Medication Guide

ARCAPTA™ (ar-CAP-ta) NEOHALER™

(indacaterol inhalation powder)

Important: Do not swallow ARCAPTA capsules. ARCAPTA capsules are used only with the NEOHALER inhaler that comes with ARCAPTA NEOHALER. Never place a capsule in the mouthpiece of the NEOHALER inhaler.

Read the Medication Guide that comes with ARCAPTA NEOHALER before you start using it and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your health care provider about your medical condition or treatment.

What is the most important information I should know about ARCAPTA NEOHALER?

ARCAPTA NEOHALER has been approved for COPD only. Therefore, ARCAPTA NEOHALER is NOT to be used in asthma.

ARCAPTA NEOHALER can cause serious side effects, including:

- **People with asthma who take long-acting beta$_2$ adrenergic-agonist (LABA) medicines, such as ARCAPTA NEOHALER, have an increased risk of death from asthma problems.**
- **It is not known if LABA medicines, such as ARCAPTA NEOHALER, increase the risk of death in people with chronic obstructive pulmonary disease (COPD).**
- Get emergency medical care if:
  - breathing problems worsen quickly
  - you use your rescue inhaler medicine, but it does not relieve your breathing problems.

What is ARCAPTA NEOHALER?

ARCAPTA NEOHALER is used long term, 1 time each day, in controlling symptoms of chronic obstructive pulmonary disease (COPD) in adults with COPD.

LABA medicines such as ARCAPTA NEOHALER help the muscles around the airways in your lungs stay relaxed to prevent symptoms, such as wheezing, cough, chest tightness and shortness of breath.

ARCAPTA NEOHALER is not for use to treat sudden symptoms of COPD. Always have a short-acting beta$_2$-agonist medicine with you to treat sudden symptoms. If you do not have an inhaled, short-acting bronchodilator, contact your healthcare provider to have one prescribed for you.

It is not known if ARCAPTA NEOHALER is safe and effective in people with asthma.

ARCAPTA NEOHALER should not be used in children. It is not known if ARCAPTA NEOHALER is safe and effective in children.

Who should not use ARCAPTA NEOHALER?

Do not use ARCAPTA NEOHALER if you:

- **have asthma.**
- **have had an allergic reaction to indacaterol or any of the ingredients in ARCAPTA NEOHALER. Ask your healthcare provider if you are not sure. See the end of the Medication Guide for a list of ingredients in ARCAPTA NEOHALER.**

What should I tell my healthcare provider before using ARCAPTA NEOHALER?

Tell your healthcare provider about all of your health conditions, including if you:

- have heart problems
- have high blood pressure
- have seizures
- have thyroid problems
- have diabetes
- are pregnant or planning to become pregnant. It is not known if ARCAPTA NEOHALER can harm your unborn baby.

- are breastfeeding. It is not known if ARCAPTA NEOHALER passes into your milk and if it can harm your baby.
- are allergic to ARCAPTA NEOHALER or any of its ingredients, any other medicines, or food products.

ARCAPTA NEOHALER contains lactose (milk sugar) and a small amount of milk proteins. It is possible that allergic reactions may happen in patients who have a severe milk protein allergy.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. ARCAPTA NEOHALER and certain other medicines may interact with each other. This may cause serious side effects.

Know the medicines you take. Keep a list of your medicines with you to show your healthcare provider and pharmacist each time you get a new medicine.

How should I use ARCAPTA NEOHALER?

- **Read the step-by-step instructions for using ARCAPTA NEOHALER at the end of this Medication Guide.**
- **Use ARCAPTA NEOHALER 1 time each day at the same time of the day**.
- If you miss a dose of ARCAPTA NEOHALER, take it as soon as you remember. Do not take more than one dose in 24 hours.
- **Do not swallow ARCAPTA capsules**. ARCAPTA capsules should always be used with the NEOHALER inhaler only.
- Always use the new NEOHALER inhaler that is provided with each new prescription.
- **ARCAPTA NEOHALER does not relieve sudden symptoms of COPD**. Always have a rescue inhaler medicine with you to treat sudden symptoms. If you do not have a rescue inhaler medicine, call your healthcare provider to have one prescribed for you.
- Do not stop using ARCAPTA NEOHALER or other medicines to control or treat your COPD unless told to do so by your healthcare provider because your symptoms might get worse. Your healthcare provider will change your medicines as needed.
- **Do not use ARCAPTA NEOHALER**:
  - more often than prescribed
  - more medicine than prescribed for you, or
  - with other LABA medicines
- **Call your health care provider or get emergency medical care right away if:**
  - your breathing problems worsen with ARCAPTA NEOHALER
  - you need to use your rescue medicine more often than usual
  - your rescue inhaler medicine does not work as well for you at relieving your symptoms

What are the possible side effects with ARCAPTA NEOHALER?

