

Oral spray gel medical device

Oral spray gel is a medical device intended for daily use. It contributes to the protection against viral infections, as well as to the alleviation of symptoms of viral infections such as: influenza caused by influenza B and C viruses, the common cold caused by coronaviruses.

Oral spray gel can be used up to four times a day, as described in the instructions for use in the section "Instructions for use", both prophylactically and supportively in ongoing viral infections*.

Oral spray gel can be used in adults and in children after the first year of age.

Ingredients responsible for principal intended action of the product:

Iota-carrageenan, sodium hyaluronate, ectoine

Excipients: propylene glycol, citric acid, sodium hydrogen phosphate, sodium phosphate, water and preservatives.

Indications for use of the medical device Oral spray gel

1. SUPPORT FOR PROTECTION AGAINST THE PENETRATION AND SPREAD OF VIRUSES*

- contributes to protection against the penetration and spread of viruses*.
It can help limit the penetration of viruses into the cells of the oral and pharyngeal mucosa, which may consequently translate into reducing the possibility of developing viral infections of the upper respiratory tract caused by influenza viruses and coronaviruses, which can cause influenza or the common cold, among other things.
- contributes to protection against the spread of viruses, that is, to reduction of transmission from symptomatic or asymptomatic infected individuals to others.

Oral spray gel can be used prophylactically, to support the normal physiological functions of the of the oral and pharyngeal mucosa.

2. RELIEF OF SYMPTOMS OF VIRAL INFECTION* AND SUPPORT OF TREATMENT

- can relieve the symptoms of viral infections* of the upper respiratory tract such as pharyngitis and can support the treatment by relieving dry, non-productive cough (known as reflex cough), reducing sore throat through a moisturising effect.
- It can have a moisturising and soothing effect thanks to the content of sodium hyaluronate and ectoine and thus it contributes to protection against dryness (reduces dryness of the throat) and irritation of the oral and pharyngeal mucosa also by environmental factors.

3. SHORTENING THE DURATION OF ILLNESS

- can shorten the duration of an illness caused by a bacterial or viral infection* of the throat and tonsils.
- It may reduce the likelihood of bacterial superinfection.

Mechanism of action

Oral and pharyngeal mucosa is the body's physical protective barrier. A large number of different types of substances pass through the throat every day. It is the entrance door to our body for nutrients, but also for microorganisms such as viruses.

The specific structure of the oral and pharyngeal mucosa and the secretion of saliva prevents the entry and spread of viruses, bacteria and fungi.

The oral and pharyngeal mucosa acts as a barrier and protects against bacteria and viruses, but only when it is in good physiological condition. Damaged oral and pharyngeal mucosa increases the risk of acute and chronic infectious diseases.

Elderly people are particularly vulnerable to viral and bacterial infections and are affected by dry mouth and dry throat, which often causes damage to the oral and pharyngeal mucosa. This can increase the risk of acute and chronic infectious diseases, including frequent colds and various local infections in the mouth and throat caused by various types of viruses, like coronaviruses, including SARS-CoV-2 and influenza viruses* that can cause influenza or the common cold, among others. Given the right conditions, the virus enters host cells and multiplies, leading to the onset of disease symptoms. However, protection against infection can be promoted through daily prophylaxis.

Following the application of medical device , as described in instructions for use, the product disperses on the oral and pharyngeal mucosa and forms a protective layer, which supports the natural barrier properties of the mucosa and contributes to limiting the penetration of pathogens into the body and, through this fact, contributes to limiting the proliferation of pathogens in the body.

The protective layer formed, as a mechanical barrier, remains fully in place for up to several minutes after application of the product. After this time it gradually undergoes natural physiological processes of the oral cavity, such as salivary gland activity, tongue and cheek mechanics, i.e. it is removed.

