

VOYE Frosty Mint Nicotine Gum

Nicotine (as polacrilex) (2mg and 4mg)

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What Voye® Frosty Mint Nicotine gum is used for

Voye® Frosty Mint Nicotine gum is used to relieve withdrawal symptoms and reduce the cravings for nicotine that you get when you try to stop smoking. When you are unable to stop smoking straight away, you can use Voye® Frosty Mint Nicotine gum first to reduce your cigarette consumption (smoking reduction) in order to quit smoking.

How Voye® Frosty Mint Nicotine gum works

When you stop smoking, your body misses the nicotine that you have been absorbing. You may experience unpleasant feelings and a strong desire to smoke (craving). This indicates you were dependent on nicotine.

When you chew Voye® Frosty Mint Nicotine gum, nicotine is released and passes into your body through the lining of your mouth. The nicotine released from the gum is sufficient to relieve the unpleasant withdrawal symptoms such as irritability, restlessness, anxiety, and frustration. It will also help to relieve the sudden intense

urge to smoke but Voye® Frosty Mint Nicotine gum will not give you the “buzz” you get from smoking a cigarette.

Before you use Voye® Frosty Mint Nicotine gum

When you must not use it

Do not use

- If you have an allergy to nicotine or any of the other ingredients.
- If you are pregnant, trying to get pregnant or think you may be pregnant.
- If you are breast-feeding. Ask your doctor or pharmacist for advice.
- If you are a non-smoker or occasional smoker.

Children & adolescents: Not to be administered to persons under 18 years of age without recommendation from health care professional.

Before you start to use it

- Talk to your doctor or pharmacist
- If you have experienced a serious cardiovascular event (heart disease), or hospitalization for a cardiovascular complaint, in the previous 4 weeks (e.g., stroke, myocardial infarction, unstable angina, cardiac arrhythmia, coronary artery bypass graft and angioplasty) or if you suffer from uncontrolled hypertension (high blood pressure).
 - If you have stomach ulcer, duodenal ulcer, inflammation of the stomach or inflammation of the oesophagus.
 - If you have liver or kidney disease.
 - If you have an overactive thyroid gland or have a pheochromocytoma (a tumour of the adrenal gland that can affect blood pressure).
 - If you have diabetes, monitor your blood sugar levels more

often when starting to use Voye® Frosty Mint Nicotine gum as you may find your insulin or medication doses require adjustments.

- If you have persistent indigestion or pains in the chest.
- If you have experience of epilepsy and seizures.
- Tell your doctor or pharmacist if the above symptoms persist or worsen, or if you experience new symptoms.
- If you have rare hereditary problems of fructose intolerance.

Taking other medicines

Talk to your doctor or pharmacist if you are taking other medicines such as theophylline, clozapine, ropinirole, tacrine, insulin, imipramine, olanzapine, clomipramine, or fluvoxamine. Tell your doctor or pharmacist if you are taking or have recently taken other medicines, even those not prescribed. Stopping smoking may require the dose of these medicines to be adjusted.

How to use Voye® Frosty Mint Nicotine gum

How much to use

Adults:

Number of cigarettes you smoke per day	Dose of Gums
<20 cigarettes	One 2mg gum as required to relieve cravings
≥20 cigarettes	One 4mg gum as required to relieve cravings

Most people use between 8 to 12 gums per day. You must not exceed the following

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number of gums as stated below in any 24- hour period.

Dosage form	Maximum quantity per day
2 mg	30 pieces
4 mg	24 pieces

Chew a piece of chewing gum when you have an urge to smoke. The chewing gum is chewed to release nicotine, then rested between cheek and gum so that nicotine can be taken in through the lining of the mouth. Nicotine swallowed in the saliva is not beneficial and in excess may irritate your throat or upset your stomach causing e.g., hiccups.

You should chew only ONE gum at a time. Each gum lasts about 30 minutes. After this time the gum will have lost its strength and you should dispose of it carefully.

Smoking cessation:

The Voye® Frosty Mint Nicotine gum should be used when cigarettes normally would have been smoked or if cravings emerge. Sufficient Voye® Frosty Mint Nicotine gum should be used each day.

We suggest that you use Voye® Frosty Mint Nicotine gum for at least 3 months, 8 to 12 chewing gum per day. Stop smoking completely at the same time in order to increase your chances of success. Regular use beyond 12 months is generally not recommended.

Smoking reduction followed by smoking cessation:

You should stop smoking completely as soon as you feel able, but no later than 6 months after starting Voye® Frosty Mint

Nicotine gum. However, if this does not happen within 9 months of starting Voye® Frosty Mint Nicotine gum, you should consult a doctor.

Please note the relevant application instructions for quitting smoking.

