

Package leaflet: Information for the user

Nicochew Fruit 2 mg medicated chewing-gum Nicochew Fruit 4 mg medicated chewing-gum 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 cannot refrain from smoking after 6 months' treatment with Nicochew Fruit.

What is in this leaflet:

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

1. What Nicochew Fruit is and what it is used for

Nicochew Fruit is used to help people stop smoking.

The nicotine in Nicochew Fruit relieves nicotine withdrawal symptoms and cravings when you stop smoking or temporarily reduce smoking in order to facilitate smoking cessation. It thereby counteracts a smoking relapse in smokers who are motivated to stop smoking.

Nicochew Fruit is indicated for smokers aged 18 years and above.

When you suddenly stop providing nicotine from tobacco to your body, you may feel different kinds of discomfort, called withdrawal symptoms. By means of Nicochew Fruit you can prevent or at least reduce this discomfort, by continuing to provide a small amount of nicotine to your body during a short period of time.

Advice and support normally improve the success rate.

You must talk to a doctor if you cannot refrain from smoking after 6 months treatment with Nicochew Fruit.

2. What you need to know before you use Nicochew Fruit

Do not use Nicochew Fruit

- if you are allergic to nicotine or any of the other ingredients of this chewing-gum (listed in section 6).
- if you are a non-smoker
- if you are allergic to peanuts or soya as this chewing-gum may contain traces of soya.

Warnings and precautions

Talk to your doctor or pharmacist before using Nicochew Fruit.

You may be able to use Nicochew Fruit, 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 nicotine replacement therapy can sometimes trigger this type of reaction
- severe or moderate liver disease
- severe kidney disease
- diabetes
- overactive thyroid gland
- a tumour of the adrenal gland (phaeochromocytoma)
- stomach ulcer
- inflammation of the gullet (oesophagitis)

The chewing-gum may stick to dentures and dental bridges and may in rare cases cause their damage.

Children and adolescents

People **under 18 years of age** should not use Nicochew Fruit, unless prescribed by a doctor. Nicochew Fruit should not be used by non-smokers.

The correct dose for adults could seriously poison or be fatal to small children. It is therefore essential that you keep Nicochew Fruit out of reach and sight of children at all times.

Other medicines and Nicochew Fruit

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This is especially important if you use other medicines which contain:

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

Nicochew Fruit with food and drink

You should not eat or drink while you chew the chewing-gum since this may decrease the effect of Nicochew Fruit.

Acidic drinks (e.g. fruit juice, coffee or soda) influence the uptake of nicotine in the mouth cavity. To make sure that the best effect is achieved, you should avoid such drinks approximately 15 minutes prior to using Nicochew Fruit.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

It is very important to stop smoking during pregnancy as it may result in poor growth of your baby. It can also lead to premature births or stillbirths. Ideally you should try to give up smoking without the use of medicines containing nicotine. If you cannot do this, Nicochew Fruit should only be used after consulting the healthcare professional who is managing your pregnancy, your family doctor, or a doctor at a centre that specialises in helping people quit smoking.

Nicochew Fruit should be avoided during breast-feeding as nicotine passes into breast milk and may affect your child. If your doctor has recommended you use Nicochew Fruit during breast-feeding the chewing-gum should be taken just after breast-feeding and not during or before breast-feeding.

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

Driving and using machines

There are no known risks associated with driving or using machinery when using Nicochew Fruit.

Nicochew Fruit contains butylated hydroxytoluene

Butylated hydroxytoluene may cause local skin reactions (e.g. contact dermatitis) and local irritation to the mucous membranes in the mouth.

Nicochew Fruit contains maltitol and sorbitol

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Nicochew Fruit.

3. How to use Nicochew Fruit

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.

The strength of chewing-gum should be chosen considering your nicotine dependence. If you smoke more than 20 cigarettes per day or if you have previously failed to quit smoking using the 2 mg gum, you should choose the 4 mg gum. Otherwise the 2 mg gum should be chosen.

When treatment is started one gum may be taken every 1-2 hours. 8 -12 gums per day is normally sufficient. Do not use more than 24 pieces per day.

When used to reduce smoking in order to stop smoking:

- 2 mg chewing gum: do not take more than 24 pieces per day
- 4 mg chewing gum: do not take more than 12 pieces per day.

Smoking cessation

Duration of treatment is individual, but it usually takes at least 3 months. Thereafter the nicotine dosage should be reduced gradually. Therapy should be stopped when the dose is reduced to 1-2 pieces of gum per day. You may however take a piece of gum whenever you are tempted to smoke.

Smoking reduction

Nicochew Fruit can be used in between periods of smoking, in order to prolong smoke-free intervals in order to reduce smoking as much as possible. The number of cigarettes used should be gradually replaced by Nicochew Fruit chewing-gum. If, after 6 weeks, you have not succeeded in reducing the number of cigarettes per day to at least half of your consumption you should seek professional help.

You should try to stop smoking as soon as you feel motivated, however no later than 4 months after you started using Nicochew Fruit. Subsequently, the number of nicotine chewing-gums used should be reduced gradually, for example by quitting 1 piece of gum every 2-5 days.

If you do not succeed in making a serious attempt to stop smoking within 4 months you should seek professional help.

Regular use of Nicochew Fruit chewing-gum for more than 6 months is generally not recommended. In some cases, a longer treatment period may be necessary in order to avoid relapse. Any spare chewing-gums should be retained, as craving may suddenly occur.

Counselling and support can improve the chance of success.