Daily use of the product contributes to improving the condition of the oral and pharyngeal mucosa. The protective layer formed has a moisturising and soothing effect thanks to sodium hyaluronate and ectoine, thus helping to protect against dryness and irritation of the oral and pharyngeal mucosa by environmental factors. Strengthened and adequately moisturized mucosa can also perform its physiological and protective functions in a better way.

Oral spray gel is an oral gel that contributes to protection against viral infections*, helping to relieve the symptoms of viral infections*.

Oral spray gel can be used prophylactically, to support the normal physiological functions of the of the oral and pharyngeal mucosa.

Oral spray gel ingredients, i.e. iota-carrageenan, sodium hyaluronate and ectoine, have been the subject of in vitro and in vivo studies and clinical trials.

*concerns only influenza B and C viruses and coronaviruses

The indications of the product do not include the use with the following viruses: paramyxovirus, human influenza virus A and adenovirus subtype B, rhinovirus

Instructions for use

Wash your hands before application. Before using a new bottle for the first time, after removing the cap, press the dispenser about 5 times until the gel appears. Place the dispenser in the mouth, observing personal hygiene rules, press the dispenser. It will disperse the dose of the product in the mouth. After application on the tongue, smack your lips to make the product spread.

Do not rinse the mouth, leave on for approximately 5-10 minutes. It is recommended not to drink or eat immediately after the application of the product.

The time between applications is not equivalent to the time of product's effect.

It is recommended to apply 1 to 2 doses on the tongue at intervals of 4-5 hours between applications.

A 20 ml package contains 200 doses of the product.

The atomiser, once removed from the bottle, can be washed with soapy water, rinsed several times, dried and reused after placing it on the product bottle.

The product is intended for adults and children over one year of age.

If symptoms of discomfort occur, use of the product should be discontinued.

In case of doubt, consult your doctor or pharmacist.

For sanitary and epidemiological reasons, one package should be used by one user only.

Medical device for oral use only, applied on oral and pharyngeal mucosa - do not ingest the product.

In children under 12 years of age, use under supervision of an adult.

The medical device should be used as described in the instructions for use.

If you take more medical device than the recommended dose

A higher dose of the medical device does not pose a risk.

The product should be used as recommended.

Contraindications

- Do not use in case of hypersensitivity to any ingredient of the medical device.
 - Do not use if symptoms like itching or burning occur after use. This may indicate an allergy to the ingredients of the medical device. Then YOU SHOULD NOT USE THE PRODUCT.
 - Do not use on wounds of the oral and pharyngeal mucosa.
 - Avoid accidental contact of the product with the mucous membrane of the eye.
 - Do not use with other oral preparations without consulting your doctor.
 - The product has no effect on the ability to drive and use machines.
 - Do not use this product after the expiry date.
 - Do not use if package is damaged.
 - Do not use if the package is damaged or tampered with before first opening.
 - If the condition of the oral mucosa worsens, you experience dryness and irritation, contact a specialist.
 - If symptoms do not resolve within 7 days, contact your doctor.
 - The product is intended for paediatric use.
- Parent/guardian supervision is required when using in children.

Available packages

The product package contains a bottle of gel with instructions for use.

Available product volume: 20 ml in a glass bottle.

Storage

Store the product in an original package.

Store at room temperature, i.e. 15-25°C.

Protect from light and sources of heat.

Keep out of the reach and sight of children.

Do not use the product in the event of damage to the immediate packaging.

Do not use after the expiry date on the package.

An empty container, unused or expired product must be disposed of (recycled) in accordance with the applicable rules.

Medical device does not contain any substances harmful to the environment.

Undesirable side-effect and serious incidents relating to the use of the medical device should be reported to the manufacturer or distributor's address.

Contact information



Manufacturer:
Laboratoire L'Idéal Parisien Sp. z o.o.
Ogrodowa 8
32-064 Niegoszowice
tel./fax +48 (12) 283 88 60

Distributor:

medical device 



Date of preparation of the instructions for use: 03.08.2022

Information on the package