What is the most important information I should know about AIRDUO RESPICLICK?

AIRDUO RESPICLICK can cause serious side effects, including:

- People with asthma who take long-acting beta2-adrenergic agonist (LABA) medicines, such as salmeterol (one of the medicines in AIRDUO RESPICLICK), have an increased risk of death from asthma problems. It is not known whether fluticasone propionate, the other medicine in AIRDUO RESPICLICK, reduces the risk of death from asthma problems seen with LABA medicines.
- Call your healthcare provider if breathing problems worsen over time while using AIRDUO RESPICLICK. You may need different treatment.
- Get emergency medical care if:
  - your breathing problems worsen quickly.
  - you use your rescue inhaler, but it does not relieve your breathing problems.
- AIRDUO RESPICLICK should be used only if your healthcare provider decides that your asthma is not well controlled with a long term asthma control medicine, such as an inhaled corticosteroid. When your asthma is well controlled, your healthcare provider may tell you to stop taking AIRDUO RESPICLICK. Your healthcare provider will decide if you can stop AIRDUO RESPICLICK without loss of asthma control. Your healthcare provider may prescribe a different asthma control medicine for you, such as an inhaled corticosteroid.
- Adolescents who take LABA medicines may have an increased risk of being hospitalized for asthma problems.

What is AIRDUO RESPICLICK?

- AIRDUO RESPICLICK combines the inhaled corticosteroid (ICS) medicine fluticasone propionate and the LABA medicine salmeterol.
- ICS medicines such as fluticasone propionate help to decrease inflammation in the lungs. Inflammation in the lungs can lead to breathing problems.
- LABA medicines such as salmeterol help the muscles around the airways in your lungs stay relaxed to prevent symptoms, such as wheezing, cough, chest tightness, and shortness of breath. These symptoms can happen when the muscles around the airways tighten. This makes it hard to breathe.
- AIRDUO RESPICLICK is a prescription medicine used to control symptoms of asthma and to prevent symptoms such as wheezing in people 12 years of age and older. AIRDUO RESPICLICK contains salmeterol. LABA medicines such as salmeterol increase the risk of death from asthma problems.

AIRDUO RESPICLICK is not for people 12 years of age and older with asthma who are well controlled with an asthma control medicine, such as a low or medium dose of an inhaled corticosteroid medicine.

AIRDUO RESPICLICK is not used to relieve sudden breathing problems.

It is not known if AIRDUO RESPICLICK is safe and effective in children younger than 12 years of age.

Do not use AIRDUO RESPICLICK:

- to treat sudden, severe symptoms of asthma.
- if you have a severe allergy to milk proteins. Ask your healthcare provider if you are not sure.
- if you are allergic to fluticasone propionate or any of the inactive ingredients in AIRDUO RESPICLICK. See the end of this leaflet for a complete list of ingredients in AIRDUO RESPICLICK.

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

- have heart problems.
- have high blood pressure.
- have seizures.
- have thyroid problems.
- have diabetes.
- have liver problems.
- have weak bones (osteoporosis).
- have an immune system problem.
- have eye problems, such as glaucoma or cataracts.
- are allergic to milk proteins.
- have any type of viral, bacterial, fungal, or parasitic infection.
- are exposed to chickenpox or measles.
- are pregnant or plan to become pregnant. It is not known if AIRDUO RESPICLICK may harm your unborn baby.
- are breastfeeding. It is not known if the medicines in AIRDUO RESPICLICK pass into your breast milk and if they can harm your baby.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines,
How should I use AIRDUO RESPICLICK?
- Read the step-by-step instructions for using AIRDUO RESPICLICK at the end of this Medication Guide.
- AIRDUO RESPICLICK comes in 3 different strengths. Your healthcare provider prescribed the strength that is best for you.
- Use AIRDUO RESPICLICK exactly as your healthcare provider tells you to use it. Do not use AIRDUO RESPICLICK more often than prescribed.
- Use 1 inhalation of AIRDUO RESPICLICK 2 times each day. Use AIRDUO RESPICLICK at the same time each day, about 12 hours apart. If you miss a dose of AIRDUO RESPICLICK, just skip that dose. Take your next dose at your usual time. Do not take 2 doses at one time.
- If you take too much AIRDUO RESPICLICK, call your healthcare provider or get to the nearest hospital emergency room right away if you have any unusual symptoms, such as worsening shortness of breath, chest pain, increased heart rate, or shakiness.
- Do not use other medicines that contain a LABA for any reason. Examples of other medicines that contain a LABA include salmeterol, formoterol fumarate, arformoterol tartrate, and indacaterol. Ask your healthcare provider or pharmacist if any of your other medicines are LABA medicines.
- Do not stop using AIRDUO RESPICLICK unless told to do so by your healthcare provider because your symptoms might get worse. Your healthcare provider will change your medicines as needed.
- AIRDUO RESPICLICK does not relieve sudden asthma symptoms. You should not take extra doses of AIRDUO RESPICLICK to relieve sudden asthma symptoms. If you do not have a rescue inhaler, call your healthcare provider to have one prescribed for you.
- Call your healthcare provider or get medical care right away if:
  - your breathing problems get worse.
  - you need to use your rescue inhaler more often than usual.
  - your rescue inhaler does not work as well to relieve your symptoms.
  - your peak flow meter results decrease. Your healthcare provider will tell you the numbers that are right for you.
  - you have asthma and your symptoms do not improve after using AIRDUO RESPICLICK regularly for one week.

