

SKIIP NICOTINE MINI LOZENGES

Nicotine Polacrilex 2mg & 4mg (Mint/Cinnamon/Cherry Flavours)

What is in this leaflet:

1. What SKIIP Mini Lozenges are used for
2. How SKIIP Mini Lozenges work
3. Before you use SKIIP Mini Lozenges
4. How to take SKIIP Mini Lozenges
5. While you are using SKIIP Mini Lozenges
6. Side effects
7. Storage and disposal of SKIIP Mini Lozenges
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of Revision

What SKIIP Mini Lozenges are used for

It is indicated for relief of withdrawal symptoms including nicotine craving, associated with quitting smoking.

It should preferably be used in conjunction with a behavioural support program.

How SKIIP Mini Lozenges Work

They deliver a lower, steady level of nicotine to your blood through the lining of your mouth, temporarily relieving craving and nicotine withdrawal symptoms when you quit smoking. When used as directed, they help you to regulate, control and gradually reduce your body's craving for nicotine.

Before you use SKIIP Mini Lozenges

When you must not take it

You should not use SKIIP Mini Lozenges if:

- You are allergic to nicotine or any of the ingredients listed at the end of this leaflet.
- You are a non-smoker.
- You are under 18 years of age

If you are in hospital because of a heart attack, severe heart rhythm disturbances or a stroke, you should try to quit smoking without using NRT unless your doctor tells you to use it. Once you are discharged from hospital, you may use NRT in consultation with your doctor. If you have diabetes you should monitor your blood sugar levels

more often than usual when starting SKIIP Mini Lozenges as you may find your insulin or other medication requirements alter.

If you have 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.

If you have epilepsy or are taking medicine for seizures, you should not use SKIIP Mini Lozenges unless your doctor has told you to.

Do not use SKIIP Mini Lozenges if you are under 18 years of age. The levels of nicotine in NRT are suitable for people who are giving up smoking but not for children under 18. Children are more likely to be affected by nicotine and it could cause severe toxicity which can be fatal.

Make sure you keep nicotine containing products out of the reach and sight of children at all times.

Do not use the medicine after the expiry date printed on the pack. If you take it after the expiry has passed, it may not work as well. Do not use SKIIP Mini Lozenges if the packaging is torn or shows signs of tampering.

Do not use this medicine to treat any other complaint unless your doctor or pharmacist says it is safe. Do not give this medicine to anyone else even if they have the same symptoms as you.

Before you start to use it

You must tell your pharmacist or doctor if:

- You have an uncontrolled, overactive thyroid gland. Nicotine may make your symptoms worse.
- You have a stomach or duodenal ulcer or inflammation of the oesophagus. Swallowing nicotine can make your symptoms worse. Some people have reported

getting mouth ulcers. If your symptoms do get worse, you should talk to your doctor and you might want to use a non-oral type of NRT such as patches.

- You have heart or circulation problems including heart failure or stable angina or high blood pressure.
- You have had a stroke.
- You have any serious liver or kidney disease. You may be more prone to side effects.
- You are a diabetic.
- You have been diagnosed as having a tumor of the adrenal glands (phaeochromocytoma). Nicotine may make your symptoms worse.
- You have any allergies to any other medicines.
- You are pregnant or intend to become pregnant.
- You are breastfeeding or planning to breastfeed.
- You have ever experienced seizures.

If you have not told your pharmacist or doctor about any of the above, tell them before you use SKIIP Mini Lozenges.

If you are pregnant or breastfeeding, then you should try to quit smoking without the use of SKIIP Mini Lozenges if possible. However, it is better to stop smoking using NRT than to continue smoking.

If you are pregnant: Smoking during pregnancy has risks such as poor growth of your baby before birth, premature birth or still birth. Stopping smoking is the best way to improve both your health and that of your baby. The earlier you stop smoking, the better.

Ideally, if you are pregnant, you should stop smoking without using NRT. However, if you have tried and this hasn't worked, NRT

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may be recommended to help you stop smoking. This is because it is better for your developing baby than if you carry on smoking. The decision to use NRT should be made as early on in your pregnancy as possible and you should aim to use it for only 2-3 months. Remember, the most important thing is to stop smoking.

Products that are taken intermittently, such as lozenges is preferable to nicotine patches. However, patches may be preferred if you have nausea or sickness.

