



## A Comprehensive Review on Lozenges in Healthcare

Vinutha S\*, R Yoganada, N Maruthi, T.S Nagaraja, Snehalatha

Department of Pharmaceutics, SJM college of Pharmacy, Chitradurga-577501, Karnataka, India.

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### ABSTRACT

Lozenges are solid medicated dosage forms containing a drug along with flavouring and Sweetening agents and are intended to be sucked and held in mouth or pharynx which dissolve or disintegrate slowly in the mouth. Development of lozenges dated back to 20<sup>th</sup> century and is still remain in the commercial production and have a bright future as novel method of delivering drugs for local and systemic effect. Lozenges provides the several advantages as pharmaceutical formulations however with some disadvantages. Lozenges as a dosage form can be adapted for drug delivery across buccal route, labial route, gingival route and sublingual route. Lozenges are of different types and are manufactured by different methods. The acceptance for lozenges as a dosage form is high by adults and also more by children. The present review covers more or less all aspects associated with lozenges it includes various research performed till date, advantages, disadvantages, classification, evaluation parameters, packing and application of lozenges.

**Keywords:** Lozenges, heating and congealing, melting and moulding, dysphagia.

### INTRODUCTION

Oral drug delivery is simple, most convenient, safest, non-invasive and most economical System. It continues to be the preferential route of administration, it is the most popular route due to ease of ingestion, pain avoidance, versatility and most importantly, patient compliance. The most facing challenges in oral drug delivery are to overcome problems like pill-swallowing difficulty, delivery of unpalatable drugs and reducing dosing frequency. Pill swallowing difficulty primarily affects the patients having dysphagia, geriatric and pediatric populations.<sup>1</sup>

The intraoral route is the most preferred due to its convenience and rapid onset of action. Intraoral dosage forms have evolved as an alternative to conventional tablets, capsules and liquid preparations. Most of the intraoral dosage forms are intended to disintegrate, dissolve or release the drug in the oral cavity, where it has opportunity to be locally absorbed, in part or whole and alternatively may be swallowed and subsequently absorbed along the gastro-intestinal tract (GIT).<sup>2</sup>

The word "Lozenge" comes from the French word "Lozenge," which refers to a four-sided geometric diamond shape. Lozenge and pastille have been produced in pharmacies during the twentieth century and are still manufactured commercially.<sup>3</sup>

Lozenges are solid preparations that contain one or more medicaments, usually in a flavoured, sweetened base, that are intended to dissolve or disintegrate slowly in the mouth or these are medicated candy intended to be dissolved slowly in the mouth to lubricate and soothe the irritated tissues of throat. They can be prepared by molding or by compression of sugar-based tablets. Molded lozenges are sometimes referred to as 'pastilles', whereas compressed lozenges may be referred to as 'troches'. They are used for patients who cannot swallow solid oral dosage forms well as for medications designed to be released slowly to yield a constant level of drug in the oral cavity or to bathe the throat tissues in a solution of the drug. More amount of the drug will be absorbed from the buccal cavity and less will be swallowed and lost in GI Tract. Most of the lozenge formulations are available as Over the Counter (OTC) products where there is no need of prescription from a medical practitioner while some are prescribed by the medical practitioners.<sup>4</sup>

Medicated lozenges are designed to increase retention of dosage form in oral cavity which increases bioavailability, reduces gastric irritation and bypasses first pass metabolism. Lozenges should dissolve slowly in mouth and possess some degree of smoothness, with their shape being without corners. Lozenges are formulated with various shapes, like flat, circular, octagonal, biconvex, rod shaped etc.



They are intended to treat local irritation or infection of mouth or pharynx and may also be used for systemic drug absorption. Lozenges are intended to achieve local effect as soothing and purging the throat. Lozenges are also used for systemic effect provided the drug is well absorbed through the buccal linings or when it is swallowed.<sup>5</sup>

#### **Advantages of Lozenges<sup>6</sup>**

- It can be given to those patients who have difficulty in swallowing.
- It is easy to administer to geriatric and paediatric population.
- It has a pleasant taste.
- It extends the time of drug in the oral cavity to elicit a specific effect.
- Easy to prepare, with minimum amount of equipment and time.
- Do not require water intake for administration.
- Technique is non-invasive, as is the case with parenteral.
- They increase the retention time of the dosage form in oral cavity which increases bioavailability.
- They reduce gastric irritation and bypasses first pass metabolism.
- Taste of the drugs can be masked by sweeteners and flavours used in the formulation.
- It can reduced dosing frequency.
- It can improve onset of action.

