

CALCINASE

Calcitonin (Salmon) Nasal Spray/ *Calcitonin (Salmon) BP*

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What Calcinase Nasal Spray is used for

Calcinase Nasal Spray is used to treat osteoporosis (thin and weak bones) in women after the menopause to reduce the risk of spinal fractures.

How Calcinase Nasal Spray works

Calcinase Nasal Spray contains the active substance calcitonin (salmon, synthetic).

Calcitonin is a hormone that occurs naturally in the body of both humans and animals. It regulates the level of calcium in the blood. Calcitonin is used to reverse bone loss and may also help on bone formation.

Before you use Calcinase Nasal Spray

When you must not take it

If you are allergic (hypersensitive) to calcitonin (salmon, synthetic) or any of the other ingredients of Calcinase.

If you have a very low level of calcium in your blood (hypocalcaemia).

Before you start to take it

Take special care with Calcinase Nasal Spray

Before treatments with Calcinase Nasal spray tell your doctor if you think you may be allergic to calcitonin (salmon, synthetic).

Your doctor will perform a skin test before you start using Calcinase Nasal Spray. If you have a sore nose, do not start using Calcinase Nasal spray.

Tell your doctor who will examine your nose before you start using Calcinase Nasal spray.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any medicines, including medicines obtained without prescription. It is particularly important to tell your doctor if you are taking a medicine containing lithium, as the dose of lithium may need to be changed.

Use in children and adolescents (age under 18 years)

Use of Calcinase Nasal spray is not recommended in patients under 18 years of age.

Older people

Calcinase Nasal spray can be used can be used by older patients without any special requirements.

Pregnancy and breast-feeding

Calcinase Nasal spray should not be used in pregnant and breast-feeding women.

If you are, or think you may be pregnant, ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Calcinase Nasal spray may cause tiredness, dizziness and disturbed vision which could affect your reactions. If this happens to you, do not drive or use any machines.

Important information about some of the ingredients of Calcinase Nasal spray

This product contains benzalkonium chloride, which can cause swelling of the inside of your nose, especially with long term use. If you notice any nasal congestion, contact your doctor. Your doctor may decide to prescribe another treatment for you.

How to take Calcinase Nasal Spray

How much to take/When to take it/How long to take it?

Always use Calcinase Nasal Spray exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

This medicine is for nasal use only.

Your pharmacist has stored Calcitonin Nasal Spray in a refrigerator. Before you start using it, you should let the spray reach room temperature. You should store Calcinase Nasal Spray at room temperature.

The usual dose is one spray puff (200 IU) daily. It is recommended that you administer Calcinase Nasal spray to alternating nostrils.

It is recommended that you also take an adequate amount of calcium and vitamin D whilst using Calcinase Nasal Spray. Ask your doctor for advice.

Before the nasal spray is used for the first time, the pump must be primed as described below in the 'Instructions for use of Calcinase Nasal Spray'. The instructions should be followed carefully.

Instructions for use of Calcinase Nasal Spray

Please read the instructions carefully so that you know how to use your nasal spray. These instructions tell you about:

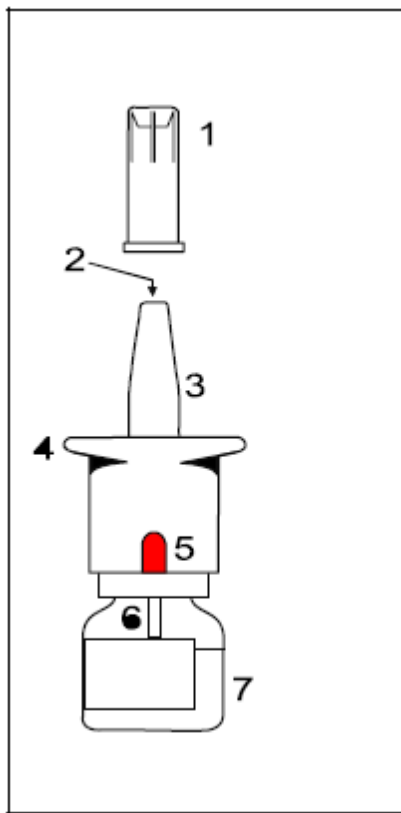
- A.** The different parts of your nasal spray.
- B.** How to prepare a new nasal spray for use.
- C.** Using the nasal spray.
- D.** Checking the counter

Always follow your doctor's instructions regarding dose carefully.

