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Indacaterol Oral Inhalation

pronounced as (in" da ka' ter ol)

Why is this medication prescribed?

Indacaterol inhalation is used to control wheezing, shortness of breath, coughing, and chest tightness caused by chronic obstructive pulmonary disease (COPD; a group of diseases that affect the lungs and airways, which includes chronic bronchitis and emphysema). Indacaterol is in a class of medications called long-acting beta agonists (LABAs). It works by relaxing and opening air passages in the lungs, making it easier to breathe.

How should this medicine be used?

Indacaterol inhalation comes as a powder-filled capsule to inhale by mouth using a special inhaler. It is usually inhaled once a day. Use indacaterol inhalation at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Use indacaterol inhalation exactly as directed. Do not use more or less of it or use it more often than prescribed by your doctor.

Do not swallow indacaterol capsules.

Do not use indacaterol inhalation to treat sudden attacks of COPD. Your doctor will prescribe a short-acting beta agonist medication such as albuterol (Accuneb, Proair, Proventil, Ventolin) to use during attacks. If you were using this type of medication on a regular basis before you began treatment with indacaterol, your doctor will probably tell you to stop using it regularly, but to continue to use it to treat attacks.

If your COPD symptoms become worse, if indacaterol inhalation becomes less effective, if you need more doses than usual of the medication you use to treat sudden attacks, or if the medication you use to treat attacks does not relieve your symptoms, your condition may be getting worse. Do not use extra doses of indacaterol. Call your doctor right away.

Indacaterol inhalation controls the symptoms of COPD but does not cure the condition. Continue to use indacaterol inhalation even if you feel well. Do not stop using indacaterol inhalation without talking to your doctor. If you suddenly stop using indacaterol, your symptoms may become worse.

Before you use the indacaterol inhaler for the first time, ask your doctor, pharmacist, or respiratory therapist to show you how to use it. Practice using the inhaler while he or she watches.

Indacaterol capsules should only be used with the inhaler that comes with your prescription. Do not use the inhaler to inhale any other type of capsules. Do not put indacaterol capsules into the mouthpiece of the inhaler. Do not blow into the mouthpiece.

The inhaler is made to pierce the capsule so that the powder can be released. However, it is possible that the capsule may break into small pieces inside the inhaler. If this happens, a screen in the inhaler should stop the pieces of capsule from reaching your mouth as you inhale the medication. Very tiny pieces of the capsule may reach your mouth or throat, but they are not harmful if swallowed or inhaled. The capsule is less likely to break if you are careful to store the capsules properly, to keep the capsules in the foil package until you are ready to use them, and to pierce each capsule only once.

Store the capsules in the package and remove them immediately before use. Dispose of any capsules that are removed from the packaging that are not used right away. Do not store the capsules inside the inhaler. Avoid exposing the capsules to moisture, and handle them with dry hands.

Keep the inhaler dry; do not wash it. Always use the new inhaler that comes with each refill of your medication.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before using indacaterol inhalation,

- tell your doctor and pharmacist if you are allergic to indacaterol inhalation, any other medications, any of the ingredients in indacaterol inhalation, or milk. Ask your pharmacist or check the Medication Guide for a list of the ingredients.
- tell your doctor if you use another LABA such as such as arformoterol (Brovana), formoterol (Perforomist, in Bevespi Aerosphere, Duaklir Pressair, Dulera, Symbicort), olodaterol (Striverdi Respimat, in Stiolto Respimat), salmeterol (Serevent, in Advair), or vilanterol (in Anoro Ellipta, Breo Ellipta, Trelegy Ellipta). Your doctor will tell you which medication you should use and which medication you should stop using.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: aminophylline; antidepressants such as amitriptyline, amoxapine, clomipramine (Anafranil), desipramine (Norpramin), doxepin (Silenor, Zonalon), imipramine (Tofranil), nortriptyline (Pamelor), protriptyline (Vivactil), and trimipramine (Surmontil); beta blockers such as atenolol (Tenormin, in Tenoretic), labetalol (Trandate), metoprolol (Kaspargo, Lopressor, Toprol XL, in Dutoprol), nadolol (Corgard, in Corzide), and propranolol (Hemangeol, Inderal, Innopran); chlorpromazine; citalopram (Celexa); clarithromycin (Biaxin); diet pills; diuretics ('water pills'); droperidol (Inapsine); epinephrine (Primatene Mist); erythromycin (E.E.S., Erythrocin); certain medications for irregular heartbeat such as amiodarone (Cordarone, Pacerone), disopyramide

(Norpace), dofetilide (Tikosyn), flecainide (Tambocor), procainamide, quinidine (in Nuedexta), and sotalol (Betapace); methadone (Dolophine, Methadose); medications for colds such as phenylephrine (Sudafed PE), and pseudoephedrine (Sudafed); monoamine oxidase (MAO) inhibitors including isocarboxazid (Marplan), linezolid (Zyvox), phenelzine (Nardil), rasagiline (Azilect), selegiline (Emsam, Zelapar), and tranylcypromine (Parnate); moxifloxacin (Avelox); steroids such as dexamethasone, methylprednisolone (Depo-Medrol, Medrol, Solu-Medrol), and prednisone (Rayos); pimozone (Orap); theophylline (Theochron, Theo-24); and thioridazine. Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Many other medications may also interact with indacaterol inhalation, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.

- tell your doctor if you have asthma. Your doctor will tell you not to use indacaterol inhalation unless you are using it along with an inhaled steroid medication.
- tell your doctor if you have or have ever had diabetes, seizures, high blood pressure, irregular heartbeat, QT prolongation (an irregular heart rhythm that can lead to fainting, loss of consciousness, seizures, or sudden death); or heart or thyroid disease.
- tell your doctor if you are pregnant, plan to become pregnant, or are breast-feeding. If you become pregnant while using indacaterol inhalation, call your doctor.
- you should know that indacaterol inhalation sometimes causes wheezing and difficulty breathing immediately after it is inhaled. If this happens, call your doctor right away. Do not use indacaterol inhalation again unless your doctor tells you that you should.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

Inhale the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not take more than one dose in 24 hours.

What side effects can this medication cause?

Indacaterol inhalation may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- cough
- sore throat
- runny nose
- headache
- nausea
- shaking of a part of the body that you cannot control
- nervousness
- difficulty falling asleep or staying asleep
- muscle cramps

- muscle or bone pain
- swelling of the arms or legs

Some side effects can be serious. If you experience any of these symptoms, call your doctor immediately or get emergency medical treatment:

- swelling of the face, mouth, or tongue, hives, rash, difficulty swallowing or breathing
- fast, pounding, or irregular heartbeat
- chest pain

Indacaterol inhalation may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the packaging it came in, tightly closed, and out of reach of children. Store it at room temperature and away from light, excess heat and moisture (not in the bathroom).

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include the following:

- chest pain
- fast, pounding, or irregular heartbeat
- nervousness

- shaking of a part of the body that you cannot control
- headache
- dry mouth
- nausea
- dizziness
- extreme tiredness
- difficulty falling asleep or staying asleep
- muscle cramps

What other information should I know?

Keep all appointments with your doctor.

Before having any laboratory test (especially those that involve methylene blue), tell your doctor and the laboratory personnel that you are using indacaterol.

Do not let anyone else use your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Arcapta[®]

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