COVISPRAY

Filmogen barrier to remove contaminants including viruses (mechanical mode of action).

PRESENTATION: 15 ml Spray (approx. 140 sprays).

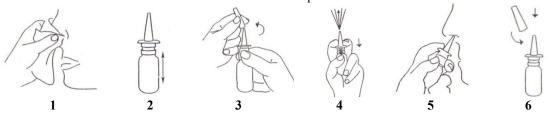
COMPOSITION: Aqua; filmogen glycerol (glycerol: 9.80%, HPC (hydroxypropylcellulose); Solagum TM, S1-cyanidin (derived from plant extracts: *T. parthenium (aerial parts), C. longa (rhizomes), U. dioica (roots), C. sinensis (leaves);* preservatives (Sodium benzoate, Potassium sorbate, Citric acid)

MODE OF ACTION: When COVISPRAY is sprayed on the nasal surface, it forms a stable filmogen barrier which helps prevent viral contact with the nasal mucosa. The osmotic properties of COVISPRAY generate an outward flow of hypotonic liquid from the inner parts of the nasal mucosa, which detaches contaminants (viral particles, cell debris, bacteria, etc.). These contaminants are then retained in the absorbent film or evacuated with nasal discharge. This mechanical cleaning action helps to protect the nasal mucosa and reconstitute the natural defensive nasal barrier.

Each application is effective for about 4 hours. Clinical results in patients in the early phase of viral infection show a significant reduction in the manifestation and severity of respiratory symptoms.

DIRECTIONS:

- 1 Clean your nose thoroughly before using the product.
- 2 Shake the bottle.
- 3 Remove the protective cap.
- 4 Before first use, press on the sprayer until a fine mist of product appears.
- 5 Insert the nozzle upright into one nostril, close the other nostril with one finger and spray the product by pressing on the sprayer. Repeat the same process in the other nostril while breathing in very slightly. Wipe excess product with a clean tissue.
- 6 Clean the nasal insert after each use and close the bottle with the cap.



FOR USE AS PREVENTIVE TREATMENT: Apply 2 sprays in each nostril, while breathing in very slightly, 10-15 minutes before entering a risk area or confined places. Repeat the same process every 4 hours, if required. Do not use for more than 30 consecutive days.

FOR USE AS AN EARLY PHASE TREATMENT: Apply 2 sprays in each nostril, while breathing in very slightly, 4 times a day. The scope of use of the product does not justify prolonged treatment beyond 14 days. Seek the advice of your pharmacist or consult a doctor if symptoms and/or associated fever appear, persist or worsen.

PRECAUTIONS: This product is for topical use in the nasal cavity only and does not replace wearing a face mask and barrier gestures. Maintain constant slight air flow in the room. Read the instructions leaflet carefully before use and respect the directions. Wash hands before and after use. To avoid risk of cross infection, each spray must be used by one patient only. The mode of action of COVISPRAY is due to instant osmosis and may produce slight tingling and nasal discharge during the first 10-15 minutes following each product application. Don't blow your nose strongly and wipe the excess product with a clean tissue.

STORAGE: Keep the product out of reach and sight of children. Store at room temperature, do not refrigerate or freeze. Do not use after the expiry date, more than 30 days after 1st use, or if the container is damaged.

INTERACTIONS: Due to the product's composition and to the mechanical & topical mode of action, the probability of interaction with any systemic treatment is unlikely. For efficacy reasons, do not apply any other topical nasal treatment 15 minutes before or after the use of this product.

CONTRAINDICATIONS: Check the product's composition and do not use if you are sensitive or allergic to any of the ingredients. In the absence of sufficient specific safety data, we do not recommend the use of this product in pregnant or breastfeeding women without medical advice. Do not use in children below 12 years of age and in patients suffering from asthma or severe respiratory conditions.

SIDE EFFECTS: COVISPRAY is not toxic if accidentally swallowed. Avoid contact with the eyes. In case of contact, flush thoroughly with water. If you observe any type of allergic reaction in the minutes following product application (strong persistent irritation, burning sensation, swelling...), cease using the product and flush your nose thoroughly with clear water, and if necessary, consult a medical professional. If you notice any serious incidents due to the use of this product, please notify immediately the manufacturer/distributor and national competent authorities.

The packaging (including the container) can be disposed of as household waste after use.

CE

Leaflet revision/version: PIR b11-0521

MANUFACTURERDISTRIBUTOR:VITROBIO SASname, adresse, contact

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MEDICAL DEVICE

MADE IN France