A. The different parts of the spray bottle.

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1. Protective cap: Keeps the nozzle clean and protects the jet. Always replace the protective cap after you have used the nasal spray.

2. Jet: The tiny hole from which the medicine sprays out.

3. Nozzle: The part you insert into your nostril.

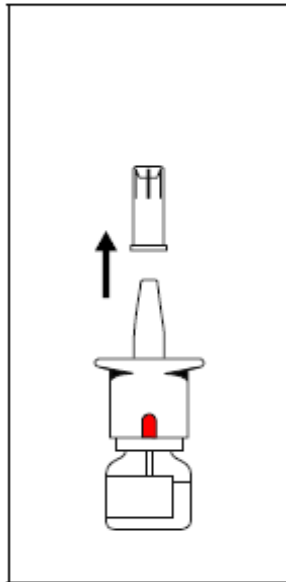
4. Pump: The part you press down to operate the spray.

5. Counter: The dose counter window on new nasal spray shows  as shown in the picture. The display will change as you use the pump (see below).

6. Dip tube: The tube inside the spray bottle that draws up the medicine when you press the pump.


7. Bottle: Contains enough medicine for at least 14 metered doses.

B. Preparing a new nasal spray bottle for use:

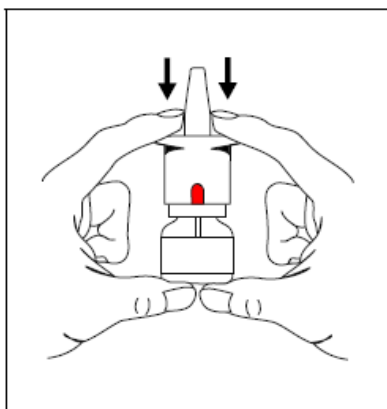


• **NEVER** shake the nasal spray bottle as this could cause air bubbles which may affect your dose.

The dose counter window of a new nasal spray bottle is in the position

marked  in the picture.

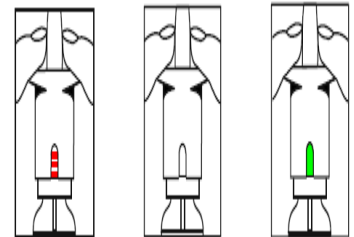
• First, remove the protective cap.



• Hold the nasal spray upright in one or two hands and press down firmly on the pump **3 times**.

This primes the new spray by clearing the air out of the dip tube. You will only need to do this once when you start a **new** spray.

Do not worry if a little medicine sprays out; this is normal.



As you press the pump, watch the changes in the dose counter window:



• When the green is showing in the dose counter window, your new nasal spray is ready to use.

• Follow the instructions for “Using your spray”.

C. Using your nasal spray



• After removing the protective cap, bend your head forward slightly and insert the nozzle into one of your nostrils. Try to hold the nasal spray upright, as shown in the picture.

• Press the pump firmly **only once**.

• Remove the nasal spray from your nose and breathe in deeply through your nostril to help keep the medicine in your nose.

• If your doctor has told you to take two puffs at a time, repeat this procedure in your other nostril.

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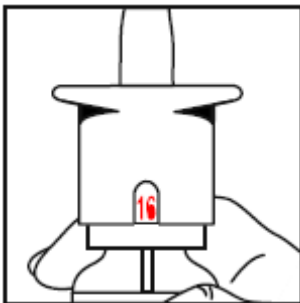
• After use, clean the nozzle with a dry tissue and replace the protective cap.

D. Checking the counter

Every time you use the nasal spray the number in the dose counter window will change. The number displayed tells you how many puffs you have already taken. The Nasal Spray is guaranteed to deliver 14 metered doses. You may be able to obtain 2 additional doses.