For example, do the following:

• 1. Step 1 – 0 to 6 weeks: Reduce cigarette consumption by 50%

Chew a piece of Voye® Frosty Mint Nicotine gum whenever you feel the urge to smoke. Aim to cut your cigarette consumption in half by the end of the 6th week - or even sooner if you can.

• 2. Step 2 - within 6 months

Keep reducing your cigarette consumption until you quit smoking completely. Chew Voye® Frosty Mint Nicotine gum whenever you feel the urge to smoke to avoid relapse. Aim to quit smoking within 6 months, or sooner if you can.

• 3. Step 3 - within 9 months: Quit smoking!

If you forget to use it

Do not take double dose if you forget to use.

If you use too much (overdose)

If you have used more than the recommended dosage, you may experience nausea, vomiting, increased salivation, pain in your abdomen, diarrhea, sweating, headache, dizziness, hearing disturbance or weakness. At higher dose, you will experience low blood pressure, weak and irregular pulse, difficult to breath, collapse and spasm. If you do get any of these effects, seek medical treatment immediately. If excessive amount of nicotine

is swallowed, activated charcoal reduces the gastrointestinal absorption of nicotine.

While you are using it

Things you must do

Use the Voye® Frosty Mint Nicotine gum technique. Chew only one piece of gum at a time.

Things you must not do

Do not give this product to children. Doses of nicotine tolerated by an adult or adolescent smoker can produce severe toxicity in children that may be fatal.

Things to be careful of

Avoid swallowing the gum. If a child has used or swallowed the gum, seek medical treatment immediately. Nicotine ingestion by a child may result in severe poisoning.

Side effects

Like all medicines, Voye® Frosty Mint Nicotine gum can cause side effects. As many of the effects are due to nicotine, they can also occur when nicotine is obtained by smoking.

Effects related to smoking (nicotine withdrawal)

You may experience unwanted effects because you have stopped smoking, or you have reduced the amount of nicotine you are taking. These effects include:

- Dizziness
- Headache
- Irritability or aggression
- Feeling low
- Anxiety Restlessness
- Poor concentration
- Increased appetite or weight gain
- Urge to smoke (craving)
- Sleeplessness or sleep disturbance
- Lowering of heart rate

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Side effects of Voye® Frosty Mint Nicotine gum

Most of the undesirable effects reported by the subjects occur during the early phase of treatment and are mainly dose dependent. Irritation in the mouth and throat may be experienced, however most subjects adapt to this with ongoing use.

Allergic reactions (including symptoms of anaphylaxis) occur rarely during use of Voye® Frosty Mint Nicotine gum. The chewing gum may stick to and in rare cases, damage dentures.

Side effects observed in postmarketing experience (frequency category estimated from clinical trial):

The commonly reported side effect is diarrhoea.

Uncommonly reported side effects include fast heartbeat, burping, soreness of the tongue, oral mucosal blistering and exfoliation, prickling/tingling sensation of the mouth, body weakness, chest discomfort and pain, malaise, pain in jaw, abnormal dream, wheezing, voice disorder, shortness of breathing, nasal congestion, oropharyngeal pain, sneezing, throat tightness, increase sweating, skin itching, skin rash, hives, flushing and high blood pressure.

Rarely reported side effects include difficulty swallowing, mouth numbness and retching.

If you notice these or any other unwanted effects not listed in this leaflet, tell your doctor or pharmacist.

When you stop smoking, you may also develop mouth ulcers.

The reason why this happens is unclear.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and disposal of Voye® Frosty Mint Nicotine gum

Storage

Keep out of reach and sight of children.

Store below 30°C. Protect from light.

Do not use the chewing gum after the 'EXP' date on the box and blister.

Disposal

Dispose of Voye® Frosty Mint Nicotine gum sensibly.

Product description

What it looks like

White to off-white, coated, square chewing-gum pieces

Ingredients

Active Ingredient: Nicotine polacrilex

Inactive Ingredients:

Chewing gum base, Sorbitol, Maltitol, Menthol, Acesulfame potassium, Sucralose, Calcium Carbonate, Talc, Sodium carbonate anhydrous, Sodium bicarbonate, Titanium Dioxide, Peppermint flavour, Gelatin, Carnauba wax.

MAL Numbers:

Voye Frosty Mint 4mg Nicotine Gum (MALxxxxxxx)

Voye Frosty Mint 2mg Nicotine Gum (MALxxxxxxx)

Manufacturer

Fertin India Pvt. Ltd.

Plot No. L-10 & L-11, Cuncolim Industrial Estate, Cuncolim, Salcette, Goa-403703, India

Product Registration Holders

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Date of revision

06/06/2025

Serial Number

NPRA (R2) 25/041