

Package leaflet: Information for the user

Nicotinell Tropical Fruit 2 mg medicated chewing-gum Nicotinell Tropical Fruit 4 mg medicated chewing-gum nicotine

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

Always take this medicine exactly as described in this leaflet or as your pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your doctor or 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.**

What is in this leaflet:

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

1. What Nicotinell Tropical Fruit is and what it is used for

Nicotinell Tropical Fruit belongs to a group of medicines which are used to help you stop smoking.

Nicotinell Tropical Fruit chewing-gum contains the active substance nicotine. When chewed, nicotine is released slowly and absorbed through the lining of the mouth. This medicinal product is used to relieve nicotine craving and withdrawal symptoms in nicotine dependency. It thereby

- counteracts the relapse in smoking in smokers who are motivated to stop or
- facilitate smoking reduction in smokers who cannot or are reluctant to stop.

Patient counselling and support normally improve the success rate.

Nicotinell Tropical Fruit is indicated for smokers aged 18 years and above.

2. What you need to know before you take Nicotinell Tropical Fruit



Do not take Nicotinell Tropical Fruit

- if you are allergic to nicotine or any of the other ingredients of this medicine (listed in section 6).
- if you are a non-smoker.



Warnings and precautions

Talk to your doctor before using Nicotinell Tropical Fruit if you have:

- any heart problems you should consult a healthcare professional before using any nicotine replacement therapy product. While using a nicotine replacement therapy product, if you experience an increase in heart problems, the use of the product should be reduced or discontinued

- recently had a heart attack or stroke or suffer from severe heart rhythm problems or chest pain, you should try to quit smoking without using any nicotine replacement therapy products unless your doctor tells you to use them
- high blood pressure (uncontrolled hypertension)
- problems with your circulation
- diabetes, you should monitor your blood sugar levels more often than usual when you start using nicotine gum. Your insulin or medicine requirements may change.
- overactive thyroid glands
- overactive adrenal glands (pheochromocytoma),
- suffer from impaired kidney and/or liver function
- fructose intolerance
- oesophagitis, inflammation in the mouth or throat, gastritis or peptic ulcer
- a history of epilepsy (fits)

In these conditions it is not sure that it is suitable for you to use Nicotinell Tropical Fruit.

People having problems with the joint of the jawbone and denture wearers may experience difficulty in chewing the gum. If you do, it is recommended that you use a different pharmaceutical form of nicotine replacement therapy. Chewing the Nicotinell Tropical Fruit may loosen fillings or dental implants.

Do not smoke while taking Nicotinell Tropical Fruit, since you may obtain a high concentration of nicotine, causing you to feel unwell.



Children and adolescents

Nicotinell should not be used by adolescents 12-17 years of age without prescription from a healthcare professional.

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

Nicotinell Tropical Fruit are not to be used in children under 12 years old.



Other medicines and Nicotinell Tropical Fruit

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

No information is available on interactions between Nicotinell Tropical Fruit chewing-gum and other medicines. However, the action of some drugs may be affected if you stop smoking.

This is particularly important if you use drugs containing

- theophylline (a medicine used for the treatment of bronchial asthma),
- tacrine (a medicine used to treat Alzheimer's disease),
- olanzapine and clozapine (for the treatment of schizophrenia).

Nicotinell Tropical Fruit with food and drink

Coffee, acidic and soft drinks may decrease the absorption of nicotine and should be avoided for 15 minutes before chewing a Nicotinell Tropical Fruit chewing-gum. Do not eat or drink while you have a gum in your mouth.



Fertility, pregnancy and breast-feeding

Pregnancy

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 and even stillbirths. It is best if you can give up smoking without the use of medicines containing nicotine. If you cannot manage this, Nicotinell Tropical Fruit should only be used after consulting a healthcare professional.

Breast-feeding

Nicotinell Tropical Fruit should be avoided during breast-feeding as nicotine is found in breast milk and may affect your child. If a healthcare professional has recommended you to use Nicotinell Tropical Fruit during breast-feeding, the gum should be chewed just after breast-feeding and not during the two hours before breast-feeding.

