



Nicotinell
NICOTINE

Nicotinell Rapid Relief 1 mg/spray Oromucosal Spray

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

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you have not achieved a reduction in the number of sprays or in cigarette/e-cigarette consumption after 6 weeks of treatment or if you have not been able to stop smoking/vaping after 6 months of treatment with Nicotinell Rapid Relief 1 mg/Spray.

What is in this leaflet

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1. What Nicotinell Rapid Relief 1 mg/Spray is and what it is used for

Nicotinell Rapid Relief 1 mg/Spray is used to treat tobacco or vaping dependence in adults.

Nicotinell Rapid Relief 1 mg/Spray is used to help you stop smoking or vaping when you want to quit or to cut down smoking before stopping completely. This is a type of treatment called Nicotine Replacement Therapy (NRT).

Nicotinell Rapid Relief 1 mg/Spray relieves nicotine withdrawal symptoms including cravings, symptoms you get when stopping smoking/vaping. When you suddenly stop providing nicotine from tobacco to your body, you get hit by different kinds of unpleasant feelings called withdrawal symptoms. By using Nicotinell Rapid Relief 1 mg/Spray you can prevent or reduce these unpleasant feelings and cravings for smoking/vaping. This is because you continue to provide a small amount of nicotine to your body for a short period of time. Nicotinell Rapid Relief 1 mg/Spray does not contain the tar, carbon monoxide or other toxins in cigarette/e-cigarette smoke.

To improve the chances of helping you to stop smoking/vaping, you should also seek counselling advice and support, if you can.

2. What you need to know before you use Nicotinell Rapid Relief 1 mg/Spray

DO NOT use Nicotinell Rapid Relief 1 mg/Spray

- 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 18 years**.
- If you have **never smoked/vaped**.

Warnings and precautions

Talk to your doctor before taking this medicine if you suffer from the following conditions. You may be able to have Nicotinell Rapid Relief 1 mg/Spray, but need to discuss with your doctor first if you have:

- Recently (within 3 months) had a **heart attack** or **stroke**
- **Chest pain** (unstable angina), or resting angina
- A **heart condition** that effects your heart rate or rhythm
- **High blood pressure** which is not being controlled by medicines
- Ever had **allergic reactions** that involve swelling of the lips, face and throat (angioedema) or itchy skin rash (urticaria). Using NRT can sometimes trigger this type of reaction.
- Severe or moderate **liver disease**
- Severe **kidney disease**
- **Diabetes**
- An overactive **thyroid gland**
- A tumour of the **adrenal gland** (phaeochromocytoma)
- **Stomach or duodenal ulcer**
- **Oesophagitis**

Nicotinell Rapid Relief 1 mg/Spray should not be used by **non-smokers/non-vapers**.

Children and adolescents

Do not give this medicine to children and adolescents.

The correct dose for adults could seriously poison or even be life-threatening for small children. It is therefore essential that you keep Nicotinell Rapid Relief 1 mg/Spray out of sight and reach of children at all times.

Other medicines and Nicotinell Rapid Relief 1 mg/Spray

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This is especially important if you take medicines containing:

- **theophylline** to treat asthma
- **tacrine** for Alzheimer's disease
- **clozapine** for schizophrenia
- **ropinirole** to treat Parkinson's disease

Nicotinell Rapid Relief 1 mg/Spray with food and drink

Do not eat or drink when administering the oromucosal spray.

Pregnancy, breast-feeding and fertility

It is very important to stop smoking/vaping during **pregnancy** because it can result in poor growth of your baby. It can also lead to premature births or stillbirths. It is best if you can give up smoking/vaping without the use of medicines containing nicotine. If you cannot manage this, Nicotinell Rapid Relief 1 mg/Spray should only be used after consulting the healthcare professional who is managing your pregnancy, your family doctor, or a doctor in a centre that is specialised in helping people quit smoking/vaping.

Nicotinell Rapid Relief 1 mg/Spray should be avoided during **breast-feeding** as nicotine is found in breast milk and may affect your child. If your doctor has recommended you to use Nicotinell Rapid Relief 1 mg/Spray, the spray should be taken just after breast-feeding and not during the 2 hours before breast-feeding.

The effects of vaping on your body during pregnancy and breast-feeding are not established.

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

Driving and using machines

No effects on the ability to drive cars or use machines have been observed.

Nicotinell Rapid Relief 1 mg/Spray contains ethanol, sodium, propylene glycol and benzyl alcohol

This medicine contains 7 mg of ethanol in each spray which is equivalent to 100 mg/ml.

The amount of ethanol per spray of this medicine is equivalent to less than 2.5 ml beer or 1 ml wine

The small amount of alcohol in this medicine will not have any noticeable effects.

This medicine contains 0.5 mg sodium (main component of cooking/table salt) per spray. This is equivalent to 0.025 % of the recommended maximum daily dietary intake of sodium for an adult.

This medicine contains 10.95 mg propylene glycol in each spray which is equivalent to 156.43 mg/ml.

