

NICOTINE ORAL POUCH- nicotine lozenge
Guangzhou Shuimu Jiahe Trading Co., Ltd.

reduces withdrawal symptoms, including nicotine craving, associated with quitting smoking

Microcrystalline cellulose, mannitol, propylene glycol sodium chloride, sodium bicarbonate, acesulfame, edible essence.

Nicotine (8 mg per pouch)

Ask a doctor or pharmacist before use if you are: Using a non-nicotine stop smoking drug. Taking a prescription medicine for depression or asthma. Your prescription dose may need to be adjusted.

Keep out of reach of children

Stop smoking aid

If you are pregnant or breast-feeding, only use this medicine on the advice of your health care provider. Smoking can seriously harm your child. Try to stop smoking without using any nicotine replacement medicine. This medicine is believed to be safer than smoking. However, the risks to your child from this medicine are not fully known.

To use, place one pouch between your gum and lip. Leave it in place. Do not chew or swallow the pouch.

-You may feel a slight tingling sensation.-Do not eat or drink 15 minutes before using or while the pouch is in your mouth, to maximize the experience.

-If you are using this product to change your habits, using at least a certain number of pouches per day initially may help manage urges.-Do not use more than one pouch at a time or continuously use one pouch after another, as this may cause hiccups, heartburn, nausea, or other side effects.-Do not exceed your personal tolerance. It is recommended to start slowly and assess your response.

-Do not use more than 6 pouches in 5 hours. Do not use more than 20 pouches per day.

-It is important to be mindful of your usage. If you feel you need to use the pouch for a longer period to manage your habits, consider consulting your health care provider for a plan.



NICOTINE ORAL POUCH

nicotine lozenge

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:87494-001
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NICOTINE (UNII: 6M3C89ZY6R) (NICOTINE - UNII:6M3C89ZY6R)	NICOTINE	8 mg in 100 mg

Inactive Ingredients

Ingredient Name	Strength

SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
CEFATRIZINE PROPYLENE GLYCOLATE (UNII: 3731IA5GI9)	
ACESULFAME (UNII: MA3UYZ6K1H)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
FLAVOR SPICE MINT N&A110589 (UNII: KG6KU384XW)	
MANNITOL (UNII: 3OWL53L36A)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Product Characteristics

Color	white	Score	score with uneven pieces
Shape	SQUARE	Size	10mm
Flavor	MINT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:87494-001-01	45 mg in 1 BOX, UNIT-DOSE; Type 0: Not a Combination Product	03/08/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M022	03/08/2026	

Labeler - Guangzhou Shuimu Jiahe Trading Co., Ltd. (700938261)

Establishment

Name	Address	ID/FEI	Business Operations
Guangzhou Shuimu Jiahe Trading Co., Ltd.		700938261	manufacture(87494-001)

Revised: 3/2026

Guangzhou Shuimu Jiahe Trading Co., Ltd.