PACKAGE LEAFLET

NARLISIM® Spray Medical Device, Class IIa

Solution for nasal use 20 ml bottle

INDICATIONS:

NARLISIM[®] Spray is a solution for nasal use indicated in case of obstruction of the nostrils to facilitate the elimination of mucus; NARLISIM[®] Spray can also be used as an adjunct in the treatment of the most common respiratory tract infections.

COMPOSITION: Pirometaxina[®] (Pyrrolidone Carboxylic Acid (4%) and Copper Sulfate Pentahydrate), Sodium Chloride, Sodium Hydroxide, Purified Water.

INSTRUCTIONS FOR USE:

For correct use of the NARLISIM Spray medical device®, do the following:

- Remove the cover.
- Tilt your head back slightly and insert the tip of the bottle into your nostril.
- Press the tabs to spray the dose into the nostril.
- Repeat the same procedure for the other nostril.
- Lift your head and remove any excess liquid.
- Avoid blowing your nose after administration of the product in order to prolong the effect.
- Close the bottle and store in a dry place, away from heat and light sources.

DOSAGE: CHILDREN OVER 3 YEARS OLD:

1 nebulizer in each nostril, 2 - 3 times a day

ADULTS:

1 - 2 nebulization's in each nostril, 3 - 4 times a day

WARNINGS:

- NARLISIM[®] Spray is for nasal use only. Do not ingest.
- Use one spray for each person.
- Do not use during pregnancy.
- In children under the age of three, NARLISIM[®] Spray should be used under medical advice.
- Do not use in case of hypersensitivity or incompatibility with any of the ingredients of NARLISIM[®] Spray. A slight and temporary burning sensation can be felt on application and is associated with the characteristics of the solution necessary to ensure its effectiveness.
- Use only on intact mucosa.
- In children under the age of six, it is advised that the administration be done by an adult.
- Long-term use of NARLISIM[®] Spray, as with all topical products, may give rise to local irritation and sensitization. If this happens, stop treatment and consult your doctor or pharmacist.
- Do not use NARLISIM[®] Spray if, when you first open the case, it appears to be damaged or not intact.
- Do not use NARLISIM[®] Spray after the date of expiry indicated on the box.
- Keep NARLISIM[®] Spray out of the sight and reach of children.

CONSERVATION:

Store in a dry place, away from heat sources (recommended temperature between 10 and 30° C) and light. The expiration date refers to NARLISIM[®] Spray unopened, properly stored. The expiry date is indicated on the packaging.

SIDE EFFECTS:

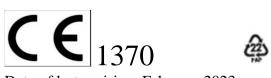
There are no known or expected side effects related to the use of NARLISIM[®] Spray. Tests carried out so far have not provided any evidence of sensitisation or other side effects.

If unwanted side effects occur, report them to the manufacturer or health authorities immediately. It is necessary to report to the Manufacturer and the competent Authorities any type of serious accident related to the medical device.

PACKING:

20 ml bottle.

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Legend of symbols	
LOT	Lot number
	Use Before (YYYY-MM)
	Maker
	Do not disperse in the environment after use
Ĩ	Refer to the instructions for use
STERILE R	Radiation sterile
	Do not use in case of damaged packaging and refer to the instructions for use
MD	Medical Device
	Unique sterile barrier system, with outer protective packaging
	Date of manufacture