

PACKAGE LEAFLET: INFORMATION FOR THE USER



Read all of this leaflet carefully because it contains important information for you.
This medicine is available without prescription. However, you still need to use Nicotinel Mint 1 mg lozenge carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if you still need to use Nicotinel lozenge after 9 months.
- If any of the side effects gets serious, or if you notice any side effect not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Nicotinel Mint lozenge is and what it is used for
2. Before you take Nicotinel Mint lozenge
3. How to take Nicotinel Mint lozenge
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1. What Nicotinel Mint lozenge is and what it is used for

Nicotinel Mint lozenge contains nicotine, which is one of the substances contained in tobacco.
This medicine product belongs to a group of medicines which are used to help you to stop smoking.

When sucked, nicotine is released slowly and absorbed through the lining of the mouth.

This medicinal product is used to help people to stop smoking. The nicotine in Nicotinel Mint relieves nicotine withdrawal symptoms and cravings when you stop smoking or temporarily reduce smoking in order to facilitate smoking cessation. By relieving the withdrawal symptoms and cravings Nicotinel Mint counteracts a smoking relapse in smokers who are motivated to stop smoking.

Patient counselling and support normally improve the success rate.

Nicotinel is indicated for smokers aged 18 years and above.

2. Before you take Nicotinel Mint lozenge

Do not take Nicotinel Mint lozenge

- If you are allergic (hypersensitive) to nicotine or any of the other ingredients of Nicotinel Mint lozenge.
- If you are a non-smoker.

Take special care with Nicotinel Mint lozenge

Please check with your doctor or pharmacist before taking Nicotinel if you have:

- heart disease, e.g. heart attack, heart failure, angina, Prinzmetal's angina or abnormalities in heart beat rhythm,
- had a "stroke" (cerebrovascular accident),
- high blood pressure (uncontrolled hypertension),
- problems with your circulation,
- diabetes,
- overactive thyroid glands (hyperthyroidism),
- overactive adrenal glands (pheochromocytoma),
- kidney or liver disease,
- oesophagitis, inflammation in the mouth or throat, gastritis or peptic ulcer.

Even small quantities of nicotine are dangerous in children and may result in severe symptoms or death. It is therefore essential that you keep Nicotinel Mint lozenge out of reach and sight of children at all times.

Children and adolescents (below 18 years)

Nicotinel should **not** be used by people under 18 years of age without recommendation from a doctor.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. If you stop smoking and if you are using other medicines, your doctor may want to adjust the dose.

No information is available on interactions between Nicotinel lozenge and other medicines. However, apart from nicotine, other substances in cigarettes may have an effect on certain medicine.

Stopping smoking can affect the action of certain medicines e.g.:

- theophyllin (a medicine used for the treatment of bronchial asthma)
- tacrine (medicine used to treat Alzheimer's disease)
- olanzapine and clozapine (for the treatment of schizophrenia)
- insulin dose (medicine used for the treatment of diabetes) may need to be adjusted

Taking Nicotinel Mint lozenge with food and drink

Coffee, acidic and soft drinks may decrease the absorption of nicotine and should be avoided for 15 minutes before sucking a lozenge.

Pregnancy and breast-feeding

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. Ideally you should try to give up smoking without the use of medicines. If you cannot manage this, Nicotinel may be recommended to help as the risk to the developing baby is less than that expected from continued smoking. Nicotine in any form may cause harm to your unborn baby. Nicotinel should only be used after consulting the healthcare professional who is managing your pregnancy, or a doctor that is specialised in helping people quit smoking.

Nicotinel like smoking itself should be avoided during breast-feeding as nicotine may be found in breast milk. If your doctor has recommended you to use Nicotinel Mint lozenge during breast-feeding, the lozenge should be sucked

just after breast-feeding and not during the two hours before breast-feeding.

Driving and using machines

There is no evidence of risk associated with driving or operating machinery if the lozenge is taken according to the recommended dose but remember that smoking cessation can cause behavioural changes.

Important information about some of the ingredients of Nicotinel Mint lozenge

Nicotinel Mint lozenges contain sweeteners, including aspartame and maltitol.

Each Nicotinel Mint 1 mg lozenge contains aspartame (E951), a source of phenylalanine equivalent to 5 mg per piece and may be harmful for people with phenylketonuria.

Because Nicotinel Mint 1 mg lozenge contains maltitol (E965), a source of fructose:

- if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine,
- patients may experience a mild laxative effect.

Calorific value 2.3 kcal/g maltitol. Nicotinel Mint lozenge ingredients are suitable for diabetics. Each lozenge contains 0.9 g maltitol per lozenge.