Fertility

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



Driving and using machines

There is no evidence of risk associated with driving or operating machinery if Nicotinell Tropical Fruit chewing-gum is taken according to the recommended dose but remember that smoking cessation can cause behavioral changes.



Nicotinell Tropical Fruit contains sorbitol, butylhydroxytoluene and sodium

Because Nicotinell Tropical Fruit chewing-gum contains sorbitol, which is a source of fructose: if you have been told by your doctor that you have an intolerance to some sugars, or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, contact your doctor before taking Nicotinell Tropical Fruit chewing-gum.

Each piece of chewing-gum contains 0.1 g sorbitol, a source of 0.02 g fructose. Calorific value 1.0 kcal/piece of chewing-gum (Nicotinell Tropical Fruit 2 mg) and 0.9 kcal/piece (Nicotinell Tropical Fruit 4 mg) respectively.

The gum contains butylhydroxytoluene (E321) which may cause local irritation to mucous membranes in the mouth.

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

3. How to use Nicotinell Tropical 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 appropriate strength will depend on your nicotine dependence. You should use the 4 mg Nicotinell Tropical Fruit chewing-gum if

- you are a smoker with a strong nicotine dependency,
- you have previously failed to stop smoking with the 2 mg chewing-gum.

Otherwise 2 mg Nicotinell Tropical Fruit chewing-gum should be used.

Select your optimal strength from the following table:

Low to moderate dependency	Moderate to strong dependency	Strong to very strong dependency
Less than 20 cigarettes / day	From 20 to 30 cigarettes / day	
Nicotinell 2 mg is preferable)	Low (Nicotinell 2 mg) or high (Nicotinell 4 mg) dose forms depending on patient characteristics and preference.	Nicotinell 4 mg is preferable)

If an adverse event occurs with the use of the high dose (4 mg), use of the low dose (2 mg) should be considered.

It is important to chew the chewing-gum in a correct way to avoid discomfort (e.g. hiccups and heart burn).



Instructions for use:

Do not swallow the chewing-gum.

1. Chew one piece of chewing gum slowly until the taste becomes strong.
2. Allow the chewing-gum to rest between your gum and cheek.
3. Chew again when taste has faded.
4. Repeat this routine for about 30 minutes.

Avoid drinking coffee, acidic and soft drinks for 15 minutes before chewing a Nicotinell Tropical Fruit chewing-gum because they may decrease the absorption of nicotine. Do not eat or drink while you have a gum in your mouth.

Dosage for adults over 18 years:

Chew one piece of gum when you feel the urge to smoke.

At the beginning of the treatment, in general, one piece of chewing-gum should be chewed every one or two hours. Normally 8-12 pieces of chewing-gum per day are sufficient, irrespective of strength. Do not exceed 24 pieces a day of 2 mg chewing-gum or 15 pieces per day of 4 mg chewing-gum. Do not use more than 1 gum per hour.

Smoking cessation:

The treatment duration is individual. Normally, treatment should continue for at least 3 months. After 3 months, you should gradually reduce the number of pieces of gum chewed each day. Treatment should be stopped when you have reduced your use of the gum to 1-2 chewing-gums per day.

It is generally not recommended to use Nicotinell Tropical Fruit chewing-gum for longer than 1 year. However, some ex-smokers may need treatment with the chewing-gum for longer to avoid returning to smoking.

Counselling may improve your chances of giving up smoking.

Smoking reduction:

Nicotinell Tropical Fruit is used between periods of smoking in order to prolong smoke-free intervals and with the intention to reduce smoking as much as possible. If a reduction in the number of cigarettes per day has not been achieved after 6 weeks, professional advice should be sought. A quit attempt should be made as soon as you feel ready, but not later than 6 months after start of treatment. If a quit attempt cannot be made within 9 months after starting treatment, professional advice should be sought.

Counselling may improve your chances of giving up smoking.



If you take more Nicotinell Tropical Fruit than you should

Chewing too many chewing-gum pieces can result in the same symptoms as smoking too much. The symptoms of nicotine overdose include: weakness, pale skin, sweating, increased production of saliva, dizziness, throat burn, nausea, vomiting, diarrhoea, pain in the abdomen, disturbance of hearing and vision, headache, fast or other disturbance in heartbeat, shortness of breath, tremor and confusion..

