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.

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

- Chest pains
- Changes in the way your heart beats, for example if you notice it beating faster.

Tell your doctor if you notice any of the following:

- Nausea (feeling sick)
- Stomach pains or discomfort
- Headache
- Dizziness
- Diarrhoea.

The most frequent side effects are:

- Sore mouth and throat, jaw muscle ache
- Dizziness, headache
- Discomfort from stomach or bowels, nausea, hiccups, vomiting.

Less frequent side effects are:

- Sense of irregular hard or rapid heartbeat
- Redness of the skin
- Skin rash notable for pale red, raised, itchy bumps
- Reversible irregular rapid heart beat
- Allergic reactions such as swelling of the skin.

Some symptoms may be related to withdrawal symptoms associated with abstinence from smoking, e.g. dizziness, headache, sleeplessness. Increased frequency of mouth ulcers may occur after abstinence from smoking. The relation to nicotine is unclear. The chewing gum may stick to, and may in rare cases, damage dentures.

If you have any side effects not listed here you should tell your doctor or pharmacist.

## **STORING AND DISPOSING OF NICORETTE® chewing gum**

### **Storage:**

As with all medicines keep NICORETTE® chewing gum out of reach of children.

Keep your medicine in a cool dry place where the temperature stays at or below 25 °C.

Do not use NICORETTE® chewing gum if the blister is damaged or if the product has passed the expiry date printed on the carton.

Keep any spare blisters in the box until immediately before use.

### **Disposal:**

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

When NICORETTE® chewing gum is no longer needed, dispose of it carefully where children or animals cannot get it.

## **PRESENTATION OF NICORETTE® chewing gum**

NICORETTE® chewing gum is packed in 2 and 7 blister strips containing 15 pieces. They are supplied in a carton containing 30 and 105 pieces together with a package insert.

### **IDENTIFICATION OF NICORETTE® chewing gum**

NICORETTE® 2 mg is a square beige piece of gum.

NICORETTE® 4 mg is a square yellow piece of gum.

NICORETTE® MINT 2 mg is a square light beige piece of gum.

NICORETTE® MINT 4 mg is a square light yellow piece of gum.

NICORETTE® ICY WHITE 2 mg is a whitish coated square piece of gum.

NICORETTE® ICY WHITE 4 mg is a cream coloured coated square piece of gum.

NICORETTE® FRESHFRUIT 2 mg is a square whitish coated piece, with a characteristic fruity taste and odour.

NICORETTE® FRESHFRUIT 4 mg is a square, coated and cream coloured piece, with a characteristic fruity taste and odour.

NICORETTE® FRESHMINT 2 mg is a square whitish coated piece, with a minty taste and odour.

NICORETTE® FRESHMINT 4 mg is a square, coated and cream coloured piece, with a minty taste and odour.

### **REGISTRATION NUMBERS**

NICORETTE® 2 mg: P/34/187

NICORETTE® 4 mg: P/34/188

NICORETTE® MINT 2 mg: 30/34/0272

NICORETTE® MINT 4 mg: 30/34/0273

NICORETTE® ICY WHITE 2 mg: A46/34/0164

NICORETTE® ICY WHITE 4 mg: A46/34/0165

NICORETTE® FRESHFRUIT 2 mg: A40/34/0565

NICORETTE® FRESHFRUIT 4 mg: A40/34/0566

NICORETTE® FRESHMINT 2 mg: A40/34/0520

NICORETTE® FRESHMINT 4 mg: A40/34/0523

**NAME AND ADDRESS OF REGISTRATION HOLDER**

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