#### **Disadvantages<sup>7</sup>**

- It could be mistakenly taken as candy by children, hence should be kept out of the reach of children.
- The non-ubiquitous distribution of drug within saliva for local therapy.
- Possible draining of drug from oral cavity to stomach along with saliva.
- Hard lozenges become grainy.
- Hard candy lozenge is the high temperature required for their preparation.

#### **Medicaments<sup>8</sup>**

Drug candidates which can be incorporated in lozenges, belong to one of the following categories:

- ❖ Antiseptics
- ❖ Local anaesthetics
- ❖ Antibiotics
- ❖ Antihistamines
- ❖ Antitussives



- ❖ Analgesics
- ❖ Decongestants
- ❖ Demulcents

### **Classification of Lozenges<sup>9</sup>**



**Fig No: 01 Lozenges**

Lozenges can be classified into various classes based on site of action, texture and composition.

#### **According to the site of action**

1. Local effect

Ex: Antiseptics and Decongestants.

2. Systemic effect

Ex: Vitamins and Nicotine.

#### **According to texture and composition**

1. Chewy or caramel based medicated lozenges

2. Compressed tablet lozenges

3. Soft lozenges

4. Hard candy lozenges

5. Center filled hard lozenges

### 1. Chewy or Caramel Based Medicated Lozenges :

These are the dosage form in which medicament is incorporated into a caramel base which is chewed instead of being dissolved in mouth. Most formulations are based on the glycerinated gelatin suppository formula which consists of glycerin, gelatin and water. These lozenges are often highly fruit flavoured and may have a slightly acidic taste to cover the acrid taste of the glycerin.



**Fig No: 02 Chewy or Caramel Based Medicated Lozenges**

### 2. Compressed Tablet Lozenges:

When the active ingredient is heat sensitive, it may be prepared by compression. The granulation method is similar to that used for any compressed tablet. These tablets differ from conventional tablets in terms of organoleptic property, non-disintegrating characteristics and slower dissolution profiles.



**Fig No:03 Compressed Tablet Lozenges**

### 3.Soft Lozenges:

They are either meant for chewing or for slow drug release in mouth. They can be made from PEG 1000 or 1450, chocolate or sugar-acacia base while some soft candy formulations can also contain acacia and silica gel. Acacia is used to provide texture and smoothness and silica gel is used as a suspending agent to avoid settling of materials to the bottom of the mould cavity during the cooling. The formulation requires heating process at about 50°C, hence is only suitable to heat resistant ingredients.



**Fig No: 04 Soft Lozenges**

#### **4. Hard Candy Lozenges:**

These are mixtures of sugar and other carbohydrates in an amorphous (non-crystalline) or glassy state. They can also be regarded as solid syrups of sugars.

The moisture content and weight of hard candy lozenge should be in between, 0.5 - 1.5% and 1.5-4.5 g respectively. These should undergo a slow and uniform dissolution or erosion over 5-10 min and they should not disintegrate.

**Disadvantage:** The temperature required for their preparation is high hence heat labile materials cannot be prepared.



**Fig No: 05 Hard Candy Lozenges**

#### **5. Center filled hard lozenges**

These lozenges are hard candy type with a soft or liquid filled centre containing the active medicament.



**Fig No: 06 Center filled hard lozenges**



Table no 1: Types of hard candy Lozenges <sup>10</sup>

Sl. No.	Type of Centre filled lozenges	Composition	Fill Weight (%)
1	Liquid fill	Fruit juice, sugar syrup, hydroalcoholic solutions or Sorbitol solution	10-20
2	Fruit center	Jams and jellies whose viscosity has been modified with corn syrup or liquid sucrose	20-25
3	Paste center	Granules and crystals formulated as paste	40
4	Fat center	Medicament or flavour being suspended or dissolved in hydrogenated vegetable oil	25-32

#### Methods of preparation of Medicated lozenges<sup>5</sup>

##### a) Chewy or caramel based medicated lozenges

##### b) Compressed tablet lozenges

##### c) Soft lozenges

##### d) Hard Candy Based Lozenges

##### e) Center filled hard lozenges

##### a) Chewy or caramel based medicated lozenges

Chewy lozenges are popular with the paediatric population since they are “gummy type” lozenges

