For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only OR for Specialist Use only

Levosalbutamol Inhaler 50 mcg

Levolin Inhaler (CFC FREE)

Composition

Each actuation delivers
Levosalbutamol Tartrate equivalent to
Levosalbutamol ..... 50 mcg
Suspended in Propellant HFA 134a .... q.s.
Absolute Alcohol Content ..... 7.4 % v/v

Dosage Form

Metered Dose Inhaler

Pharmacology

Pharmacodynamics

Activation of beta2-adrenergic receptors on airway smooth muscle leads to the activation of adenylate cyclase and to an increase in the intracellular concentration of cyclic-3', 5'-adenosine monophosphate (cyclic AMP). The increase in cyclic AMP is associated with the activation of protein kinase A, which in turn, inhibits the phosphorylation of myosin and lowers intracellular ionic calcium concentrations, resulting in muscle relaxation. Levalbuterol relaxes the smooth muscles of all airways, from the trachea to the terminal bronchioles. Increased cyclic AMP concentrations are also associated with the inhibition of the release of mediators from mast cells in the airways. Levalbuterol acts as a functional antagonist to relax the airway irrespective of the spasmogen involved, thus protecting against all bronchoconstrictor challenges. While it is recognized that beta2-adrenergic receptors are the predominant receptors on bronchial smooth muscle, data indicate that there are beta-receptors in the human heart, 10% to 50% of which are beta2-adrenergic receptors. The precise function of these receptors has not been established [see *Warnings and Precautions].* However, all beta-adrenergic agonist drugs can produce a significant cardiovascular effect in some patients, as measured by pulse rate, blood pressure, symptoms, and/or electrocardiographic changes.

Pharmacokinetics

A population pharmacokinetic model was developed using plasma concentrations of (R)albuterol obtained from 632 asthmatic patients aged 4 to 81 years in three large trials. For adolescent and adult patients 12 years and older, following 90 mcg dose of levosalbutamol inhaler, yielded mean peak plasma concentrations (C_{max}) and systemic exposure ($AUC_{0\text{-}6}$) of approximately 199 pg/mL and 695 pg•h/mL, respectively, compared to approximately 238 pg/mL and 798 pg•h/mL, respectively, following 180 mcg dose of Racemic Albuterol HFA metered-dose inhaler. For pediatric patients from 4 to 11 years of age, following 90 mcg dose of levosalbutamol inhaler, yielded C_{max} and $AUC_{0\text{-}6}$ of approximately 163 pg/mL and 579 pg•h/mL, respectively, compared to approximately 238 pg/mL and 828 pg•h/mL, respectively, following 180 mcg dose of Racemic Albuterol HFA metered-dose inhaler.
These pharmacokinetic data indicate that mean exposure to (R)-albuterol was 13% to 16% less in adult and 30% to 32% less in pediatric patients given levosalbutamol inhaler as compared to those given a comparable dose of racemic albuterol. When compared to adult patients, pediatric patients given 90 mcg of levalbuterol have a 17% lower mean exposure to (R)-albuterol.

Metabolism and Elimination

Information available in the published literature suggests that the primary enzyme responsible for the metabolism of albuterol enantiomers in humans is SULT1A3 (sulfotransferase). When racemic albuterol was administered either intravenously or via inhalation after oral charcoal administration, there was a 3-to 4-fold difference in the area under the concentration-time curves between the (R)-and (S)-albuterol enantiomers, with (S)-albuterol concentrations being consistently higher, However, without charcoal pretreatment, after either oral or inhalation administration the differences were 8-to 24-fold, suggesting that (R)-albuterol is preferentially metabolized in the gastrointestinal tract, presumably by SULT1A3.
The primary route of elimination of albuterol enantiomers is through renal excretion (80% to 100%) of either the parent compound or the primary metabolite. Less than 20% of the drug is detected in the feces. Following intravenous administration of racemic albuterol, between 25% and 46% of the (R)-albuterol fraction of the dose was excreted as unchanged (R)-albuterol in the urine.

Special Populations

Hepatic Impairment

The effect of hepatic impairment on the pharmacokinetics of levosalbutamol inhaler has not been evaluated.

Renal Impairment

The effect of renal impairment on the pharmacokinetics of racemic albuterol was evaluated in 5 subjects with creatinine clearance of 7 to 53 mL/min, and the results were compared with those from healthy volunteers. Renal disease had no effect on the half-life, but there was a 67% decline in racemic albuterol clearance. Caution should be used when administering high doses of levosalbutamol inhaler to patients with renal impairment [see *Warnings and Precautions -Use in Specific Populations*].

Indications

Bronchospasm

Levolin Inhaler (CFC FREE) is indicated for the treatment or prevention of bronchospasm in adults, adolescents, and children 4 years of age and older with reversible obstructive airway disease.

