

**Patient Information**  
**Calcitonin Salmon (synthetic origin)**  
(kal" si toe' nin)  
**Nasal Spray**

Read this Patient Information before you start using Calcitonin Salmon (synthetic origin) Nasal Spray and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

**What is Calcitonin Salmon (synthetic origin) Nasal Spray?**

Calcitonin Salmon (synthetic origin) Nasal Spray is a prescription medicine used to treat osteoporosis in women more than 5 years after menopause. Calcitonin Salmon (synthetic origin) Nasal Spray should be used for women who cannot use other treatments or who choose not to use other treatments for osteoporosis.

It is not known if Calcitonin Salmon (synthetic origin) Nasal Spray lowers the chance of having bone fractures.

Calcitonin Salmon (synthetic origin) Nasal Spray has not been shown to be effective in women less than 5 years after menopause.

It is not known if Calcitonin Salmon (synthetic origin) Nasal Spray is safe and effective in children under 18 years of age.

**Who should not use Calcitonin Salmon (synthetic origin) Nasal Spray?**

Do not use Calcitonin Salmon (synthetic origin) Nasal Spray if you:

- are allergic to calcitonin salmon or any of the ingredients in Calcitonin Salmon (synthetic origin) Nasal Spray. See the end of this leaflet for a complete list of ingredients in Calcitonin Salmon (synthetic origin) Nasal Spray.

**What should I tell my healthcare provider before using Calcitonin Salmon (synthetic origin) Nasal Spray?**

**Before you use Calcitonin Salmon (synthetic origin) Nasal Spray, tell your healthcare provider if you:**

- have any other medical conditions
- have low calcium levels in your blood
- are pregnant or plan to become pregnant. It is not known if Calcitonin Salmon (synthetic origin) Nasal Spray can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if Calcitonin Salmon passes into your breast milk. You and your healthcare provider should decide if you will use Calcitonin Salmon (synthetic origin) Nasal Spray or breastfeed.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Especially tell your healthcare provider if you take:

- **lithium.** Your healthcare provider may need to change your dose of lithium while you use Calcitonin Salmon (synthetic origin) Nasal Spray.

Know the medicines you take. Keep a list of them to show your healthcare provider and

pharmacist when you get a new medicine.

### **How should I use Calcitonin Salmon (synthetic origin) Nasal Spray?**

- **For detailed instructions, see the Instructions for Use at the end of this Patient Information leaflet.**
- Use Calcitonin Salmon (synthetic origin) Nasal Spray exactly as your healthcare provider tells you to use it.
- **Do not** use Calcitonin Salmon (synthetic origin) Nasal Spray until your healthcare provider shows you and you understand how to use it correctly.
- Use 1 spray of Calcitonin Salmon (synthetic origin) Nasal Spray, 1 time each day, in 1 nostril (inside your nose).
  - Start with 1 spray in your **left** nostril on your first day, followed by 1 spray in your **right** nostril on the second day.
  - Continue to switch nostrils for your dose each day.
- Your healthcare provider should check your nose before you start using Calcitonin Salmon (synthetic origin) Nasal Spray and often while you are using it.
- Tell your healthcare provider if you start to have discomfort (irritation) in your nose that bothers you while you use Calcitonin Salmon (synthetic origin) Nasal Spray.
- Your health care provider should prescribe calcium and vitamin D to help prevent low calcium levels in your blood while you use Calcitonin Salmon (synthetic origin) Nasal Spray.
- Take your calcium and vitamin D as your healthcare provider tells you to.
- There are 14 doses (2 mL fill) or 30 doses (3.7 mL fill) (sprays) of Calcitonin Salmon (synthetic origin) Nasal Spray in each bottle. After either 14 doses (2 mL fill) or 30 doses (3.7 mL fill), each spray may not give you the right amount of medicine, even if the bottle is not completely empty. Keep track of the number of doses of medicine used from your bottle.
- If you use too much Calcitonin Salmon (synthetic origin) Nasal Spray, call your healthcare provider or go to the nearest hospital emergency room right away.

### **What are the possible side effects of Calcitonin Salmon (synthetic origin) Nasal Spray?**

#### **Calcitonin Salmon (synthetic origin) Nasal Spray may cause serious side effects, including:**

- **allergic reactions**

Some people have had an allergic reaction when using calcitonin salmon nasal spray. Some reactions may be serious and can be life threatening. Call your healthcare provider or go to the nearest hospital emergency room right away if you have any of these symptoms of an allergic reaction.