#### Manufacturing process

The candy base is cooked at 95- 125°C and transferred to planetary/ sigma blade mixer. Mass is allow to cool to 120°C. This is followed by addition of whipping agent below 105°C.The medicaments are added when the temperature is between 95-105°C.Colour is dispersed in humectants and added below 85°C followed by lubricant addition above 80°C.Chewable or caramel lozenges are formed in the form of long rope of suitable thickness then cut to a desired size and then packed by using wrappers. This process is called as **rope forming**.

##### b) Compressed tablet lozenges

##### i) Direct compression

In this method all the ingredients are thoroughly mixed and directly compressed in to lozenges tablets, Wet granulation method involves grinding of sugar by mechanical agitation and passed through sieve 40-80 mesh size, Medicament is added to sugar mass and then mixed uniformly. Sufficient amount of sugar syrup or corn syrup is added to homogeneously mixed mass for the granulation and then passed through 2-8 mesh size to obtain wet granules. These wet granules are dried and once again passed through 10-30 mesh size. Suitable flavour and lubricant are then added before compression into required size of tablet lozenges. Sugar is pulverized by mechanical agitator to a fine powder and passed through 40-80 mesh size. Add the medicament and blend the mass. Blend is subjected to granulation with sugar or corn syrup and screened through 2-8 mesh screens. Drying and milling is carried out and passed through 10-30 mesh size. Flavour and lubricant are added compression is carried out.

##### c) Soft lozenges

Soft lozenges are manufactured by **hand rolled** and then cut in to pieces by maintaining desired size and thickness. Another method involves heating of all ingredients along with medicament at about 50°C and poured into a plastic mould. Mould cavity should be overfilled if polyethylene glycol is used, as polyethylene glycol contracts as they cool. This is not required in case of chocolate as it does not shrink. Soft lozenges containing Clotrimazole is made by moulding method in which the increasing amount of polyethylene glycol, xanthan gum or xylitol. This agent increases the hardness of the lozenges and hence the disintegration time care must be taken in the quantity of these agents.



#### d) Hard Candy Based Lozenges<sup>11</sup>

##### i) Heating and Congealing Technique

Syrupy base was prepared in a beaker by dissolving the required amounts of sugar in water and kept for heating on a hot plate and the Temperature was maintained at 105-110 °C till it became thick, later The drug and other excipients (except plasticizer) were added manually and mixed thoroughly after 30 min with continue process of heating. The prepared mass was further heated for 45 min and then plasticizer was added into it. Then above syrupy base was poured into pre-cooled and pre lubricated mold and the mold was kept aside for 10-15 min. Lozenges were removed from mold and were kept for air drying. In the case of batches without plasticizer, a step of plasticizer addition was omitted from procedure.

##### ii) Melting and Mold Technique

PEG was melted on water bath and mixed with the other ingredients to form a homogeneous mixture. Subsequently, the mixture was poured into the desired shape & size stainless steel mold to forming a candy.

#### e) Center filled hard lozenges

Center filled hard lozenges are manufactured by forming a candy base or vehicle comprising sugar, corn syrup, and water, the candy base or the vehicle was heated to remove water there from to obtain a cooked candy base having a residual moisture content ranging from about 0.02% to about 5.0%. Then, subsequent cooling the candy base or vehicle to a soft state and forming the candy base in to a rope. The rope is wrapped around a filling pipe and the powder and semi-liquid center film was prepared containing, medicament in a stabilizing base including vegetable oil, and optionally sugar or gelatine, the semi- liquid or the powder center filler was dispensed into the center of the candy base or vehicle in a ratio of about 2 to 50% by weight of the medicament.