What are the possible side effects with AIRDUO RESPICLICK?
AIRDUO RESPICLICK can cause serious side effects, including:
- See “What is the most important information I should know about AIRDUO RESPICLICK?”
- fungal infection in your mouth and throat (thrush). Rinse your mouth with water without swallowing after using AIRDUO RESPICLICK to help reduce your chance of getting thrush.
- weakened immune system and increased chance of getting infections (immunosuppression).
- reduced adrenal function (adrenal insufficiency). Adrenal insufficiency is a condition where the adrenal glands do not make enough steroid hormones. This can happen when you stop taking oral corticosteroid medicines (such as prednisone) and start taking a medicine containing an inhaled steroid (such as AIRDUO RESPICLICK). When your body is under stress such as from fever, trauma (such as a car accident), infection, or surgery, adrenal insufficiency can get worse and may cause death. Symptoms of adrenal insufficiency include:
  - feeling tired
  - lack of energy
  - weakness
  - nausea and vomiting
  - low blood pressure
- sudden breathing problems immediately after inhaling your medicine. If you have sudden breathing problems immediately after inhaling your medicine, stop using AIRDUO RESPICLICK and call your healthcare provider right away.
- serious allergic reactions. Stop using AIRDUO RESPICLICK and call your healthcare provider or get emergency medical help if you get any of the following symptoms of a serious allergic reaction:
  - rash
  - hives
  - swelling of your face, mouth, and tongue
  - breathing problems
  - chest pain
- effects on heart.
  - increased blood pressure
  - a fast or irregular heartbeat
- effects on nervous system.
  - tremor
  - nervousness
- bone thinning or weakness (osteoporosis).
- slowed growth in children. The growth of a child should be checked often.
- eye problems including glaucoma and cataracts. You should have regular eye exams while using AIRDUO RESPICLICK.
- changes in laboratory blood values (sugar, potassium, certain types of white blood cells).

Common side effects of AIRDUO RESPICLICK include:
- infection of nose and throat (nasopharyngitis)  
  - back pain
- thrush in your mouth or throat. Rinse your mouth with water without swallowing after use to help prevent this.  
  - headache
  - cough

These are not all the possible side effects of AIRDUO RESPICLICK. Call your healthcare provider for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store AIRDUO RESPICLICK?
- Store AIRDUO RESPICLICK at room temperature between 59°F and 77°F (15°C and 25°C).
Avoid exposure to extreme heat, cold, or humidity.
Store AIRDUO RESPICLICK in the unopened foil pouch and only open when ready for use.
Keep the yellow cap on the inhaler closed during storage.
Keep your AIRDUO RESPICLICK inhaler dry and clean at all times.
Throw away AIRDUO RESPICLICK 30 days after opening the foil pouch, when the dose counter displays ‘0’, or after the expiration date on the product, whichever comes first.

Keep AIRDUO RESPICLICK and all medicines out of the reach of children.

General information about the safe and effective use of AIRDUO RESPICLICK.
Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use AIRDUO RESPICLICK for a condition for which it was not prescribed. Do not give AIRDUO RESPICLICK to other people, even if they have the same symptoms that you have. It may harm them.
You can ask your healthcare provider or pharmacist for information about AIRDUO RESPICLICK that is written for health professionals.

What are the ingredients in AIRDUO RESPICLICK?
Active ingredients: fluticasone propionate, salmeterol xinafoate
Inactive ingredient: lactose monohydrate (may contain milk proteins)

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

Marketed by: Teva Respiratory, LLC, Frazer, PA 19355; Manufactured by: Teva Pharmaceutical Industries Ltd., Jerusalem, Israel; Copyright ©2017, Teva Respiratory, LLC; All rights reserved; AIRDUO™ and RESPICLICK® are trademarks owned by Teva Respiratory, LLC.

For more information about AIRDUO RESPICLICK, call 1-888-482-9522 or visit our website at www.AIRDUORESPICLICK.com.

AIRDMG-001
Rev. 01/2017