Package leaflet: Information for the user Numark Sore Throat Relief Spray 1.5mg Oromucosal Spray

Benzocaine

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again
- Ask your pharmacist if you need more information or advice
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

What is in this leaflet

- 1. What Sore Throat Relief Spray is and what it is used for
- 2. What you need to know before you use Sore Throat Relief Spray
- 3. How to use Sore Throat Relief Spray
- 4. Possible side effects
- 5. How to store Sore Throat Relief Spray
- 6. Contents of the pack and other information

1. What Sore Throat Relief Spray is and what it is used for

Numark Sore Throat Relief Spray 1.5mg Oromucosal Spray (hereinafter referred to as Sore Throat Relief Spray) is used to relieve the pain of sore throats. The product contains benzocaine, which is a local anaesthetic. It has a fast action and works by numbing the pain of a sore throat.

2. What you need to know before you use Sore Throat Relief Spray

Do not use this medicine:

- in children 12 years or under
- if you have difficulty in breathing, noisy breathing or severe difficulty in swallowing. Talk to your pharmacist or doctor if this applies to you
- if you are allergic to benzocaine or any of the other ingredients (listed in section 6)
- if you have a rare blood condition called methaemoglobinaemia
- if you are pregnant or breast feeding.

Warnings and precautions

Talk to your doctor or pharmacist before using Sore Throat Relief Spray:

If your sore throat is severe or prolonged, or accompanied by fever, headache, or feeling sick.

Do not use this medicine for more than three days in a row.

Do not spray into eyes.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Driving and using machines

Sore Throat Relief Spray should not have an effect on your ability to drive or use machinery.

Sore Throat Relief Spray contains ethanol

This spray contains a small amount of ethanol (alcohol), less than 100mg per dose.

3. How to use Sore Throat Relief Spray

This medicine is for use by adults and teenagers. Please follow the handling instructions below:

- Shake the container before use
- Before use it may be necessary to press the plunger 3 times to activate the spray. If necessary this process can be repeated. Do this away from your face, into a sink
- Do not spray into eyes. If you accidentally spray into eyes, rinse them thoroughly with water.





Fig 2 Raise nozzle from vertical to horizontal position

(continued overleaf)

Fig 3

Hold your head upright and insert the nozzle well into your mouth. Hold your breath and press the plunger once to deliver a single metered spray.



Dosage:

Adults and Teenagers (13+):

- Hold breath and spray twice to the back of the throat
- Repeat every 2-3 hours if required
- Do not use more than 8 times a day.

Do not use in children 12 years and under.

Do not use for more than 3 days in a row. If symptoms do not improve, consult your pharmacist or doctor.

You should experience temporary numbness in your throat after using the spray. This means this medicine is working. Avoid eating or drinking while your throat is numb.

If you use more of this medicine than you should If you spray more than you should, and you feel drowsy or unwell in any way, you must contact a doctor immediately.

4. Possible side effects

Like all medicines, Sore Throat Relief Spray can cause side effects, although not everybody gets them.

If you experience any of the following allergic reactions stop using the spray and seek immediate medical advice:

- severe rash, itching, swelling of the face, lips or mouth
- shortness of breath or difficulty breathing

Methaemoglobinaemia (a very rare blood condition) has been reported with benzocaine use.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: <u>www.mhra.gov.uk/yellowcard</u> or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sore Throat Relief Spray

Keep out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the can and carton, after MM/YYYY. The expiry date refers to the last day of that month. Do not store above 25°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Sore Throat Relief Spray contains

Each metered dose (spray) of this medicine contains the active benzocaine 1.5mg. It also contains cetylpyridinium chloride, glycerin, ethanol, clove bud oil, peppermint, menthol, saccharin sodium 450, cremophor RH40 (polyethoxylated castor oil) and purified water.

What Sore Throat Relief Spray looks like and contents of the pack

The spray is a clear colourless to straw coloured solution available in a white aluminium can with a folding arm activator and cap.

Each can contains approximately sixty metered doses (sprays).

Marketing Authorisation Holder

Manx Pharma Ltd, Taylor Group House, Wedgnock Lane, Warwick, CV34 5YA, United Kingdom.

Distributed by

Numark Ltd., Amber Close, Tamworth, Staffs, B77 4RP, UK.

Manufacturer

Apollo Pharma Ltd, Unit 1 Irwell Works, Lower Woodhill Road, Bury, BL8 1AA, UK.

Other formats

To request a copy of this leaflet in Braille, large print or audio please call 01926 482511.

This leaflet was last revised in August 2018

URN: NST001-PIL-07-150818