When the dose counter window turns red and displays the number (16), as shown in this picture you have taken 16 spray puffs and the spray is finished.

You may notice that a little liquid is left in the nasal spray bottle, but this is normal.



If the spray mechanism becomes blocked, this may be fixed by pressing the pump forcefully; **do not** attempt to unblock it using a sharp pointed object as this may cause damage.

If you think your nasal spray is not working properly, return it to your supplier. Never try to fix the nasal spray yourself or take it apart, as this may affect your dose.

If you forget to take it

If you forget to use your nasal spray, take the spray as soon as you remember unless it is less than 4 hours before the next dose. If so, wait and take your next dose at the usual time. Do not take a double dose to make up for a forgotten one.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you take too much (overdose)

If you have accidentally taken too much Calcinase Nasal Spray, tell your doctor immediately. You may require medical attention.

While you are using Calcinase Nasal Spray

Things you must do

You must tell your doctor/ pharmacist about any herbal/ OTC drugs/ special diet you are currently taking/ or undergoing any medication for other conditions

You must keep away all the medicines away from children

Things you must not do

You must not exceed the recommended dosage

Things to be careful of

Please tell your doctor if you are pregnant/ planning to get pregnant/ or breastfeeding

Side effects

Like all medicines, Calcinase Nasal spray can cause side effects, although not everybody can get them. The more frequently observed side effects are those affecting the nose such as sore nose or and runny or stuffy nose. These are generally mild and rarely require the dose to be stopped.

Some side effects could be serious:

Increased heartbeat, nettle rash (hives), difficulty breathing, swelling of the tongue and throat, tightness in your chest, a sudden fall in blood pressure or shock. These may be signs of a severe allergic reaction (anaphylaxis) and are very rare. Swelling of your face, limbs or entire body (uncommon).

If you experience any of these, contact a doctor immediately.

Other side effects:

Very common side effects (affecting more than 1 in 10 patients):

Sore nose, runny or stuffy nose (rhinitis), swelling, redness and damage to the inside of the nose, sneezing, dry nose, nasal allergies, irritated nose, unpleasant smell.

Common side effects (affecting less than 1 in 10 patients):

- Diarrhea, stomach pain, feeling sick,
- Tiredness,
- Pain in bones or joints
- Dizziness,
- Headache,
- Change in the way things taste,
- Sudden waves of redness of the face/ or neck (flush),
- Nose bleed,
- Feeling of pressure or pain in nose, cheeks and behind eyes (inflammation of the sinuses), nasal inflammation and damage,
- Sore throat and discomfort when swallowing (pharyngitis).

Uncommon side effects (affecting less than 1 in 100 patients):

- High blood pressure (hypertension),
- Flu- like symptoms,
- Disturbed vision,
- Allergic reactions,
- Cough,
- Being sick,
- Itching.

Rare side effects (affecting less than 1 in 1000 patients):

Skin rash.

In rare cases, the effectiveness of Calcinase Nasal Spray may be reduced.

If any of the side effects gets severe, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

After using Calcinase Nasal Spray

Storage

Store unopened bottle in refrigerator at a temperature between 2°C to 8°C. Protect from freezing. Once opened the bottle may be stored at room

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temperature below 25°C in an upright position for up to 4 week.

Disposal

Please ask your pharmacist on how to dispose unused/ left medicines.

Product description

What it looks like?

Description

A clear, colourless liquid.

Pack size : Glass vial of 30 MD each

Ingredients

inactive ingredients:

Sodium Chloride, Benzalkonium Chloride, Hydrochloric Acid, Water for Injection

MAL NO: MAL10100004A

Manufacturer

Cipla Ltd.

L-147 to L147-1

Verna Industrial Estate

Goa 403722

India

Marketing Authorisation Holder

Medispec (M) Sdn Bhd,

55 & 57, Lorong Sempadan 2, (Off Boundry Road)

11400 Ayer Itam, Penang,

Malaysia

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