Do not chew Nicochew Fruit as ordinary chewing-gum. If Nicochew Fruit is chewed too quickly and without breaks, nicotine is released too quickly. This may cause discomfort (e.g. heartburn and hiccups).

Nicochew Fruit chewing technique

1. Chew Nicochew Fruit slowly until the taste becomes strong or you feel a light tingling sensation
2. Rest the chewing-gum in your mouth between your cheek and gum until the taste and/or the tingling sensation has diminished
3. Chew until the taste becomes strong again or you feel a light tingling sensation
4. Repeat this chewing routine for approximately 30 minutes

If you use more Nicochew Fruit than you should

Overdose with nicotine could occur if you smoke while chewing Nicochew Fruit. The symptoms of overdose include nausea, increased salivation, abdominal pain, diarrhoea, sweating, headache, dizziness, hearing disturbances and pronounced weakness (feeling of weakness). At high doses, these symptoms may be followed by low blood pressure, weak and irregular pulse, difficulty breathing, extreme tiredness, circulatory collapse (collapse due to very low blood pressure) and convulsions.

If a child takes Nicochew Fruit or if you take too much nicotine, contact your doctor or the emergency department at the hospital immediately.

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.

Effects related to smoking cessation (withdrawal symptoms)

Some of the side-effects you may experience when you stop smoking may be withdrawal symptoms that occur due to the reduced amount of nicotine you are taking.

These symptoms include:

- Irritability, aggression, impatience or frustration
- Anxiety, restlessness or poor concentration
- 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 sores
- Dizziness or feeling faint
- Cough, sore throat, stuffy or runny nose
- Constipation

Nicochew Fruit may cause side effects similar to those associated with nicotine administered in other forms. Side effects are generally dose dependent.

Irritation of the mouth and throat may occur, but regular use will help most people to adapt.

Stop taking Nicochew Fruit and see a doctor immediately if you experience any of the following symptoms of allergic reactions, which can be serious, such as angioedema. These are rare side effects (may affect up to 1 in 1 000 people):

- swelling of the face, tongue or throat
- difficulty in swallowing
- hives and difficulty breathing

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

- Headache,
- Cough, throat irritation,
- Hiccups, nausea

Common side effects (may affect up to 1 in 10 people):

- Local reactions such as burning sensation in the mouth, sore and inflamed mouth, taste disturbance
- Dry mouth or increased salivation
- Stomach pain or discomfort
- Vomiting, excessive gas or diarrhoea

- Tiredness
- Allergic reactions (hypersensitivity)
- Tingling sensation

Uncommon side effects (may affect up to 1 in 100 people):

- Blocked nose, sneezing
- Wheezing, shortness of breath, tightness in the throat
- Flushing, excessive sweating
- Tingling of the mouth, swollen, red, sore tongue, mouth ulcers or blisters, loss or damage to voice, sore mouth or throat, burping
- Palpitations (abnormal heartbeat), increased heart rate, high blood pressure
- Rash (incl. hives) and/or itching
- Abnormal dreams,
- Chest discomfort and pain
- Weakness, general feeling of being unwell
- Jaw-muscle ache

Rare side effects (may affect up to 1 in 1 000 people):

- Difficulty in swallowing, decreased feeling in the mouth
- Nausea
- Irregular heartbeat (arrhythmia).

Other side-effects (frequency cannot be estimated from available data):

- Blurred vision, watery eyes,
- Dry throat, stomach discomfort, lip pain,
- Redness of the skin
- Allergic reaction with swelling of the face and mouth (angioedema or anaphylaxis)
- Jaw tightness

Reporting of side effects

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Nicochew Fruit

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 carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25 °C. Store in the original package.

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 protect the environment.

6. Contents of the pack and other information

What Nicochew Fruit contains

- The active substance is nicotine. Nicochew Fruit is available in two strengths: 2 mg and 4 mg.
- The other ingredients are: Gum base* (containing butylated hydroxytoluene (E321)), calcium carbonate, sorbitol (E420), sodium carbonate anhydrous, sodium hydrogen carbonate, saccharin (E954), acesulfame potassium (E950), levomenthol, lemon liquid flavour no. 2, mango liquid flavour, lemon powder flavour, talc, maltitol (E965), acacia, titanium dioxide (E171) and carnauba wax.

*may contain traces of soya.

What Nicochew Fruit looks like and contents of the pack

Nicochew Fruit is a white to yellowish, slightly convex, rectangular chewing-gum with an approximate size of 18x12x5 mm.

Package sizes:

2, 10, 12, 20, 24, 30, 36, 40, 48, 50, 60, 70, 72, 80, 84, 90, 96, 100, 108, 110, 120, 150, 192, 200, 204, 210, 300, 492, 500 and 504 pieces blister pack

The blister pack is made of PVC/PVdC/Aluminium or PVC/PE/PVdC/Aluminium.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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

Manufacturer

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or

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

- Finland: Nicover Fruit 2 mg Lääkepurukumi
Nicover Fruit 4 mg Lääkepurukumi
- France: NICOTINE EG FRUIT 2 mg SANS SUCRE, gomme à mâcher médicamenteuse
édulcorée à l'Acésulfame potassique et Saccharine
NICOTINE EG FRUIT 4 mg SANS SUCRE, gomme à mâcher médicamenteuse
édulcorée à l'Acésulfame potassique et Saccharine
- Ireland: Nicochew Fruit 2 mg Medicated Chewing Gum
Nicochew Fruit 4 mg Medicated Chewing Gum
- Sweden: Nicochew Fruit 2 mg medicinsk tuggummi
Nicochew Fruit 4 mg medicinsk tuggummi

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