**Table 2: Material of Lozenges and their functions.**<sup>12</sup>

Sl. No	Ingredients	Examples	Role
1	Candy base Sugar Sugar free vehicles	Dextrose, sucrose, maltose, lactose. Mannitol, sorbitol, PEG 600 & 800.	These are the used as sweetening agent and impart the taste masking properties.
2	Fillers	Di calcium phosphate, calcium sulfate, calcium carbonate, lactose, microcrystalline cellulose.	These are the used to Improve the flowability.
3	Lubricants	Magnesium stearate, calcium stearate, stearic acid and PEG, vegetable oils and fats.	These are the used to avoid sticking of candy to the teeth.
4	Binders	Acacia, corn syrup, sugar syrup, polyvinylpyrrolidone, gelatin, tragacanth, and methylcellulose.	These are the used to hold the particles.
5	Colouring agents	Water soluble and lakolene dyes, FD & C colors, orange color paste, red color cubes, etc.	These are the used to inhance appearance and organoleptic properties of dosage form.
6	Flavourings agent	Menthol, eucalyptus oil, spearmint, cherry flavour, etc.	These are the used to give a taste.
7	Whipping agent	Milk protein, egg albumin, gelatin, xanthan gum, starch, pectin, algin and carrageenan.	These are the used in toffee-based confection.
8	Humectants	Glycerin, propylene glycol and sorbitol.	They improve chew mouthfeel properties.



## Components of Lozenges<sup>13</sup>

### 1. Sugar

Sucrose, a disaccharide of glucose and fructose, is obtained from sugarcane or beet. The choice of beet or cane sugar is based on availability and geographical considerations. Sucrose and sucrose products are used in medicated lozenges because of their value as neutral sweeteners, their ready solubility and their function as a “drier” to reduce the weight of the confection through crystallization.

### 2. Corn syrup

Corn syrup is used in almost every type of confection to control sucrose and dextrose crystallization, which may lead to crumbling. Corn syrup in appropriate proportion with sucrose and dextrose allows the formation of an amorphous glass and produces a candy with the desirable appearance. The following physical properties of corn syrup are extremely important in the preparation of medicated candies density, dextrose equivalent, hygroscopicity, sugar crystallization, viscosity, freezing point depression and osmotic pressure.

### 3. Sugar bases

The sugar bases frequently associated with lozenge tablets are sucrose or compressible sugar, dextrose, mannitol and sorbitol, which are available in special tableting grades from a variety of excipient manufacturers. Generally intended for direct compaction applications, they may also be utilized with the above binders in wet-granulation systems. A non-nutritive sweetener is a synthetic or natural sugar substitute whose sweetness is higher than or comparable to sucrose. Examples of nonnutritive sweeteners like xylitol, mannitol, sorbitol, invert sugar etc.

### 4. Binders

These are generally intended for compressed tablet that are used to hold the particles of mass as discrete granules and include acacia, corn syrup, sugar syrup, gelatin, polyvinyl-pyrrolidone, tragacanth and methylcellulose.

### 5. Lubricants

These are used to avoid sticking of candy to the teeth and improve flow of final troche mixture and include magnesium stearate, calcium stearate, stearic acid and PEG.

### 6. Colorants

Colorants are incorporated into medicated lozenges for appearance, product identification, and masking of physical degradation. Dyes and other organic colorants may degrade by heat or light via oxidation, hydrolysis, photo oxidation, etc and their compatibility with drug, excipients, and process conditions should be studied before selection. Suppliers of colors are excellent sources of information on current regulatory status of colorants.

### 7. Acidulants

Acidulants are generally added to medicated lozenges to fortify and strengthen their flavour profile. Organic acids such as citric, malic, fumaric, and tartaric acids are most commonly used. Citric acid alone or in combination with tartaric acid is the most common. Another use of acids in medicated lozenges is to alter the pH to maintain the integrity of the drug.

### 8. Preservatives

These are solid dosage forms, there usually is no need to incorporate preservatives. However, since hard candy lozenges are hygroscopic, the water content may increase and bacterial growth may occur if they are not packaged properly. Since the water that is present would dissolve some sucrose, the resulting highly concentrated sucrose solution is bacteriostatic in nature and would not support bacterial growth. A few comments are in order concerning the flavors and effects of preservatives.





## 9. Flavours

For hard lozenges, the emphasis is on the slow, uniform release of the medication directly onto the affected mucous membrane. This presents an additional challenge to the compounding pharmacist to develop flavour blends that effectively mask any unpleasant principles contributed by the medications, while maintaining a smooth lozenge surface texture as the tablet slowly dissolves. If the incorporated medication has no significant taste, flavouring will not be a problem. However, if the medication has a strong, disagreeable taste, special emphasis should be placed on minimizing the taste in order to enhance patient compliance. Flavour is a very complex phenomenon that is a combination of the senses of taste, touch, smell, sight and sound. The first of these taste is made of four primary tastes: sweet, bitter, sour and salty.