Nicotinel Mint 1 mg lozenge contains 9.8 mg of sodium per piece. To be taken into consideration by patients on a controlled sodium diet.

3. How to take Nicotinel Mint lozenge

Always take Nicotinel Mint Lozenge exactly as stated in this package leaflet. You should check with your doctor or pharmacist if you are not sure.

Nicotinel Mint Lozenge is available in two strengths: 1 and 2 mg.

Nicotinel Mint 1 mg lozenge is recommended in low to moderate nicotine dependent smokers. It is not recommended for smokers with a strong or very strong nicotine dependency.

Nicotinel Mint 1 mg lozenge can be used alone or in combination with Nicotinel patches.

Adults over 18 years

Treatment with Nicotinel Mint lozenges only

Select your optimal dosage from the following table:

	Low to moderate dependency	Moderate to strong dependency	Strong to very strong dependency
	← Low dosage forms acceptable →		← High dosage forms acceptable →
	Less than 20 cigarettes / day	From 20 to 30 cigarettes / day	Over 30 cigarettes / day
Treatment with Nicotinel Mint lozenge only	1 mg lozenge is preferable	Low (1 mg lozenge) or high (2 mg lozenge) dose forms depending on patient characteristics and preference	2 mg lozenge is preferable

If an adverse event occurs with the use of the high dose (2 mg lozenge), use of the low dose (1 mg lozenge) should be considered.

Instructions for use:

Do not swallow the lozenge.

1. Suck a lozenge until the taste becomes strong.
2. Allow the lozenge to rest between your gum and cheek.
3. Suck again when the taste has faded.
4. Repeat this routine until the lozenge dissolves completely (about 30 minutes).

Dosage for adults over 18 years:

Suck one lozenge when you feel the urge to smoke. In general one lozenge should be taken every one or two hours. Normally 8-12 lozenges per day are sufficient. If you still experience an urge to smoke, you can suck additional lozenges. Do not exceed 30 lozenges per day of the 1 mg strength (applies for both smoking cessation and smoking reduction).

Nicotinel lozenge should primarily be used for smoking cessation.

Smoking cessation:

To improve your chances of giving up smoking you should stop smoking completely when you start to use the lozenges and for the whole treatment period.

The treatment duration is individual. Normally, treatment should continue for at least 3 months. After 3 months, you should gradually reduce the number of lozenges used each day. Treatment should be stopped when you have reduced your use of the lozenge to 1-2 lozenges per day. It is generally not recommended to use Nicotinel Mint lozenge for longer than 6 months. However, some ex-smokers may need treatment with the lozenge for longer to avoid returning to smoking.

If you are still using the lozenge after 9 months, you should speak to your doctor or pharmacist.

Counselling may improve your chances of giving up smoking.

Smoking reduction:

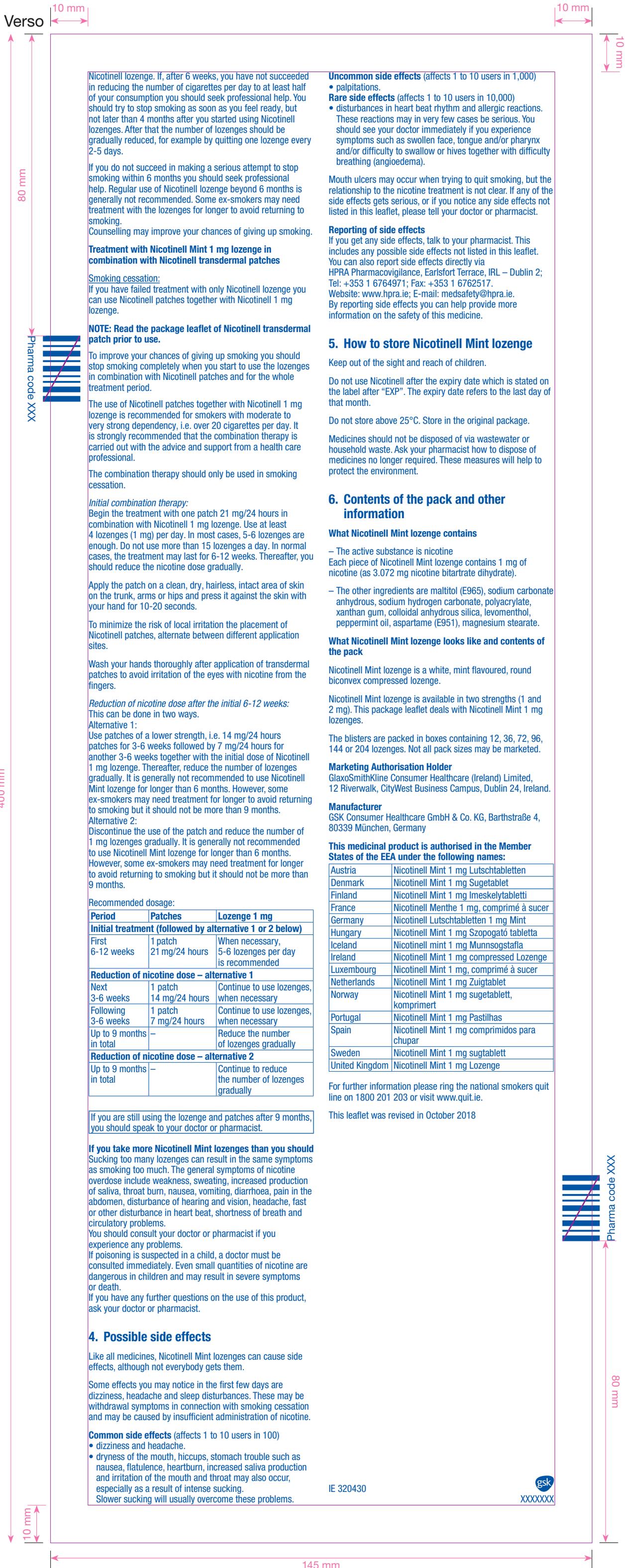
Nicotinel lozenge should be used between periods of smoking in order to prolong smoke-free intervals and with the intention to reduce smoking as much as possible. The number of cigarettes should be gradually replaced by