ARCAPTA NEOHALER can cause serious side effects, including:

- **See "What is the most important information I should know about ARCAPTA NEOHALER?"**
- If your COPD symptoms worsen over time do not increase your dose of ARCAPTA NEOHALER, instead call your healthcare provider.
- serious allergic reactions including rash, hives, swelling of the tongue, lips and face, difficulties in breathing or swallowing. Call your healthcare provider or get emergency medical care if you get any symptoms of a serious allergic reaction.
- sudden shortness of breath that may be life-threatening
- fast or irregular heartbeat (palpitations)
- increased blood pressure

- chest pain
- low blood potassium (which may cause symptoms of muscle spasm, muscle weakness or abnormal heart rhythm)
- high blood sugar

Common side effects of ARCAPTA NEOHALER include:

- runny nose
- cough
- sore throat
- headache
- nausea

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

These are not all the side effects with ARCAPTA NEOHALER. Ask your healthcare provider or pharmacist for more information.

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

How should I store ARCAPTA NEOHALER?

- Store ARCAPTA NEOHALER (inhaler and blister-packaged capsules) in a dry place 59° F to 86° F (15°C to 30°C). Protect ARCAPTA NEOHALER (inhaler and blister-packaged capsules) from moisture.
- Do not remove ARCAPTA capsules from their foil package until just before use.
- Keep ARCAPTA capsules out of the light.
- Do not store ARCAPTA capsules in the NEOHALER inhaler.
- **Keep ARCAPTA NEOHALER and all medicines out of the reach of children.**

General Information about ARCAPTA NEOHALER

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ARCAPTA NEOHALER for a condition for which it was not prescribed. Do not give ARCAPTA NEOHALER to other people, even if they have the same condition. It may harm them.

This Medication Guide summarizes the most important information about ARCAPTA NEOHALER. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about ARCAPTA NEOHALER that was written for healthcare professionals.

For more information, go to www.arcapta.com or call 1-888-669-6682.

Active ingredient: indacaterol

Inactive ingredients: lactose monohydrate (contains trace levels of milk protein)

Revised September 2012

Instructions for Use

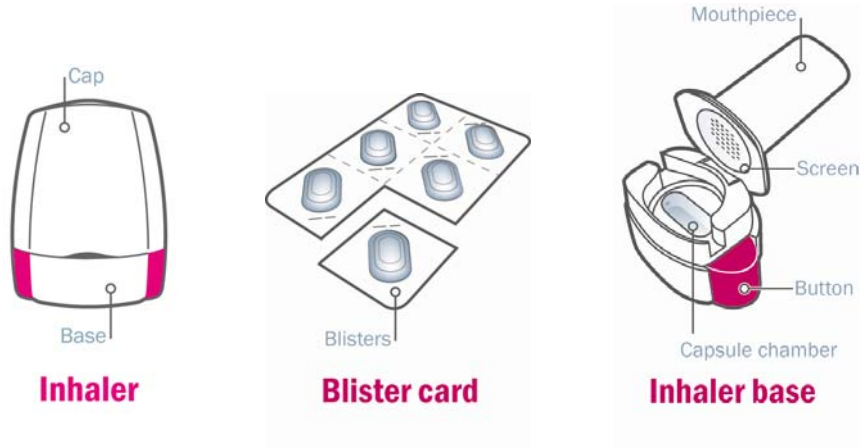
ARCAPTA™ (ar-CAP-ta) NEOHALER™

(indacaterol inhalation powder)

Do not swallow ARCAPTA capsules.

Follow the instructions below for using ARCAPTA NEOHALER. You will breathe-in (inhale) the medicine in the ARCAPTA capsules from the NEOHALER inhaler. If you have any questions, ask your healthcare provider or pharmacist.

ARCAPTA NEOHALER



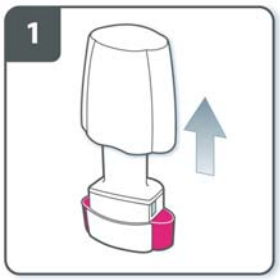
ARCAPTA NEOHALER consists of both the inhaler and the blister-packaged capsules. Each package contains ARCAPTA capsules and a NEOHALER inhaler.

- ARCAPTA capsules come in blister cards (see figure above).
- NEOHALER inhaler consists of a cap and a base (see figure above).

Your inhaler is made to give you the medicine contained in the capsules.
Do not use ARCAPTA capsules with any other capsule inhaler, and **do not** use NEOHALER inhaler to take any other capsule medicine.

How to use your inhaler

Figure A



Step 1. Pull off cap. See Figure A.

Figure B

Step 2. Open inhaler: See Figure B

Hold the base of the inhaler firmly and tilt the mouthpiece to open the inhaler.

Figure C

Step 3. Prepare capsule: See Figure C

Separate one of the blisters from the blister card by tearing along the perforation.

Take one blister and peel away the protective backing to expose the foil.

Figure D

Step 4. Remove an ARCAPTA capsule: See Figure D

Capsules should always be stored in the blister and only removed immediately before use.

With dry hands, remove one capsule from the blister by pushing the ARCAPTA capsule through the foil.