**Table No: 3 Flavour selection guide** <sup>14</sup>

Taste	Flavors that can be used
Salty	Butterscotch, Maple, Nutty, Buttery
Bitter	Spice Wild Cherry, Licorice, Chocolate, Mint, Grapefruit, Coffee, Cherry
Acrid	Raspberry, Orange, Lemon, Lime
Sour	Raspberry, Fruits, Berries, Acacia
Oily	Syrup
Sweet	Peppermint, Anise, Wintergreen
Acid	Fruit, Berry, Vanilla
Metallic	Citrus Berries, Mint, Grape, Marshmallow

### Evaluation of medicated lozenges <sup>15, 16</sup>

#### A. Quality Control

(1) **Candy base** – It has to be check for following parameters-Corn syrup, sugar delivery gears, Temperature, steam pressure and cooking speed of precookers and temperature, steam pressure, cooking speed and vacuum of candy base cookers.

#### (2) Moisture analysis -

**a) Gravimetric method-** 1g of sample is placed in vacuum oven at 60-70°C for 12-16 hrs. After specified period of time, weigh the sample and moisture content is calculated by subtraction of final weight from initial weight.

**Moisture Content =Initial weight – final weight**

**b) Karl Fisher titration-** A sample calculated to contain 10-250 mg water is taken in titration flask and titrated with Karl Fischer reagent.

#### c) Azeotropic distillation method

10-12g pulverized Candy was placed in 50ml flask to which 150-200ml toluene is added then flask is connected to reflux condenser (reflux for 1-2hrs) water collected gives the amount water present in the sample.

(3) **Determination of sugar and corn syrup ratios-**This is done by "Dextrose equivalent".

**Method:** Lane Eynon Titration method".

#### (4) Percentage reducing sugars-

3g anhydrous dextrose was dissolved in 500ml water and the Add 2 drops of methylene blue and (boiled for 2mins) titrated against 25ml of Fehling solution to yellowish red end point.

(5) **Salvage solutions-** Determined using a refractometer.

(6) **Forming checks-** Involves a check on candy rope diameter.



(7) **Cooling checks-** Visual inspection is performed in order to analyze any stress cracking due to rapid cooling, air bubble formation, surface cracking and black specks.

### B. Physical and Chemical Testing

1. **Diameter and thickness-** Diameter of the lozenges is important for uniformity of lozenges size. It can be measured using Vernier Calipers. The extent to which the diameter of the lozenges deviated from  $\pm 5\%$  of the standard value.

2. **Hardness-** The resistance of lozenges to shipping or breakage under conditions of storage, transportation and handling before usage depends on its hardness. The hardness of lollipops can be measured by using Monsanto hardness tester. The hardness was measured in terms of  $\text{kg}/\text{cm}^2$ .

3. **Weight Variation-** The USP weight variation test is done by weighing 20 lozenges.

individually, calculating the average weight and comparing the individual weights to the average.

$$\text{Weight Variation} = \frac{\text{Average weight} - \text{Initial weight}}{\text{average Weight}}$$

4. **Drug excipients interaction studies-** Determined by FTIR.

5. **Friability** - Determined by Friabilator operated at 25rpm for 4min.

6. **In-vitro drug release-** This is carried out in USP II paddle type dissolution apparatus.

7. **Drug content-**Lozenges was powdered and dissolved in 5ml of suitable solvent in 50 ml volumetric flask and volume made up to 50 ml with pH 6.8 Phosphate buffer. From this solution 1 ml taken and diluted with pH 6.8 Phosphate buffer in 50 ml volumetric flask then sonicated for 30 min then filtered using filter paper and the absorbance of the solution is measured spectrophotometrically.

8. **In vitro mouth Dissolving Time-** Mouth Dissolving Time was determined by each batch formulation using USP disintegration apparatus, where lozenges were placed in each tube of the apparatus and time taken for the lozenges to dissolve completely was noted by using 100ml phosphate buffer of pH 6.8 at 37°C. This test was done in triplicate. The average dissolving time for lozenges was calculated and presented with standard deviation.