Pharma code XXX

Pharma code XXX

80 mm

145 mm



Nicotinell lozenge. 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 ready, but not later than 4 months after you started using Nicotinell lozenges. After that the number of lozenges should be gradually reduced, for example by quitting one lozenge every 2-5 days.

If you do not succeed in making a serious attempt to stop smoking within 6 months you should seek professional help. Regular use of Nicotinell lozenge beyond 6 months is generally not recommended. Some ex-smokers may need treatment with the lozenges for longer to avoid returning to smoking. Counselling may improve your chances of giving up smoking.

Treatment with Nicotinell Mint 1 mg lozenge in combination with Nicotinell transdermal patches

Smoking cessation:

If you have failed treatment with only Nicotinell lozenge you can use Nicotinell patches together with Nicotinell 1 mg lozenge.

NOTE: Read the package leaflet of Nicotinell transdermal patch prior to use.

To improve your chances of giving up smoking you should stop smoking completely when you start to use the lozenges in combination with Nicotinell patches and for the whole treatment period.

The use of Nicotinell patches together with Nicotinell 1 mg lozenge is recommended for smokers with moderate to very strong dependency, i.e. over 20 cigarettes per day. It is strongly recommended that the combination therapy is carried out with the advice and support from a health care professional.

The combination therapy should only be used in smoking cessation.

Initial combination therapy:

Begin the treatment with one patch 21 mg/24 hours in combination with Nicotinell 1 mg lozenge. Use at least 4 lozenges (1 mg) per day. In most cases, 5-6 lozenges are enough. Do not use more than 15 lozenges a day. In normal cases, the treatment may last for 6-12 weeks. Thereafter, you should reduce the nicotine dose gradually.

Apply the patch on a clean, dry, hairless, intact area of skin on the trunk, arms or hips and press it against the skin with your hand for 10-20 seconds.

To minimize the risk of local irritation the placement of Nicotinell patches, alternate between different application sites.

Wash your hands thoroughly after application of transdermal patches to avoid irritation of the eyes with nicotine from the fingers.

Reduction of nicotine dose after the initial 6-12 weeks:

This can be done in two ways.

Alternative 1:

Use patches of a lower strength, i.e. 14 mg/24 hours patches for 3-6 weeks followed by 7 mg/24 hours for another 3-6 weeks together with the initial dose of Nicotinell 1 mg lozenge. Thereafter, reduce the number of lozenges gradually. It is generally not recommended to use Nicotinell Mint lozenge for longer than 6 months. However, some ex-smokers may need treatment for longer to avoid returning to smoking but it should not be more than 9 months.

Alternative 2:

Discontinue the use of the patch and reduce the number of 1 mg lozenges gradually. It is generally not recommended to use Nicotinell Mint lozenge for longer than 6 months. However, some ex-smokers may need treatment for longer to avoid returning to smoking but it should not be more than 9 months.