Do not swallow ARCAPTA capsule.

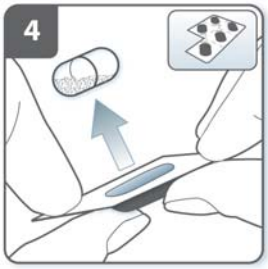


Figure E

Step 5. Insert capsule: See Figure E

Place the capsule into the capsule chamber.

Do not place a capsule directly into the mouthpiece.

Figure F

Step 6. Close the inhaler: See Figure F

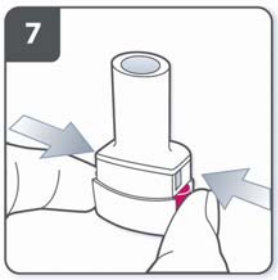
Close the inhaler fully. You should hear a '**click**' as it fully closes.

Figure G

Step 7. Pierce the capsule: See Figure G

Hold the inhaler upright.

Press both buttons fully one time. You should hear a **'click'** as the capsule is being pierced.



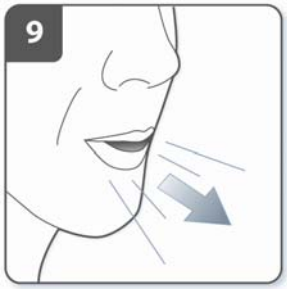
Do not press the piercing buttons more than one time.

Figure H

Step 8. Release the buttons fully. See Figure H

Figure I

Step 9. Breathe out: See Figure I



Before placing the mouthpiece in your mouth, breathe out fully.

Never blow into the mouthpiece.

Figure J

Step 10. Inhale the medicine: See Figure J

Before breathing in, place the mouthpiece in your mouth and close your lips around the mouthpiece. Hold the inhaler with the buttons to the left and right (not up and down).

Breathe in rapidly and steadily, as deeply as you can. **Do not press the piercing buttons.**

Figure K

Note: See Figure K

As you breathe in through the inhaler, the capsule spins around in the chamber and you should hear a whirring noise.

If you do not hear a whirring noise, the capsule may be stuck in the capsule cavity. If this occurs, open the inhaler and carefully loosen the capsule by tapping the base of the device. Do not press the piercing buttons to loosen the capsule. (**Repeat steps 9 and 10 if needed**).

Figure L

Step 11. Hold breath: See Figure L

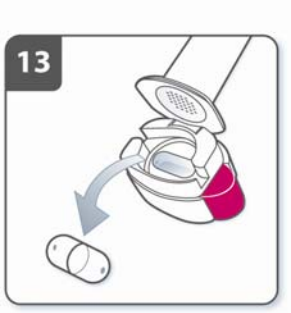
Continue to hold your breath as long as comfortably possible while removing the inhaler from your mouth. Then breathe out.

Open the inhaler to see if any powder is left in the capsule. **If there is**

powder left in the capsule, close the inhaler and repeat steps 9 to 12. Most people are able to empty the capsule in one or two inhalations.

Some people may cough soon after inhaling the medicine. If you do, don't worry, as long as the capsule is empty, you have received the full dose.

Figure M



Step 12. Remove capsule: See Figure M

After you have finished taking your daily dose of the ARCAPTA NEOHALER, open the mouthpiece again, remove the empty capsule by tipping it out, and discard it. Close the inhaler and replace the cap.

Do not store the capsules in the NEOHALER device.

Additional Information

Occasionally, very small pieces of the capsule can get past the screen and enter your mouth. If this happens, you may be able to feel these pieces on your tongue. It is not harmful if these pieces are swallowed or inhaled. **The chances of the capsule shattering will be increased if the capsule is pierced more than once (Step 7).** Therefore it is recommended that you follow the storage directions, remove the capsule from the blister immediately before use and pierce each capsule only once.

How to clean your inhaler

Cleaning the device is not necessary, however, if desired, a clean, dry lint-free cloth, or a clean, dry soft brush may be used to wipe the inhaler between uses.

Remember:

- ARCAPTA capsules should be stored in the blister, and only removed immediately before use.
- Do not breathe into the NEOHALER inhaler.
- Do not place the ARCAPTA capsule directly into the mouthpiece of the NEOHALER inhaler.
- Do not store the ARCAPTA capsule in the NEOHALER inhaler chamber.
- Always release the push buttons prior to inhalation
- Do not wash the NEOHALER inhaler. **Keep it dry.**
- Always keep the NEOHALER inhaler and ARCAPTA capsules in a dry place.
- Always use the new NEOHALER inhaler that comes with your refill.
- Do not use ARCAPTA capsules with inhalers from other medicines.
- Keep this and all drugs out of the reach of children.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured by:
Novartis Pharma Stein AG
Stein, Switzerland

Distributed by:
Novartis Pharmaceuticals Corporation
East Hanover, New Jersey 07936

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T2012-XX/T2012-XX
Revised September 2012/September 2012