Dosage and Method of Administration

Recommended Dosages:

The recommended dosage of Levolin Inhaler (CFC FREE) for adults and children 4 years of age and older is 2 inhalations (90 mcg of levalbuterol free base) repeated every 4 to 6 hours; in some patients, 1 inhalation (45 mg of levalbuterol free base) every 4 hours may be sufficient. More frequent administration or a larger number of inhalations is not routinely recommended.
If a previously effective dosage regimen fails to provide the usual response, this may be a marker of destabilization of asthma and requires reevaluation of the patient and the treatment regimen, giving special consideration to the possible need for anti-inflammatory treatment, e.g., corticosteroids.

Administration

For oral inhalation only

- Shake well before use.
- Avoid spraying in the eyes.
- Prime the inhaler before using for the first time and when the inhaler has not been used for more than 3 days by releasing 4 test sprays into the air, away from the face.
- To maintain proper use of Levolin inhaler, it is critical to wash the actuator with warm water and air-dry thoroughly at least once a week. The inhaler may cease to deliver levalbuterol tartrate if not properly cleaned and dried thoroughly. Keep the plastic actuator clean to prevent medication build-up and blockage. If the actuator becomes blocked with levalbuterol tatrate, wash the actuator to remove the blockage.

Contraindications

Levolin Inhaler (CFC FREE) is contraindicated in patients with a history of hypersensitivity to levalbuterol, racemic albuterol, or any other component of levosalbutamol inhaler. Reactions have included urticaria, angioedema, rash, bronchospasm, anaphylaxis, and oropharyngeal edema.

Warnings and Precautions

Paradoxical Bronchospasm

Levosalbutamol inhaler can produce paradoxical bronchospasm, which may be life-threatening. If paradoxical bronchospasm occurs, Levosalbutamol inhaler should be discontinued immediately and alternative therapy instituted. It should be recognized that paradoxical bronchospasm, when associated with inhaled formulations, frequently occurs with the first use of a new canister.

Deterioration of Asthma

Asthma may deteriorate acutely over a period of hours or chronically over several days or longer. If the patient needs more doses of levosalbutamol inhaler than usual, this may be a marker of destabilization of asthma and requires reevaluation of the patient and treatment regimen, giving special consideration to the possible need for anti-inflammatory treatment, e.g., corticosteroids.

Use of Anti-Inflammatory Agents

The use of a beta-adrenergic agonist alone may not be adequate to control asthma in many patients. Early consideration should be given to adding anti-inflammatory agents, e.g., corticosteroids, to the therapeutic regimen.

Cardiovascular Effects

Levosalbutamol inhaler, like other beta-adrenergic agonists, can produce clinically significant cardiovascular effects in some patients, as measured by heart rate, blood pressure, and symptoms. Although such effects are uncommon after administration of levosalbutamol inhaler at recommended doses, if they occur, the drug may need to be discontinued. In addition, betaagonists have been reported to produce electrocardiogram (ECG) changes, such as flattening of the T-wave, prolongation of the QTc interval, and ST segment depression. The clinical significance of these findings is unknown. Therefore, levosalbutamol inhaler, like all sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

Do Not Exceed Recommended Dose

Fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs in patients with asthma. The exact cause of death is unknown, but cardiac arrest following an unexpected development of a severe acute asthmatic crisis and subsequent hypoxia is suspected.

Immediate Hypersensitivity Reactions

Immediate hypersensitivity reactions may occur after administration of racemic albuterol, as demonstrated by rare cases of urticaria, angioedema, rash, bronchospasm, anaphylaxis, and oropharyngeal edema. The potential for hypersensitivity must be considered in the clinical evaluation of patients who experience immediate hypersensitivity reactions while receiving levosalbutamol inhaler.

Coexisting Conditions

Levosalbutamol inhaler, like all sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, hypertension, and cardiac arrhythmias; in patients with convulsive disorders, hyperthyroidism, or diabetes mellitus; and in patients who are unusually responsive to sympathomimetic amines. Clinically significant changes in systolic and diastolic blood pressure have been seen in individual patients and could be expected to occur in some patients after the use of any beta-adrenergic bronchodilator.
Large doses of intravenous racemic albuterol have been reported to aggravate preexisting diabetes mellitus and ketoacidosis.

Hypokalemia

As with other beta-adrenergic agonist medications, levosalbutamol inhaler may produce significant hypokalemia in some patients, possibly through intracellular shunting, which has the potential to produce adverse cardiovascular effects. The decrease is usually transient, not requiring supplementation.

Use in special population

Pediatric Use

Pediatric Patients 4 Years of Age and Older

The safety and efficacy of levosalbutamol inhaler have been established in pediatric patients 4 years of age and older in an adequate and well-controlled clinical trial.

