



# Apolact Nasale TDC

**APOLACT NASAL TDC** is a unique and innovative intranasal spray solution. It contains a mixture of Apo-lactoferrin and lactoferrin in liposomes with sorbitol and it is specially designed for hygiene, hydration and protection of the nasal cavity.

Lactoferrin is an iron chelating glycoprotein, belonging to the transferrin family and naturally present in the secretions of the respiratory system. It is an innate component of non-antibody immunity and is widely studied for its multiple beneficial effects. However, this glycoprotein by its nature is unstable and is particularly sensitive to bacterial and human proteases (enzymes inactivating proteins); this results in a denaturation of the protein and its inactivation.

APOLACT NASAL TDC, thanks to modern liposome microencapsulation technology, overcomes these problems and it is the first advanced formulation that guarantees the apolactoferrin and lactoferrin mixture effectiveness at the level of the nasal mucous membranes. Liposomes are lipid spheres that convey, protect and subsequently free apolactoferrin and lactoferrin mixture, protecting them from

denaturation, preserving their biological stability and improving their bioavailability and therefore effectiveness.

Lactoferrin has an iron-carrying action. Its iron-free form, apolactoferrin, is more active than lactoferrin itself (5 times), since the bond with iron occurs in the open form of apoprotein. This allows easier access to the Fe<sup>3+</sup> or complexed ions. Liposomal lactoferrin is an extremely multifunctional protein and has a broad spectrum of biological activities:

- Antimicrobial activity (antibacterial, antiviral, antifungal and antibiofilm): lactoferrin has both a marked bacteriostatic activity, by binding free iron (an essential cofactor for microbial growth), and bactericidal, linked to the ability to damage the cell wall of some Gram bacteria -negative. The antiviral activity of lactoferrin is due to its ability to bind to the plasma membrane glycosaminoglycans. This prevents the entry of the virus by blocking the infection from the beginning. Lactoferrin also inhibits SARS-CoV-2 infection, binding to the adhesion proteins (spike proteins) present on the surface of the coronavirus. These proteins mediate the entry of the virus into the host cell. Lactoferrin

acts directly on the viral capsid by blocking the early stages of virus-cell interaction. Furthermore, the antiviral activity is also due to the chelation of iron which, subtracted from the viral enzymes, are deprived of the cofactor necessary for their activation.

- Immunostimulating activity: lactoferrin is naturally present in the respiratory system secretions and it is an important component of the innate immune system. It plays a role in the first line of defense against microbial infections and acts as a natural barrier of the respiratory mucosa, since many pathogens (including viruses) tend to come into contact with the body through the mucous membranes.

- Anti-inflammatory activity: lactoferrin has a marked anti-inflammatory activity and it is considered a natural antioxidant. In the antioxidant defense mechanism, lactoferrin sequesters the catalytic iron generated by the processes of cell destruction; in this way it minimizes the damage produced by free radicals which, during inflammatory processes, are associated with the production of pro-inflammatory cytokines and decreases the ferric ions availability for the microorganisms that invade the host.

#### **INDICATIONS**

The medical device APOLACT NASAL TDC is useful for the hygiene, hydration and drainage of the nasal cavities and for the protection of the nasal mucous membranes.

#### **COMPOSITION**

Mixture of Apolactoferrin and Lactoferrin in Liposomes, Sorbitol, Sodium Chloride, EDTA, Monobasic Sodium Phosphate, Dibasic Sodium Phosphate, Water.

#### **INSTRUCTIONS FOR USE**

2 sprays per nostril are recommended 2-3 times a day. Before administration, it is recommended to carefully clean the nasal cavity. Each delivery is equivalent to about 0.1 ml of solution.

#### **PRECAUTIONS FOR USE AND WARNINGS**

Lactoferrin is a protein extracted from cow's milk and therefore its use is not recommended in case of allergy to milk proteins. External use.

#### **STORAGE**

Keep the package tightly closed at a temperature not exceeding 25 ° C in a cool and dry place, away from light and heat sources.

#### **PACKAGING**

20 ml bottle with spray dispenser.

#### **MANUFACTURER**

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#### **European Patent**