

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

Nicorette Novum 10 mg/16 hour transdermal patch
Nicorette Novum 15 mg/16 hour transdermal patch
Nicorette Novum 25 mg/16 hour transdermal patch

nicotine

2. STATEMENT OF ACTIVE SUBSTANCE(S)

10 mg/16 hours: 1 transdermal patch contains: 15.8 mg nicotine (10 mg delivered over 16 hours)
15 mg/16 hours: 1 transdermal patch contains: 23.6 mg nicotine (15 mg released over 16 hours)
25 mg/16 hours: 1 transdermal patch contains: 39.4 mg nicotine (25 mg released over 16 hours)

3. LIST OF EXCIPIENTS

triglycerides (medium chain), basic butylated methacrylate copolymer, PET film.
Acrylate-matrix: acrylic adhesive (solution), potassium hydroxide, croscarmellose sodium, aluminum acetylacetonate. Protective film: PET film (aluminum coated on one side and siliconized on both sides).

4. PHARMACEUTICAL FORM AND CONTENTS

Transdermal patches

10 mg/16 hours:
7 transdermal patches
14 transdermal patches

15 mg/16 hours:
7 transdermal patches
14 transdermal patches
21 transdermal patches
28 transdermal patches

25 mg/16 hours:
7 transdermal patches
14 transdermal patches
21 transdermal patches
28 transdermal patches

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 WARNING(S), IF NECESSARY

8. EXPIRY DATE

Exp. date:

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

The used patch is folded together with the sticky side inwards and stored safely so that children cannot gain access to the patch. Then hand in to the pharmacy.

11. NAME AND ADDRESS OF THE MARKETING AUTHORIZATION HOLDER

McNeil Sweden AB
Solna, Sweden

12. MARKETING AUTHORIZATION NUMBER

10 mg/16 hours: MA No. 23996

15 mg/16 hours: MA No. 23997

25 mg/16 hours: MA No. 23998

13. BATCH NUMBER

Batch:

14. GENERAL CLASSIFICATION FOR SUPPLY

Over-the-counter Medicinal product

15. INSTRUCTIONS ON USE

Front:

Help in connection with smoking cessation

10 mg/16 h: Step 3: For those who taper off after 15 mg/16 hour patches

7 transdermal patches for 1 week

14 transdermal patches for 2 weeks

15 mg/16 hours: Step 2 For those who smoke no more than 20 cigarettes/day or who are tapering off after 25 mg/16 hour patches

7 transdermal patches for 1 week

14 transdermal patches for 2 weeks

21 transdermal patches for 3 weeks

28 transdermal patches for 4 weeks

25 mg/16 h: Step 1: For those who smoke more than 20 cigarettes/day

7 transdermal patches for 1 week

14 transdermal patches for 2 weeks

21 transdermal patches for 3 weeks

28 transdermal patches for 4 weeks

Back

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

Usual Dosage:

Week	1-8	9-10	11-12
If you smoke more than 20 cigarettes/day	25 mg/16 hours Step 1	15 mg/16 hours Step 2	10 mg/16 hours Step 3
If you smoke no more than 20 cigarettes/day	15 mg/16 hours step 2	10 mg/16 hours step 3	10 mg/16 hours step 3

Put the patch on in the morning and take it off at bedtime.

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

Combination therapy with some other Nicorette medicines: See the package leaflet.

16. INFORMATION IN BRAILLE

Nicorette Novum 10 mg/16 hours

Nicorette Novum 15 mg/16 hours

Nicorette Novum 25 mg/16 hours

17. UNIQUE IDENTIFIER – 2D BARCODE

Not applicable.

18. UNIQUE IDENTIFIER — HUMAN-READABLE DATA

Not applicable.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BAG

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

Nicorette Novum 10 mg/16 hour transdermal patch
Nicorette Novum 15 mg/16 hour transdermal patch
Nicorette Novum 25 mg/16 hour transdermal patch

nicotine

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

Exp. date:

4. BATCH NUMBER

Batch:

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

10 mg/16 hours
15 mg/16 hours
25 mg/16 hours

6. OTHER

Keep out of the sight and reach of children.