Pediatric Patients less than 4 Years of Age

Levosalbutamol inhaler is not indicated for pediatric patients less than 4 years of age. A clinical trial in pediatric patients below the age of 4 years showed no statistical significant difference between treatment groups in the primary efficacy endpoint. There was an increased incidence of asthma-related adverse reactions reported in pediatric patients below the age of 4 years treated with levosalbutamol inhaler compared to placebo.
Levosalbutamol inhaler was evaluated in one 4-week, multicenter, randomized, modified-blind, placebo-controlled, parallel group trial of 196 pediatric patients ages birth to <4 years of age with asthma or reactive airway disease (68 patients birth to <2 years of age and 128 patients 2 to <4 years of age). Levosalbutamol inhaler 45 mcg (N=23), Levosalbutamol inhaler 90 mcg (N=42), levalbuterol inhalation solution 0.31 mg (N=63), and placebo HFA (N=68) were administered three times daily. Levosalbutamol inhaler or placebo HFA was delivered with the holding chamber with mask. The primary efficacy endpoint was the mean change in Pediatric Asthma Caregiver Assessment (PACA) total score from baseline over the 4 week treatment period. There was no statistical difference in the change in PACA total score between levosalbutamol HFA and placebo. Regarding safety, an increased number of treatment-emergent asthma-related adverse reactions were reported in levosalbutamol HFA-treated patients. Eight subjects reported asthma-related adverse reactions for levosalbutamol HFA compared to 3 subjects for placebo. There was one subject that discontinued treatment due to asthma in the levosalbutamol HFA group compared to zero subjects in the placebo group (Table 1). Other adverse reactions were consistent with those observed in the clinical trial population of patients 4 years of age and older *[see Undesirable Effects].*

Table 1: Asthma-related Adverse Reactions in a 4-Week Clinical Trial in Children Birth to <4 Years of Age*

	Levosalbutamol HFA 45-90 mcg (n=65)	Levalbuterol inhalation solution 0.31 mg (n=63)	Placebo (n=68)
Asthma-related adverse reactions*, n (%)	8 (12%)	6 (10%)	3 (4%)
Treatment discontinuations due to asthma, n (%)	1 (2%)	2 (3%)	0

*This table includes the following Preferred Terms (whether considered by the investigator to be related or unrelated to drug): asthma, cough, hypoxia, status asthmaticus, tachypnea

Geriatric Use

Clinical studies of levosalbutamol inhaler did not include sufficient numbers of subjects aged 65 and older to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant diseases or other drug therapy.

Renal Impairment

Albuterol is known to be substantially excreted by the kidney, and the risk of toxic reactions may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

Drug Interactions

Other short-acting sympathomimetic aerosol bronchodilators or epinephrine should not be used concomitantly with levosalbutamol inhaler. If additional adrenergic drugs are to be administered by any route, they should be used with caution to avoid deleterious cardiovascular effects.

Beta-blockers

Beta-blockers: Beta-adrenergic receptor blocking agents not only block the pulmonary effect of beta-adrenergic agonists, such as levosalbutamol inhaler, but may produce severe bronchospasm in asthmatic patients. Therefore, patients with asthma should not normally be treated with beta-blockers. However, under certain circumstances, e.g., as prophylaxis after myocardial infarction, there may be no acceptable alternatives to the use of beta-adrenergic blocking agents in patients with asthma. In this setting, cardioselective beta-blockers should be considered, although they should be administered with caution.

Diuretics

The ECG changes or hypokalemia that may result from the administration of non-potassium-sparing diuretics (such as loop and thiazide diuretics) can be acutely worsened by beta-agonists, especially when the recommended dose of the beta-agonist is exceeded. Although the clinical significance of these effects is not known, caution is advised in the coadministration of beta-agonists with non-potassium-sparing diuretics. Consider monitoring potassium levels.

Digoxin

Mean decreases of 16% to 22% in serum digoxin levels were demonstrated after single-dose intravenous and oral administration of racemic albuterol, respectively, to normal volunteers who had received digoxin for 10 days. The clinical significance of these findings for patients with obstructive airway disease who are receiving levosalbutamol inhaler and digoxin on a chronic basis is unclear. Nevertheless, it would be prudent to carefully evaluate the serum digoxin levels in patients who are currently receiving digoxin and levosalbutamol inhaler.

Monoamine Oxidase Inhibitors or Tricyclic Antidepressants

Levosalbutamol inhaler should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors or tricyclic antidepressants, or within 2 weeks of discontinuation of such agents, because the action of albuterol on the vascular system may be potentiated. Consider alternative therapy in patients taking MAO inhibitors or tricyclic antidepressants.