Recommended dosage:

Period	Patches	Lozenge 1 mg
Initial treatment (followed by alternative 1 or 2 below)		
First 6-12 weeks	1 patch 21 mg/24 hours	When necessary, 5-6 lozenges per day is recommended
Reduction of nicotine dose – alternative 1		
Next 3-6 weeks	1 patch 14 mg/24 hours	Continue to use lozenges, when necessary
Following 3-6 weeks	1 patch 7 mg/24 hours	Continue to use lozenges, when necessary
Up to 9 months in total	–	Reduce the number of lozenges gradually
Reduction of nicotine dose – alternative 2		
Up to 9 months in total	–	Continue to reduce the number of lozenges gradually

If you are still using the lozenge and patches after 9 months, you should speak to your doctor or pharmacist.

If you take more Nicotinell Mint lozenges than you should

Sucking too many lozenges can result in the same symptoms as smoking too much. The general symptoms of nicotine overdose include weakness, sweating, increased production of saliva, throat burn, nausea, vomiting, diarrhoea, pain in the abdomen, disturbance of hearing and vision, headache, fast or other disturbance in heart beat, shortness of breath and circulatory problems.

You should consult your doctor or pharmacist if you experience any problems.

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

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

4. Possible side effects

Like all medicines, Nicotinell Mint lozenges 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.

Common side effects (affects 1 to 10 users in 100)

- dizziness and headache.
- dryness of the mouth, hiccups, stomach trouble such as nausea, flatulence, heartburn, increased saliva production and irritation of the mouth and throat may also occur, especially as a result of intense sucking.

Slower sucking will usually overcome these problems.

Uncommon side effects (affects 1 to 10 users in 1,000)

- palpitations.

Rare side effects (affects 1 to 10 users in 10,000)

- disturbances in heart beat rhythm and allergic reactions. These reactions may in very few cases be serious. You should see your doctor immediately if you experience symptoms such as swollen face, tongue and/or pharynx and/or difficulty to swallow or hives together with difficulty breathing (angioedema).

Mouth ulcers may occur when trying to quit smoking, but the relationship to the nicotine treatment is not clear. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your pharmacist. 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 Nicotinell Mint lozenge

Keep out of the sight and reach of children.

Do not use Nicotinell after the expiry date which is stated on the label after "EXP". The expiry date refers to the last day of that month.

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

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Nicotinell Mint lozenge contains

– The active substance is nicotine

Each piece of Nicotinell Mint lozenge contains 1 mg of nicotine (as 3.072 mg nicotine bitartrate dihydrate).

– The other ingredients are maltitol (E965), sodium carbonate anhydrous, sodium hydrogen carbonate, polyacrylate, xanthan gum, colloidal anhydrous silica, levomenthol, peppermint oil, aspartame (E951), magnesium stearate.

What Nicotinell Mint lozenge looks like and contents of the pack

Nicotinell Mint lozenge is a white, mint flavoured, round biconvex compressed lozenge.

Nicotinell Mint lozenge is available in two strengths (1 and 2 mg). This package leaflet deals with Nicotinell Mint 1 mg lozenges.

The blisters are packed in boxes containing 12, 36, 72, 96, 144 or 204 lozenges. Not all pack sizes may be marketed.

Marketing Authorisation Holder

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

Manufacturer

GSK Consumer Healthcare GmbH & Co. KG, Barthstraße 4, 80339 München, Germany

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

Austria	Nicotinell Mint 1 mg Lutschtabletten
Denmark	Nicotinell Mint 1 mg Sugetablet
Finland	Nicotinell Mint 1 mg lmeskelytabletti
France	Nicotinell Menthe 1 mg, comprimé à sucer
Germany	Nicotinell Lutschtabletten 1 mg Mint
Hungary	Nicotinell Mint 1 mg Szopogató tablettá
Iceland	Nicotinell mint 1 mg Munnsogstafla
Ireland	Nicotinell Mint 1 mg compressed Lozenge
Luxembourg	Nicotinell Mint 1 mg, comprimé à sucer
Netherlands	Nicotinell Mint 1 mg Zuigtablett
Norway	Nicotinell Mint 1 mg sugetablett, komprimert
Portugal	Nicotinell Mint 1 mg Pastilhas
Spain	Nicotinell Mint 1 mg comprimidos para chupar
Sweden	Nicotinell Mint 1 mg sugtablett
United Kingdom	Nicotinell Mint 1 mg Lozenge

For further information please ring the national smokers quit line on 1800 201 203 or visit www.quit.ie.

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