With large overdoses, these symptoms may be followed by exhaustion, low blood pressure, circulatory collapse, coma, difficulty breathing and seizures.

Stop using the gums and contact a doctor or hospital immediately for assessment of risk and advice if you have taken more of the drug than you should, or if a child has taken the drug by mistake.

If poisoning is suspected in a child, a doctor must be consulted immediately. Even small quantities of nicotine are dangerous and possibly life-threatening in children and may result in severe symptoms or death.



If you forget to use Nicotinell Tropical Fruit

Do not take a double dose to make up for a forgotten dose.

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.

Some effects you may notice in the first few days are dizziness, headache and sleep disturbances. These may be withdrawal symptoms in connection with smoking cessation and may be caused by insufficient administration of nicotine. Other possible withdrawal symptoms in connection with smoking cessation may be insomnia, cough, weakness, tiredness, feeling unwell and flu-like symptoms.

Stop taking Nicotinell and contact immediately a doctor if you get any of the following symptoms of a serious allergic reaction (angioedema or anaphylactic reaction)

- swelling of face, tongue or throat
- difficulty swallowing
- hives
- breathing difficulties

These side effects are rare.

Other side effects that may occur:

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

- feeling sick (nausea)

Common (may affect up to 1 in 10 people)

- inflammation of the mouth mucus, oral discomfort
- sore throat
- vomiting
- stomach discomfort, stomach pain
- diarrhea
- indigestion/heartburn
- flatulence
- hiccups
- constipation
- dizziness and headache
- insomnia
- cough
- dryness of the mouth
- mouth, throat and jaw muscle ache may also occur.

Uncommon (may affect up to 1 in 100 people)

- palpitations
- red skin rash (erythema) and itching of raised bumps of the skin (urticaria).

Rare (may affect up to 1 in 1,000 people)

- disturbances in heart beat rhythm
- hypersensitivity reaction

Not known

- increased secretion of saliva
- difficulty in swallowing
- tremor
- ulcerative stomatitis

Mouth ulcers may be related to quitting smoking and not to your treatment.

The gum can stick to and rarely damage dentures or other dental work.

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

5. How to store Nicotinell Tropical 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 and blister after “EXP”. The expiry date refers to the last day of that month.

Do not store above 25°C.

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 Nicotinell Tropical Fruit contains

Nicotinell Tropical Fruit medicated chewing-gum is available in two strengths.

The **active substance** is nicotine.

Each piece of Nicotinell Tropical Fruit chewing-gum contains 2 mg or 4 mg nicotine (as 10 mg or 20 mg nicotine polacrillin (1:4)).

The other ingredients are:

Gum base (containing butylhydroxytoluene (E321)), xylitol, calcium carbonate (E170), sorbitol (E420), mannitol (E421), sodium carbonate anhydrous, sodium hydrogen carbonate, natural mint flavouring, polacrillin, glycerol, sucralose, levomenthol, mango flavouring, gelatine, titanium dioxide (E171), acesulfame potassium (E950), carnauba wax and talc.

Nicotinell Tropical Fruit medicated chewing gum is sugar free.

What Nicotinell Tropical Fruit looks like and contents of the pack

Each piece of coated chewing-gum is off-white in colour and rectangular in shape.

The chewing-gums are packed in blisters containing 12 chewing-gums. The blisters are packed in boxes containing 12, 24, 48, 84, 96 or 204 pieces of chewing-gum.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

GlaxoSmithKline Consumer Healthcare (Ireland) Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.

Manufacturer

Fertin Pharma A/S, Dandyvej 19, DK-7100 Vejle

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

DK	Nicotinell Tropical Fruit medicinsk tyggegummi 2 mg and 4 mg
FI	Nicotinell Tropical Fruit 2 mg and 4 mg lääkepurukumi
FR	Nicotinell Fruit Exotique
IE	Nicotinell Tropical Fruit 2mg and 4 mg Medicated Chewing Gum
IS	Nicotinell Tropical Fruit 2 mg and 4 mg lyfjatyggiúmmí
NO	Nicotinell 2 mg and 4 mg medisinsk tyggegummi Tropical Fruit
SE	Nicotinell Tropical Fruit 2 mg and 4 mg

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