

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

Nicorette Peppermint 2 mg medicated chewing gum
Nicorette Peppermint 4 mg medicated chewing gum

nicotine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 chewing gum contains 2 mg of nicotine (as nicotine resinate)
1 chewing gum contains 4 mg of nicotine (as nicotine resinate)

3. LIST OF EXCIPIENTS

2 mg:

xylitol, butylhydroxytoluene, sodium bicarbonate, sodium carbonate, magnesium oxide, acesulfame potassium, peppermint oil, levomenthol, acacia gum, titanium dioxide (E171), carnauba wax, talc.

4 mg:

xylitol, butylhydroxytoluene, sodium carbonate, magnesium oxide, acesulfame potassium, peppermint oil, levomenthol, acacia gum, titanium dioxide (E 171), quinoline yellow (E104), carnauba wax, talc.

4. PHARMACEUTICAL FORM AND CONTENTS

Medicated chewing gum

- 10 pieces of medicated chewing gums
- 12 pieces of medicated chewing gums
- 15 pieces of medicated chewing gums
- 24 pieces of medicated chewing gums
- 30 pieces of medicated chewing gums
- 48 pieces of medicated chewing gums
- 90 pieces of medicated chewing gums
- 96 pieces of medicated chewing gums
- 105 pieces of medicated chewing gums
- 204 pieces of medicated chewing gums
- 210 pieces of medicated chewing gums

5. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNINGS, IF NECESSARY

8. EXPIRY DATE

EXP:

9. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORIZATION HOLDER

McNeil Sweden AB
Solna, Sweden

12. MARKETING AUTHORIZATION NUMBER

2 mg: MA No. 20036
4 mg: MA No. 20037

13. BATCH NUMBER

Batch:

14. GENERAL CLASSIFICATION FOR SUPPLY

Over-the-counter Medicinal product.

15. INSTRUCTIONS ON USE

2 mg:
Front:
If you smoke no more than 20 cigarettes/day

Helps you stop smoking

Back:

For adults over 18 years of age. Help with withdrawal symptoms associated with abrupt smoking cessation and smoking cessation with tapering off. Choose the strength of gum based on your nicotine addiction. Use 2 mg if you smoke no more than 20 cigarettes/day.

Abrupt cessation of smoking

Dosage: Take 1 chewing gum when you would normally smoke a cigarette or if you feel like smoking.

1 chewing gum can be taken every one to two hours.

Usual dose: 8-12 chewing gums/day.

No more than 24 chewing gums/day.

To maximize the chances of success, it is important not to underdose.

The duration of treatment is individual. Normally, the treatment should last for at least 3 months when quitting smoking, then the number of chewing gums is gradually reduced.

For smoking cessation with tapering or combination therapy with Nicorette transdermal patch: See the package leaflet.

Adolescents between 12 and 17 years should only use Nicorette if they have received it on prescription from healthcare personnel.

Nicorette chewing technique

1. Chew Nicorette gum slowly until the flavor becomes strong.
2. Let the chewing gum rest in your mouth for a while.
3. Chew again when the taste has subsided.

4 mg:

Front:

If you smoke more than 20 cigarettes/day

Help in connection with smoking cessation

Back:

For adults over 18 years of age. Help with withdrawal symptoms associated with abrupt smoking cessation and smoking cessation with tapering off.

Choose the strength of gum based on your nicotine addiction. Use 4 mg if you smoke more than 20 cigarettes/day.

Abrupt cessation of smoking

Dosage: Take 1 chewing gum when you would normally smoke a cigarette or if you feel like smoking.

1 chewing gum can be taken every one to two hours.

Usual dose: 8-12 chewing gums/day.

No more than 24 chewing gums/day.

To maximize the chances of success, it is important not to underdose.

The duration of treatment is individual. Normally, the treatment should last for at least 3 months when quitting smoking, then the number of chewing gums is gradually reduced.

For smoking cessation with tapering: See the package leaflet.

Adolescents between 12 and 17 years should only use Nicorette if they have received it on prescription from healthcare personnel.

Nicorette chewing technique

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16. INFORMATION IN BRAILLE

Nicorette Peppermint 2 mg
Nicorette Peppermint 4 mg

17. UNIQUE IDENTIFIER – 2D BARCODE

Not applicable.

18. UNIQUE IDENTIFIER — HUMAN-READABLE DATA

Not applicable.

INFORMATION TO BE INCLUDED ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE MEDICINAL PRODUCT

Nicorette Pepparmint 2 mg medicated chewing gum
Nicorette Pepparmint 4 mg medicated chewing gum

nicotine

2. MARKETING AUTHORIZATION HOLDER

McNeil

3. EXPIRY DATE

{Exp. date}

4. BATCH NUMBER

{Batch no.}

5. OTHER