

Package leaflet: information for the user
Nicospray 1 mg/spray oromucosal spray, solution

nicotine

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 been able to stop smoking after 6 months of treatment with Nicospray.

What is in this leaflet

1. What Nicospray is and what it is used for
2. What you need to know before you use Nicospray
3. How to use Nicospray
4. Possible side effects
5. How to store Nicospray
6. Contents of the pack and other information

1. What Nicospray is and what it is used for

Nicospray is used to help you stop smoking when you want to quit or to cut down smoking before stopping completely. This is a type of treatment called Nicotine Replacement Therapy (NRT).

Nicospray relieves nicotine withdrawal symptoms including cravings, symptoms you get when stopping smoking. 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 Nicospray you can prevent or reduce these unpleasant feelings and cravings for smoking. This is because you continue to provide a small amount of nicotine to your body for a short period of time. Nicospray does not contain the tar, carbon monoxide or other toxins in cigarette smoke.

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

2. What you need to know before you use Nicospray

DO NOT use Nicospray

- 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**.

Warnings and precautions

Talk to your doctor before taking this medicine if you suffer from the following conditions. You may be able to have Nicospray, 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 affects 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**
- History of **epilepsy** or **seizures**

Nicospray should not be used by **non-smokers**.

Children and adolescents

Do not give this medicine to children and adolescents.

Other medicines and Nicospray

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

Nicospray 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 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 without the use of medicines containing nicotine. If you cannot manage this, Nicospray 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.

Nicospray 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 Nicospray, the spray should be taken just after breast-feeding and not during the 2 hours before breast-feeding.

Smoking 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.

Nicospray contains ethanol

This medicine contains 7 mg ethanol (alcohol) in each single spray. The amount in 1 single spray of this medicine is equivalent to less than 1 ml beer or 1 ml wine.

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

Nicospray contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per spray, that is to say essentially 'sodium-free'.

Nicospray contains propylene glycol

This medicine contains 10.5 mg propylene glycol in each single spray.

Nicospray contains benzyl alcohol

This medicine contains 0.018 mg benzyl alcohol in each single spray. Benzyl alcohol may cause allergic reactions and mild local irritation.

Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding or if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

3. How to use Nicospray

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 Nicospray.

Consult your doctor if you have not achieved a reduction in the number of sprays or in cigarette consumption after 6 weeks of treatment or if you need to use Nicospray for longer than 6 months. Normally you should take Nicospray for 3 months. Nicospray should be taken for no longer than 6 months.

The instructions about how to use Nicospray depend on whether you are stopping smoking immediately or are cutting down the number of cigarettes gradually before stopping completely.

Stopping smoking immediately

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

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 a cigarette or have cravings to smoke. 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 this means about 1 or 2 sprays every 30 minutes to 1 hour.

For example, if you smoke an average of 15 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 Nicospray.

Stopping smoking gradually

The aim is to start by gradually replacing some of your cigarettes with Nicospray. After

achieving this, you then stop smoking cigarettes completely while using the spray. Finally, you stop using the spray.

When you feel a strong urge to smoke, use 1-2 sprays instead of a cigarette to help you manage your cravings. The spray is to replace a cigarette, do not smoke shortly after using the spray. Using the spray without reducing your number of cigarettes will make you feel sick (see section 'If you use more Nicospray than you should'). Cut down the number of cigarettes you smoke per day, as many as possible and replace them by a spray. If a reduction in 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, gradually reduce the number of sprays per day. When you have reduced to 2-4 sprays per day, stop using Nicospray.

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 again after treatment has stopped. Save any remaining doses of the spray, as craving for smoking 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 Nicospray mouth spray correctly.

How to load the dispenser

- If you are using Nicospray 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 Nicospray with your index finger 3 times until a fine spray appears.
- 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 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 Nicospray than you should

Overdosing of nicotine may occur if you smoke at the same time as you take Nicospray. If a child takes Nicospray or if you have used more Nicospray than you should, contact your doctor or go to the nearest hospital **immediately**. Doses of nicotine that are tolerated by adult smokers 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.

Nicospray 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 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 (*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 Nicospray 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
- 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
- Runny nose

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
- Redness of the skin
- Allergic reactions including swelling of the face and mouth (angioedema or anaphylaxis)
- Abnormal heart rhythm
- Seizure

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 HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nicospray

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date (<abbreviation use for expiry date on the packaging, for example 'EXP' >) which is stated on the bottle and outer packaging. The expiry date refers to the last day of that month.

After first opening use within 6 months.

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 Nicospray contains

- The active substance is nicotine. Each 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 flavour (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 "Nicospray contains ethanol,

sodium, propylene glycol and benzyl alcohol”.

What Nicospray looks like and contents of the pack

Nicospray oromucosal spray, solution is packed in:

- i) 15 ml amber glass bottles (Type III) with a mechanical spray pump and an overcap.
or
- ii) 15 ml externally plastic coated amber glass bottles (Type III) with a mechanical spray pump and an overcap.
or
- iii) 15 ml amber glass bottles (Type III) with a mechanical spray pump, placed in a plastic protective outer case with overcap.

The visible parts of the spray pump are the following: PP actuator, PP housingcap, LDPE/PP compound diptube.

Nicospray oromucosal spray, solution is a clear colourless to brownish solution.

Each bottle contains 13.2 ml of solution which provides at least 150 sprays. Nicospray is supplied in packs of either 1 or 2 bottles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer

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

STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

This medicinal product is authorised in the Member States of the EEA under the following names:

Netherlands: Nicotine STADA 1 mg/spray, spray voor oromucosaal gebruik, oplossing
Germany: Nicotin AL 1 mg/Sprühstoß Spray zur Anwendung in der Mundhöhle, Lösung
France: NICOTINE EG 1 mg/dose, solution pour pulvérisation buccale
Ireland: Nicospray 1 mg/spray oromucosal spray, solution

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