  - trouble breathing
  - swelling of your face, throat or tongue
  - fast heartbeat
  - chest pain
  - feel dizzy or faint

If you might be allergic to calcitonin salmon, your healthcare provider should do a skin test before you use Calcitonin Salmon (synthetic origin) Nasal Spray.

- **low calcium levels in your blood (hypocalcemia)**

Calcitonin Salmon (synthetic origin) Nasal Spray may lower the calcium levels in your blood. If you have low blood calcium before you start using Calcitonin Salmon (synthetic origin) Nasal Spray, it may get worse during treatment. Your low blood calcium must be treated before you use Calcitonin Salmon (synthetic origin) Nasal Spray. Most people with low blood calcium levels do not have symptoms, but some people may have symptoms. Call your healthcare provider right away if you have any of these symptoms of low blood calcium:

  - numbness or tingling in your fingers, toes, or around your mouth

Your healthcare provider should:

- do blood tests while you use Calcitonin Salmon (synthetic origin) Nasal Spray
- prescribe calcium and vitamin D to help prevent low calcium levels in your blood while you use Calcitonin Salmon (synthetic origin) Nasal Spray.

Take your calcium and vitamin D as your healthcare provider tells you to.

- **nose irritation**

Irritation of your nose can happen while you are using Calcitonin Salmon (synthetic origin) Nasal Spray, especially if you are over 65 years of age. Call your healthcare provider right way if you have any of these symptoms of nose irritation:

- crusting
- dryness
- redness or swelling
- nose sores (ulcers)
- nose bleeds

Your healthcare provider may stop your treatment with Calcitonin Salmon (synthetic origin) Nasal Spray until your nose irritation symptoms go away.

- **risk of cancer**

People who use calcitonin salmon, the medicine in Calcitonin Salmon (synthetic origin) Nasal Spray, may have an increased risk of cancer.

- **increase of certain cells (sediment) in your urine**

Your healthcare provider should test your urine often while you are using Calcitonin Salmon (synthetic origin) Nasal Spray.

**The most common side effects of Calcitonin Salmon (synthetic origin) Nasal Spray include:**

- back pain
- muscle aches
- headache
- runny nose

These are not all the possible side effects of Calcitonin Salmon (synthetic origin) Nasal Spray. For more information, ask your healthcare provider or pharmacist.

Tell your healthcare provider right away if you have any side effect that bothers you or does not go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**How do I store Calcitonin Salmon (synthetic origin) Nasal Spray?**

- Store open bottles of Calcitonin Salmon (synthetic origin) Nasal Spray at room temperature between 20°C to 25°C (68°F to 77°F) for 30 days (2 mL fill) or 35 days (3.7 mL fill).
- Store unopened bottles of Calcitonin Salmon (synthetic origin) Nasal Spray in the refrigerator between 2°C to 8°C (36°F to 46°F). Do not freeze.
- Store Calcitonin Salmon (synthetic origin) Nasal Spray bottles in an upright position.
- Safely throw away Calcitonin Salmon (synthetic origin) Nasal Spray in the trash after you have used 14 doses (2 mL fill) or 30 doses (3.7 mL fill) (sprays).

**Keep Calcitonin Salmon (synthetic origin) Nasal Spray and all other medicines out of the reach of children.**

**General information about the safe and effective use of Calcitonin Salmon (synthetic origin) Nasal Spray.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use Calcitonin Salmon (synthetic origin) Nasal Spray for a condition for which it was not prescribed. Do not give Calcitonin Salmon (synthetic origin) Nasal Spray to other people, even if they have the same symptoms you have. It may harm them.

This Patient Information summarizes the most important information about Calcitonin Salmon (synthetic origin) Nasal Spray. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about Calcitonin Salmon (synthetic origin) Nasal Spray that is written for health professionals.

For more information, call 1-800-706-5575.

### **What are the ingredients in Calcitonin Salmon (synthetic origin) Nasal Spray?**

**Active Ingredients:** calcitonin salmon

**Inactive Ingredients:** benzalkonium chloride, hydrochloric acid, purified water and sodium chloride.

#### **APOTEX INC.**

#### **CALCITONIN SALMON (SYNTHETIC ORIGIN) NASAL SPRAY**

Manufactured by  
Apotex Inc.  
Toronto, Ontario  
Canada M9L 1T9

Manufactured for  
Apotex Corp.  
Weston, FL  
33326

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