9. **In vitro buoyancy studies** - The rate of the drug absorption was determined by the rate of drug dissolution from the lozenges. Thus, the rate of dissolution and bioavailability may be directly related to the efficacy of the lozenge. The magnetic stirrers were used and the dissolution medium pH 6.8 phosphate buffer, 100ml was placed in the beaker containing the lozenges and stirred at 100rpm. 5ml aliquot samples were withdrawn at 5 min. interval and replaced immediately with an equal volume of fresh fluid i.e., simulated salivary fluid. Each aliquot was diluted and they were analysed by UV Visible spectrophotometer.

### (D) Stability testing

**Lozenges are subjected to stability testing under following conditions-**

- ❖ 1-2 months at 60°C
- ❖ 3-6 months at 45°C
- ❖ 9-12 months at 37°C
- ❖ 36-60 months at 25° C and 4°C.

(2) Stability testing of product in package-

Lozenges in their final packs are subjected to following conditions for stability testing:

- ❖ 25°C at 80%RH for 6-12 months



- ❖ 37°C at 80%RH for 3 months
- ❖ 25°C at 70%RH for 6-12 months.

#### Storage:

Lozenges should be stored away from heat and out of the reach of children. They should be protected from extremes of humidity. Depending on the storage requirement of both the drug and base, either room temperature or refrigerated temperature is usually indicated.

#### Packaging:

Hard candies are hygroscopic and frequently prone to absorption of atmospheric moisture. Considerations must include the hygroscopic nature of the candy base, storage conditions of the lozenges, length of time they are stored and the potential for drug interactions. These products should be stored in tight containers to prevent drying. This is especially true of the chewable lozenges that may dry out excessively and become difficult to chew. If a disposable mold with a cardboard sleeve is used, it is best to slip this unit into a properly labelled, sealable plastic bag. Packaging should be proper and attractive.

#### Applications of lozenges <sup>17</sup>

**Antifungal lozenges:** Oral lozenges, such as clotrimazole and nystatin, are used to treat fungal infections.

**Nicotine lozenges:** Nicotine lozenges are used as a method to quit smoking. The lozenges release nicotine into bloodstream when u suck on the lozenges, according to the Mayo clinic. Nicotine smokings are intended to be used as often as necessary, until the craving to smoke ceases.

**Zinc lozenges:** Zinc is used as an antioxidant to help your body fight infections. When contained in lozenges, zinc is thought to help reduce the duration of colds and symptoms. Yet, the Mayo clinic notes that there are conflicting studies on whether those zinc claims are accurate.

**Throat/cough lozenges:** sore throat lozenges contain an anesthetic, such as benzocaine, to soothe your throat. The anesthetic works by numbing the affected area to provide temporary relief. Some throat lozenges also might contain an antibiotic to treat diseases of the throat, including strep throat. Cough lozenges which suppress coughing, can contain ingredients, such as menthol or eucalyptus.

**Erectile dysfunction lozenges:** According to the New Zealand men's clinic, lozenges are available to treat erectile dysfunction. The lozenges are administered up to the 30 minutes before intercourse erectile dysfunction lozenges have less side effects than tablet forms.

**Morning sickness lozenges:** Prenatal lozenges contain pyridoxine, or vitamin B6 helps to relieve nausea and vomiting symptoms. The use of prenatal lozenges should be taken as directed by your physician, since high doses of B6 during pregnancy can cause side effects in your newborn.

Table no :4 List of marketed Lozenges <sup>18</sup>

Products	Ingredients	Indication
Cepacol	Menthol, Benzocaine	Sore Throat
Chloraseptic	Benzocaine	Relief of minor sore throat and mouth pain
Clotrimazole lozenge	Clotrimazole	Oral thrush
Koflet-h	Madhu	Alleviate cough and quickly relieves throat irritation
Locketts	Eucalyptus and menthol	Nasal congestion and sore throat
Nicorette	Nicotine	Smoking cessation
Strepsils	Amylmetacr esol, dichlorobenzyl alcohol	Sore throat and blocked nose
Sualin	Glycyrrhiza Glabra	Influenza, bronchitis, sore throat, cold and cough, congestion of head and lungs
Sucrets	Dextromethorphan Hydrobromide	Sore throat
Therazinc	Zinc Gluconate	Common cold and flu



Vicks	Menthol	Sore throat
Vigroids	Liquorices	Expectorant

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