This medicine contains 0.018 mg benzyl alcohol in each spray which is equivalent to 0.26 mg/ml. Benzyl alcohol may cause allergic reactions.

3. How to use Nicotinell Rapid Relief 1 mg/Spray

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

People under **18 years of age** should not use Nicotinell Rapid Relief 1 mg/Spray.

Consult your doctor if you have not achieved a reduction in the number of sprays or in cigarette/e-cigarette consumption after 6 weeks of treatment or if you need to use Nicotinell Rapid Relief 1 mg/Spray for longer than 6 months. Normally you should take Nicotinell Rapid Relief 1 mg/Spray for 3 months. Nicotinell Rapid Relief 1 mg/Spray should be taken for no longer than 6 months.

The instructions about how to use Nicotinell Rapid Relief 1 mg/Spray depend on whether you are stopping smoking immediately or are cutting down the number of cigarettes gradually before stopping completely.

Stopping smoking/vaping immediately

The aim is to stop smoking/vaping immediately and use the spray to relieve the cravings to smoke/vape.

Do not use more than 2 sprays at a time or 4 sprays per hour for 16 hours. The maximum dose is 64 sprays over 16 hours in any 24-hour period.

Step 1: Weeks 1–6

Use 1 or 2 sprays when you would normally smoke/vape a cigarette/e-cigarette or have cravings to smoke/vape. Use one spray first and if your cravings do not disappear within a few minutes use the second spray. If 2 sprays are required, future doses may be delivered as 2 consecutive sprays. For most smokers/vapers this means about 1 or 2 sprays every 30 minutes to 1 hour.

For example, if you smoke/vape an average of 15 cigarettes/e-cigarettes per day, you should use 1 or 2 sprays at least 15 times during the day.

Step 2: Weeks 7–9

Start reducing the number of sprays per day. By the end of week 9 you should be using HALF the average number of sprays per day that you used in Step 1.

Step 3: Weeks 10–12

Continue reducing the number of sprays per day so that you are not using more than 4 sprays per day during week 12. When you have reduced to 2–4 sprays per day, you should stop using Nicotinell Rapid Relief 1 mg/Spray.

Stopping smoking/vaping gradually

The aim is to start by gradually replacing some of your cigarettes/e-cigarettes with Nicotinell Rapid Relief 1 mg/Spray. After achieving this, you then stop smoking/vaping cigarettes/e-cigarettes completely while using the spray. Finally, you stop using the spray.

When you feel a strong urge to smoke/vape, use 1–2 sprays instead of a cigarette to help you manage your cravings. The spray is to replace a cigarette/e-cigarette, do not smoke/vape shortly after using the spray. Using the spray without reducing your number of cigarettes/e-cigarettes will make you feel sick (see section 'If you use more Nicotinell Rapid Relief 1 mg/Spray than you should'). Cut down the number of cigarettes/e-cigarettes you smoke/vape per day, as much as possible and replace them with a spray. If a reduction in cigarette/e-cigarette consumption has not been achieved after 6 weeks of treatment, seek the advice from a doctor. As soon as you feel ready, you should quit completely but no later than 12 weeks after start of treatment. After quitting smoking/vaping gradually reduce the number of sprays per day. When you have reduced to 2–4 sprays per day, stop using Nicotinell Rapid Relief 1 mg/Spray.

Do not use more than 2 sprays at a time or 4 sprays per hour for 16 hours. The maximum dose is 64 sprays over 16 hours in any 24-hour period.

You may be tempted to smoke/vape again after treatment has stopped. Save any remaining doses of the spray, as craving for smoking/vaping may suddenly occur. If you have a craving, use one or two sprays if one spray does not help within a few minutes.

Follow the instructions to ensure you use Nicotinell Rapid Relief 1 mg/Spray correctly.

How to load the dispenser

If you are using Nicotinell Rapid Relief 1 mg/Spray for the first time you must first load the spray pump.

Point the spray safely away from you and any other adults, children or pets that are near you.

Press the top of the dispenser with your index finger 3 times in the air until a fine spray appears (priming).

If you do not use the spray for 2 days, this loading procedure will need to be repeated.

How to use the dispenser

1. After priming, point the spray nozzle as close to the open mouth as possible.
2. Press firmly the top of the dispenser and release one spray into your mouth, avoiding the lips.
3. Direct the spray tube between the cheek and the lower gum / teeth, aiming for the inside of the cheek, avoiding the lips.

Do not inhale while spraying to avoid getting spray down your throat.

For best results do not swallow for a few seconds after spraying.

Care should be taken not to spray the eyes whilst administering the mouth spray. If you get spray in your eye(s), rinse thoroughly with water.

Do not eat or drink when administering the mouth spray.

If you use more Nicotinell Rapid Relief 1 mg/Spray than you should

Overdosing of nicotine may occur if you smoke/vape at the same time as you take Nicotinell Rapid Relief 1 mg/Spray. If a child takes Nicotinell Rapid Relief 1 mg/Spray or if you have used more Nicotinell Rapid Relief 1 mg/Spray than you should, contact your doctor or go to the nearest hospital **immediately**. Doses of nicotine that are tolerated by adult smokers/vapers during treatment may produce severe symptoms of poisoning in **children** and may prove **fatal**.