If you are breastfeeding: Tobacco smoke causes breathing difficulties and other problems in babies and children. If you need to use NRT to help you quit, the amount of nicotine your baby may receive is much smaller and less harmful than breathing in secondhand smoke. Do not use patches if you are breastfeeding. You should use NRT products that are taken intermittently (e.g. mini lozenges, lozenges or gums rather than patches) and breastfeed just before you take the product. This allows as long a time as possible between NRT use and feeding and will help your baby to get the smallest amount of nicotine possible.

Taking other medicines

Tell your pharmacist or doctor if you are using any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Stopping smoking, with or without nicotine replacement products such as SKIIP Mini Lozenges may alter the absorption of some medicines. The doses of the other medicines that you are using may need to be changed. Other medicines may be affected by SKIIP Mini Lozenges or affect how well SKIIP Mini Lozenges work.

Your pharmacist or doctor can tell you what to do if you are taking any of these medicines.

If you have not told your pharmacist or doctor about any of these things, tell him/her before you take any SKIIP Mini Lozenges.

How to use SKIIP Mini Lozenges

How much to use

A. Abrupt Cessation of Smoking For smokers who smoke less than 20 cigarette a day

Step 1 (Week 1 to 6)

- 1 lozenge (2mg) every 1 to 2 hours

Step 2 (Week 7 to 9)

- 1 lozenge (2mg) every 2 to 4 hours

Step 3 (Week 10 to 12)

- 1 lozenge (2mg) every 4 to 8 hours

To help stay smoke free over the next 12 weeks: Take a lozenge in situations when strongly tempted to smoke.

During weeks 1 to 6, it is recommended that users take at least 9 lozenges per day. Do not use more than 20 lozenges (2mg) per day.

Do not use more than 1 lozenge per hour. Those who use the lozenges beyond 6 months are recommended to seek additional help and advice from a healthcare professional.

For smokers who smoke 20 or more cigarettes a day

Step 1 (Week 1 to 6)

- 1 lozenge (4mg) every 1 to 2 hours

Step 2 (Week 7 to 9)

- 1 lozenge (4mg) every 2 to 4 hours

Step 3 (Week 10 to 12)

- 1 lozenge (4mg) every 4 to 8 hours

To help stay smoke free over the next 12 weeks: Take a lozenge in situations when strongly tempted to smoke.

During weeks 1 to 6, it is recommended that users take at least 9 lozenges per day. Do not use more than 20 lozenges (4mg) per day.

Do not use more than 1 lozenge per hour. Those who use lozenges beyond 6 months are recommended to seek additional help and advice from a healthcare professional.

B. Gradual Cessation of smoking (reduce to quit)

Use a lozenge whenever there is a strong urge to smoke in order to reduce the number of cigarettes smoked

The number of lozenges a day is variable and depends on the user's needs.

It should not exceed 20 lozenges per day.

Consult your healthcare professional if a reduction in cigarette consumption has not been achieved after 6 weeks of usage.

When to use it

You can take it before or after food.

How long to use it

Follow a 12-week program. If you still feel the need to use SKIIP Mini Lozenges to keep from smoking after week 12, please consult your healthcare professional.

If you forget to use it

If you miss a dose of SKIIP Mini Lozenges, take it as soon as you remember but do not exceed the maximum daily dose.

If you use too much (overdose)

If you accidentally take more than the maximum daily dose, all

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nicotine intakes should be stopped immediately and contact your healthcare professional. Activated charcoal may reduce absorption of nicotine if given within one or two hours after ingestion.

While you are using SKIIP Mini Lozenges

Things you must do

Use SKIIP Mini Lozenges exactly as your pharmacist or doctor has told you to.

Tell all your doctors, dentists and pharmacists that you are using SKIIP Mini Lozenges.

Tell your doctor or pharmacist if you become pregnant while using SKIIP Mini Lozenges.

Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give SKIIP Mini Lozenges to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Driving and using machines

It is thought that SKIIP Mini Lozenges will not affect your ability to drive or use any tools or machines.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while taking SKIIP Mini Lozenges.

SKIIP Mini Lozenges help most people, but they may have unwanted side effects in a few people.

All medicines can have side effects.

Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Stopping smoking itself can cause some symptoms such as dizziness, headache, sleep disturbance, cough and cold-like symptoms. Symptoms such as depression, irritability, anxiety and insomnia may also be related to withdrawal symptoms associated with giving up smoking.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your pharmacist or doctor if you notice any of the following and they worry you:

- Sore or swollen throat
- Slightly sore or irritated mouth or tongue
- Nausea
- Hiccups
- Stomach upsets
- Vomiting
- Diarrhoea
- Indigestion/heartburn
- Flatulence
- Constipation
- Dry mouth
- Insomnia
- Cough
- Excess saliva
- Dizziness
- Headache
- Palpitations (feeling your heartbeat)

These are the more common side effects of SKIIP Mini Lozenges. Mostly these are mild and short-lived. You may experience these side effects as you decrease the number of lozenges that you use.

If any of the following happen, stop using SKIIP Mini Lozenges and tell your doctor immediately or go to accident and emergency at your nearest hospital:

- Fast or very irregular heartbeat
- Severe allergic reaction, symptoms of which include sudden wheeziness or tightness of the chest, rash and feeling faint.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may also occur in some people. Tell your pharmacist or doctor if you notice anything else that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Transferred dependence

Some people worry that they will quit smoking but become dependent on SKIIP Mini Lozenges. This is very rare and, if it did happen, it is less harmful to you than continuing to smoke and an easier habit to break.

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 SKIIP Mini Lozenges

Storage

Store at or below 30°C.

Keep out of reach and sight of children.

Disposal

Medicine 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.

Product Description

What it looks like

- 2mg mini lozenge (Mint flavor)

SKIIP NICOTINE MINI LOZENGES

Nicotine Polacrilex 2mg & 4mg (Mint/Cinnamon/Cherry Flavours)

- White to off white oval shaped lozenges debossed with “A516” on one side and plain on the other side.

2mg mini lozenge (Cherry flavor)

- White to off white oval shaped lozenges debossed with “A501” on one side and plain on the other side.

2mg mini lozenge (Cinnamon flavor)

- White to off white oval shaped lozenges debossed with “A503” on one side and plain on the other side.

4mg mini lozenge (Mint flavor)

- White to off white oval shaped lozenges debossed with “A435” on one side and plain on the other side.

4mg mini lozenge (Cherry flavor)

- White to off white oval shaped lozenges debossed with “A415” on one side and plain on the other side.

4mg mini lozenge (Cinnamon flavor)

- White to off white oval shaped lozenges debossed with “A421” on one side and plain on the other side.

Ingredients

Active ingredient

Nicotine Polacrilex 2mg & 4mg

Inactive ingredient

For Mint Flavour:

Mannitol

Xanthan gum

Sodium alginate

Povidone

Hydroxypropyl cellulose

Sodium carbonate

Potassium bicarbonate

Acesulfame potassium

Sucralose

Peppermint Flavour

Colloidal silicon dioxide

Magnesium stearate

For Cherry Flavour:

Mannitol

Xanthan gum

Sodium alginate

Povidone

Hydroxypropyl cellulose

Sodium carbonate

Potassium bicarbonate

Acesulfame potassium

Sucralose

Cherry Flavour

Colloidal silicon dioxide

Magnesium stearate

For Cinnamon Flavour:

Mannitol

Xanthan gum

Sodium alginate

Povidone

Hydroxypropyl cellulose

Sodium carbonate

Potassium bicarbonate

Acesulfame potassium

Sucralose

Cinnamon Flavour

Colloidal silicon dioxide

Magnesium stearate

MAL Number

MALXXXXXXA

SKIIP Nicotine Mini Lozenge 2mg (Mint Flavour)

MAL25026001AZ

SKIIP Nicotine Mini Lozenge 4mg (Mint Flavour)

MAL25026004AZ

SKIIP Nicotine Mini Lozenge 2mg (Cinnamon Flavour)

MAL25026003AZ

SKIIP Nicotine Mini Lozenge 4mg (Cinnamon Flavour)

MAL25026006AZ

SKIIP Nicotine Mini Lozenge 2mg (Cherry Flavour)

MAL25026002AZ

SKIIP Nicotine Mini Lozenge 4mg (Cherry Flavour)

MAL25026005AZ

Manufacturer

Rubicon Research Limited

Plot K-30/4 & K-30/5,

Additional MIDC,

Ambernath, Thane,

421506, Maharashtra, India.

Product Registration Holder

Wellesta Healthcare Sdn. Bhd.

C208, Centre Wing, Metropolitan

Square, Jalan PJU 8/1, Damansara

Perdana, 47820 Petaling Jaya,

Selangor, Malaysia.

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18/07/2025

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