nicorette®

2 mg and 4 mg Lozenge nicotine compressed lozenge

What you should know about nicorette® fruit lozenge
nicorette® fruit 2 mg Lozenge
(2 mg nicotine compressed lozenge)
nicorette® fruit 4 mg Lozenge
(4 mg nicotine compressed lozenge)

INFOGRAPHIC

INFORMATION FOR THE USER

nicorette®

Please read this leaflet carefully before you start using this medicine. It contains important information on how to use it safely. Keep the leaflet, you might need it again.
If you think you are having side-effects, have any questions or are not sure about anything please ask your doctor, nurse or pharmacist.

1 What this medicine is for

NICORETTE® fruit lozenge is a nicotine replacement therapy (NRT). It is used to reduce and (or present Behavioural support in combination with NRT can help you to stop smoking. As soon as you are ready you should aim to stop smoking completely.
You can also use the lozenge on these occasions when you can’t or don’t want to smoke e.g. Social situations such as a party, in the pub or when at work.

When making a quit attempt behavioural therapy, advice and support will normally improve the success rate. If you have quit smoking and want to stop using NICORETTE® fruit lozenge but are finding this difficult you should contact your doctor, nurse or pharmacist for advice.

Below is the dosage information for the NICORETTE® fruit lozenge. This shows the number of lozenges you should be using, when you should take them, how you should take them and the maximum amount of time you should be using Nicotine Replacement Therapy (NRT) for.

Children under 12 years
Do not give this product to children under 12 years.

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**Possible side-effects**
Like all medicines, NICORETTE® fruit lozenges can have side-effects. As many of the effects are due to nicotine, they can also occur when nicotine is obtained by smoking.

**Effects related to stopping smoking (nicotine withdrawal)**
You may experience unwanted effects because by stopping smoking you have reduced the amount of nicotine you are taking. You may also experience these effects if you under use NICORETTE® fruit lozenges before you are ready to reduce your nicotine intake.

**These effects include:**
- irritability or aggression
- feeling low
- anxiety
- restlessness
- poor concentration
- increased appetite or weight gain
- urges to smoke (craving)
- night time awakening or sleep disturbance
- sweating or heat flushes

**Effects of too much nicotine**
You may also get these effects if you are not used to inhaling tobacco smoke.

**These effects include:**
- feeling faint
- nausea
- headache

**Side-effects for nicorette® fruit lozenges**
If you notice any of the following: fast heart rate, chest pain, abnormal breathing, or loss of consciousness, seek medical attention immediately.

**Uncommon side-effects:**
- may affect up to 1 in 100 people:
  - increased dreams
  - sudden reddening of the face and/or neck

**Other side-effects:**
- not listed in this leaflet. You can also report side-effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard
- Not all information on the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard may affect more than 1 in 10 people:
  - dry mouth
  - tingling of the mouth
  - numbness or tingling of the mouth
  - excessive sweating
  - itching
  - rash
  - wheezing and shortness of breath
  - coughing
  - blocked nose, sneezing
  - blocked or runny nose
  - burning sensation in the mouth
  - hives (urticaria)
  - unusual weakness
  - chest discomfort and pain
  - jaw-muscle ache
  - muscle tightness
  - muscle stiffness
  - muscle ache
  - difficulty in swallowing
  - chest pain or discomfort
  - difficulty in breathing
  - feeling of wanting to be sick (vomiting)
  - strange taste in the mouth
  - itchy swelling of the body
  - vision changes
  - unusual tiredness or weakness
  - feeling of having to go to the toilet more often
  - feeling of wanting to vomit
  - unexpected pain in the legs
  - feeling of feeling low
  - feeling faint
  - feeling sick (nausea)
  - bad smell
  - fever
  - dry skin
  -rash
  - muscle cramps
  - feeling of being unwell
  - general feeling of discomfort or being unwell or out of sorts (malaise)
  - unexplained bleeding or bruising
  - unusual swelling
  - increased appetite or weight gain
  - feeling of wanting to be sick (nausea)
  - feeling of wanting to vomit
  - unusual tiredness or weakness
  - feeling of having to go to the toilet more often
  - feeling of feeling low
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  - muscle cramps
  - feeling of being unwell
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**Rare side-effects:**
- may affect up to 1 in 1,000 people:
  - allergic reactions (hypersensitivity)
  - burning sensation in the mouth
  - dizziness
  - abnormality that may affect organs or systems other than the organs or systems listed above

**What the medicine looks like**
NICORETTE® fruit 2 mg lozenge is an oval, white to off-white lozenge imprinted with a “n” on one side and “2” on the other side. The product licence holder is McNeil SL6 3UG, UK. This leaflet was prepared in April 2018.

**Contact a doctor or your nearest hospital Accident and Emergency department immediately.** Take this leaflet and the pack with you.

**Who makes nicorette® fruit lozenges?**
The Product Licence holder is McNeil Products Ltd, Maidenhead, Berkshire, SL6 3UG, UK. The manufacturer is McNeil AB, Helsingborg, Sweden.

**Pack types and pack sizes:**
Loose-fill packed in a plastic bottle (“flip pack”) containing 20 lozenges and supplied in packs of 20 (±20) or 60 (±60) lozenges. Blister packed in sheets of 12 and contains in a cardboard box supplied in packs of 24 (±12) lozenges. Not all pack types and pack sizes may be marketed.

**What happens 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 Yellow Card Scheme at:**
www.mhra.gov.uk/yellowcard

**What is in this medicine?**
- Nicotine (as nicotine resinate).
- Mannitol (E421)
- Xanthan gum (E415)
- Tutti Frutti Flavour (liquid flavour contains butyrate, and citral the spray dried flavour also contains gum arabic (E414), Sodium carbonate anhydrous (E510)), Sodium chloride (E500), Acetosyringone (E227), Magnesium stearate (E451b), Hypromellose (E464), Titanium dioxide (E171), Ployoxmery 80, Stearyl Glucos (contains hypromellose (E464), microcrystalline cellulose (E460), and potassium aluminium silicate (E553)).

**How to store nicorette® fruit lozenges**
- Store in a dry place away from direct sunlight.
- Do not store above 25°C.
- Do not store in the refrigerator.
- Keep NICORETTE® fruit lozenge out of the sight and reach of children.
- Keep NICORETTE® fruit lozenge out of the sight and reach of animals.
- Keep NICORETTE® fruit lozenge out of the sight and reach of children.
- Do not use NICORETTE® fruit lozenge after the ‘Use before’ date on the bottle, box or blister strip.
- Dispose of lozenges sensibly away from children and animals.
- NICORETTE® fruit lozenge does not require any special storage conditions.
- Do not use this product after the ‘Use before’ date on the bottle, box or blister strip.

**Further information**
- NICORETTE® fruit lozenge contains 2 or 4 milligrams of nicotine (as nicotine resinate).
- Other ingredients are: Mannitol (E421), Xanthan gum (E415), Tuff Fruit Flavour (liquid flavour contains orange oil, orange oil terpenes, lemon) butyrate, and citral the sprayed flavour also contains gum arabic (E414), Sodium carbonate anhydrous (E510), Sodium chloride (E500), Acetosyringone (E227), Magnesium stearate (E451b), Hypromellose (E464), Titanium dioxide (E171), Ployoxmery 80, Stearyl Glucos (contains hypromellose (E464), microcrystalline cellulose (E460), and potassium aluminium silicate (E553)).
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