The symptoms of overdose are feeling sick (nausea), vomiting, too much saliva, stomach pain, diarrhoea, sweating, headache, dizziness, changed hearing, and feeling very weak. At high doses, these symptoms may be followed by low blood pressure, weak and irregular pulse, difficulty breathing, extreme tiredness, circulatory collapse and general convulsions.

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

4. Possible side effects

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

Nicotinell Rapid Relief 1 mg/Spray can give the same side effects as other forms of nicotine. The side effects generally depend on the dose you take.

Effects related to stopping smoking (nicotine withdrawal)

Some of the unwanted effects that you experience when stopping smoking/vaping can be withdrawal symptoms due to decreases in nicotine intake.

These effects include:

- Irritability, aggression, impatience or frustration
- Feeling anxious, restless or having difficulty concentrating
- Night time awakening or sleep disturbance
- Increased appetite or weight gain
- Feeling low
- Urges to smoke/vape (craving)
- Lowering of heart rate
- Bleeding gums or mouth ulcers
- Dizziness or light-headedness
- Cough, sore throat, stuffy or runny nose
- Constipation

If you notice any of the following serious rare side effects, stop taking Nicotinell Rapid Relief 1 mg/Spray and contact a doctor immediately (signs of angioedema):

- Swollen face, tongue or pharynx
- Difficulty to swallow
- Hives and difficulties to breathe

Very common: may affect more than 1 in 10 people:

- Hiccups (these are particularly common)
- Headache, nausea (feeling sick)
- Throat irritation

Common: may affect up to 1 in 10 people:

- Local effects such as burning sensation, inflammation in the mouth, changes in taste perception
- Dry mouth or increased amounts of saliva
- Feelings of dyspepsia
- Pain or discomfort in tummy (abdomen)
- Vomiting, flatulence or diarrhoea
- Feeling tired (fatigue)
- Hypersensitivity (allergy)
- Tingling
- Cough

Uncommon: may affect up to 1 in 100 people:

- Effects on the nose such as stuffiness, sneezing
- Runny nose
- Wheezing (bronchospasm), or feeling like breathing requires more effort than usual (dyspnoea), throat tightness
- Skin flushing (blushing), or increased sweating
- Oral effects such as mouth tingling, inflammation of the tongue, mouth ulcers, damage to the lining of the mouth, or changes in the sound of your voice, pain in the mouth and throat, belching, bleeding gums
- Palpitations (an unusual awareness of your heart beating), increase of heart rate, hypertension
- Rash and/or itching (pruritus, urticaria) of the skin
- Abnormal dream
- Chest discomfort and pain
- Weakness, feeling unwell

Rare: may affect up to 1 in 1,000 people

- Difficulty swallowing, reduced sensations in the mouth
- Retching

Not known: frequency cannot be estimated from the available data:

- Blurred vision, increased tear production (lacrimation)
- Dry throat, stomach discomfort, pain in the lips
- Abnormal heart rhythm
- Redness of the skin
- Allergic reactions including swelling of the face and mouth (angioedema or anaphylaxis)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 or search for the MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nicotinell Rapid Relief 1 mg/Spray

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the bottle and carton after EXP. The expiry date refers to the last day of that month.

Use within 6 months after first opening.

This medicine does not require any special storage conditions.

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 to protect the environment especially the aquatic environment in the case of nicotine.

6. Contents of the pack and other information

What Nicotinell Rapid Relief 1 mg/Spray contains

- The active substance is nicotine. One spray delivers 1 mg nicotine in 0.07 ml solution. 1 ml solution contains 13.6 mg nicotine.
- The other ingredients are: propylene glycol (E1520), glycerol (E422), ethanol anhydrous, poloxamer 407, glycine (E640), sodium hydrogen carbonate (E500(ii)), levomenthol, mint flavor (contains benzyl alcohol, propylene glycol (E1520), pulegone), cooling agent (contains menthol, menthol carboxamide, essential oil, propylene glycol (E1520)), sucralose (E955), acesulfame potassium (E950), sodium hydroxide (E524), water purified.

For excipients with known effect, please refer to section 2.

What Nicotinell Rapid Relief 1 mg/Spray looks like and contents of the pack

Nicotinell Rapid Relief 1 mg/Spray is a clear, colourless to brownish solution with a spicy mint flavour.

Nicotinell Rapid Relief 1 mg/Spray is packed in:

15 ml blue coloured amber glass bottles with a mechanical spray pump and an overcap.

Each bottle contains 13.2 ml of solution which provides 150 sprays.

Nicotinell Rapid Relief 1 mg/Spray is supplied in packs of either 1 or 2 bottles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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Manufacturer

Galenica Pharmaceutical Industry S.A.1, Asklipiou 4-6, Krioneri, Attiki, 14568, Greece.

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