PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Schedule 2

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

SINUMAX® ALLERGY NASAL SPRAY

Levocabastine hydrochloride

Read all of this leaflet carefully because it contains important information for you

SINUMAX ALLERGY NASAL SPRAY is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use SINUMAX ALLERGY NASAL SPRAY carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share SINUMAX ALLERGY NASAL SPRAY with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve within 8 weeks.

1.0 WHAT SINUMAX ALLERGY NASAL SPRAY CONTAINS

Each milliliter of nasal spray contains 0,5 mg levocabastine as active substance**.**

Preservatives: Benzalkonium chloride and disodium edetate

Other ingredients: Disodium hydrogen phosphate anhydrous, hypromellose, polysorbate 80, propylene glycol, sodium dihydrogen phosphate monohydrate, purified water

2.0 WHAT SINUMAX ALLERGY NASAL SPRAY IS USED FOR

SINUMAX ALLERGY NASAL SPRAY is for the relief of seasonal nasal complaints, such as sneezing, runny and itchy nose, associated with allergies.

3.0 BEFORE YOU USE SINUMAX ALLERGY NASAL SPRAY

Do not use SINUMAX ALLERGY NASAL SPRAY:

If you are (hypersensitive) allergic to levocabastine hydrochloride or any of the other ingredients of SINUMAX ALLERGY NASAL SPRAY. If you are not sure, talk to your doctor or pharmacist about this.

Take special care with SINUMAX ALLERGY NASAL SPRAY:

Kidney disorder

Do not use SINUMAX ALLERGY NASAL SPRAY if you have kidney problems, unless your doctor advises you to do so.

Pregnancy and Breastfeeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before using SINUMAX ALLERGY NASAL SPRAY.
Safety in pregnancy and breastfeeding has not been established.
You should not use SINUMAX ALLERGY NASAL SPRAY during the breastfeeding period.

Taking other medicines with SINUMAX ALLERGY NASAL SPRAY

Always tell your healthcare professional if you are taking other medicine. (This includes complementary or traditional medicines).
There may be an interaction with alcohol and SINUMAX ALLERGY NASAL SPRAY.

Driving and using machinery

SINUMAX ALLERGY NASAL SPRAY usually does not affect alertness or concentration. However, should you feel drowsy, be careful while driving or operating machinery.

4.0 HOW TO USE SINUMAX ALLERGY NASAL SPRAY

Do not share medicines prescribed for you with any other person. Always use SINUMAX ALLERGY NASAL SPRAY as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

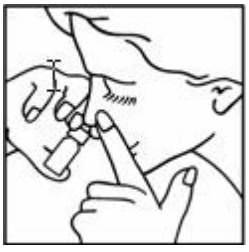
SINUMAX ALLERGY NASAL SPRAY comes as a suspension.

Shake the bottle well before each use.

For adults and children over 5 years, the usual dose is **2 sprays of SINUMAX ALLERGY NASAL SPRAY for each nostril twice a day.** For children (6 months to 5 years) the usual dose is **1 spray of SINUMAX ALLERGY NASAL SPRAY for each nostril twice a day.**

Follow your doctor's directions carefully.

1. Shake the bottle well before removing the cap.
2. Before using SINUMAX ALLERGY NASAL SPRAY for the first time, remove the cap and squeeze the bottle once or twice until a fine spray appears in the air.
3. Blow your nose.
4. Hold the bottle as shown in the picture. Tilt your head slightly forward. Keep one nostril tightly closed and insert the nozzle into the other nostril.
5. Spray twice, while breathing in through the same nostril.



6. Repeat steps 4 and 5 for the other nostril.

Treatment should be continued until your symptoms get better.

Do not use for longer than:

- 8 weeks in adults and children over 5 years of age.
- 4 weeks in children 6 months to 5 years of age.

If you use more SINUMAX ALLERGY NASAL SPRAY than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

5.0 POSSIBLE SIDE EFFECTS

SINUMAX ALLERGY NASAL SPRAY can have side effects.

Not all side effects reported for SINUMAX ALLERGY NASAL SPRAY are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using this medicine, please consult your doctor, pharmacist or healthcare professional for advice.

Stop using SINUMAX ALLERGY NASAL SPRAY and tell your doctor immediately if you notice or suspect a sudden serious allergic reaction as you may need urgent medical treatment. Signs include:

- Swelling of the face, lips, mouth or throat
- Wheezing or difficulty breathing or swallowing
- Rash or hives

If you experience any other side effect while using SINUMAX ALLERGY NASAL SPRAY, including those listed below, you should inform your doctor or pharmacist immediately.

- hard, strong or irregular heart beats (palpitations) or a fast heart beat
- difficulty breathing, shortness of breath, chest tightness

- headache
- nausea
- fatigue, drowsiness, dizziness, feeling generally unwell
- irritation, discomfort, pain, burning, or dryness of the skin that comes in contact with SINUMAX ALLERGY NASAL SPRAY
- Sinusitis (signs include feeling of tension or fullness of the nose, cheeks and behind your eyes, sometimes with a throbbing ache, fever, stuffy nose and loss of sense of smell)
- throat pain
- nose bleed
- stuffy nose
- discomfort or swelling of the nose
- swelling of the eyelids
- nasal swelling

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6.0 STORING AND DISPOSING OF SINUMAX ALLERGY NASAL SPRAY

SINUMAX ALLERGY NASAL SPRAY should be stored at or below 25 °C.

Protect from light. Shake well before use.

Do not use SINUMAX ALLERGY NASAL SPRAY after the date printed after “EXP” (month and year).

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7.0 PRESENTATION OF SINUMAX ALLERGY NASAL SPRAY

SINUMAX ALLERGY NASAL SPRAY is available in 15 ml containers, containing 10 ml or 15 ml of SINUMAX ALLERGY NASAL SPRAY suspension.

8.0 IDENTIFICATION OF SINUMAX ALLERGY NASAL SPRAY

A white homogenous microsuspension.

9.0 REGISTRATION NUMBER/REFERENCE NUMBER

X/5.7.1/230

10.0 NAME AND ADDRESS OF REGISTRATION HOLDER

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11.0 DATE OF PUBLICATION

- Date of registration of SINUMAX ALLERGY NASAL SPRAY: 26 April 1994
- Date of most recent revised Patient Information Leaflet as approved by Council: August 2015