Pregnancy and Lactation

Teratogenic Effects: Pregnancy Category C

There are no adequate and well-controlled studies of levosalbutamol inhaler in pregnant women. Because animal reproduction studies are not always predictive of human response, Levosalbutamol inhaler should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
Rare instances of congenital anomalies, including cleft palate and limb defects, were reported in newborns of women treated with racemic albuterol in which the levalbuterol isomer is present. However, since multiple medications were taken during their pregnancies and there was no consistent pattern of anomalies, it was not possible to establish a relationship between racemic albuterol use and the occurrence of these congenital anomalies.
In animal studies, oral administration of levalbuterol HCl to pregnant New Zealand White rabbits found no evidence of teratogenicity at doses up to 25mg/kg/day (approximately 750 times the maximum recommended daily inhalation dose of levalbuterol tartrate for adults on a mg/m^2 basis).
However, other studies demonstrated that racemic albuterol sulfate was teratogenic in mice and rabbits at doses slightly higher than the human therapeutic range. Pregnant mice administered racemic albuterol sulfate subcutaneously resulted in a dose-related increased incidence of cleft palate in their fetuses (4.5% of fetuses at 0.25 mg/kg/day or greater, corresponding to approximately 2 times MRDI dose, 9.3% of fetuses at 2.5 mg/kg/day, approximately 20 times MRDI dose of levalbuterol tartrate for adults on a mg/m^2 basis). The drug did not induce cleft palate formation when administered subcutaneously at a dose of 0.025 mg/kg/day (approximately 0.2 times MRDI dose of levalbuterol tartrate for adults on a mg/m^2 basis). In addition, oral administration of racemic albuterol sulfate to pregnant rabbits resulted in an increased incidence of cranioschisis in fetuses (approximately 1500 times the MRDI dose of levalbuterol tartrate for adults on a mg/m^2 basis).

Non-Teratogenic Effects:

A study in which pregnant rats were dosed with radiolabeled racemic albuterol sulfate demonstrated that drug-related material is transferred from the maternal circulation to the fetus.

Labor and Delivery

Because of the potential for beta-adrenergic agonists to interfere with uterine contractility, the use of levosalbutamol inhaler for the treatment of bronchospasm during labor should be restricted to those patients in whom the benefits clearly outweigh the risk.
Levosalbutamol inhaler has not been approved for the management of preterm labor. The benefit:risk ratio when levalbuterol tartrate is administered for tocolysis has not been established. Serious adverse reactions, including maternal pulmonary edema, have been reported during or following treatment of premature labor with beta2-agonists, including racemic albuterol.

Nursing Mothers

Plasma concentrations of levalbuterol after inhalation of therapeutic doses are very low in humans. It is not known whether levalbuterol is excreted in human milk.
Because of the potential for tumorigenicity shown for racemic albuterol in animal studies and the lack of experience with the use of levosalbutamol inhaler by nursing mothers, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. Caution should be exercised when Levosalbutamol inhaler is administered to a nursing woman.

Undesirable Effects

Use of levosalbutamol inhaler may be associated with the following:

- Paradoxical bronchospasm (see *Warnings and Precautions*)
- Cardiovascular effects (see *Warnings and Precautions*)
- Immediate hypersensitivity reactions (see *Warnings and Precautions)*
- Hypokalemia (see *Warnings and Precautions)*

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared with rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Adults and Adolescents 12 Years of Age and Older

Adverse reaction information concerning levosalbutamol inhaler in adults and adolescents is derived from two 8-week, multicenter, randomized, double-blind, active-and placebo-controlled trials in 748 adult and adolescent patients with asthma that compared levosalbutamol inhaler, a marketed albuterol HFA inhaler, and an HFA-134a placebo inhaler. Table 2 lists the incidence of all adverse reactions (whether considered by the investigator to be related or unrelated to drug) from these trials that occurred at a rate of 2% or greater in the group treated with levosalbutamol inhaler and more frequently than in the HFA-134a placebo inhaler group.

Table 2: Adverse Reaction Incidence (% of Patients) in Two 8-Week Clinical Trials in Adults and Adolescents ≥ 12 Years of Age*

Body System	Preferred Term	Levosalbutamol tartrate inhaler 90 mcg (n=403)	Racemic Albuterol HFA 180 mcg (n=179)	Placebo (n=166)
Body as a Whole	Pain	4%	3%	4%
Central Nervous System	Dizziness	3%	1%	2%
Respiratory System	Asthma	9%	7%	6%
	Pharyngitis	8%	2%	2%
	Rhinitis	7%	2%	3%

* This table includes all adverse reactions (whether considered by the investigator to be related or unrelated to drug) from these trials that occurred at a rate of 2% or greater in the group treated with levosalbutamol inhaler and more frequently than in the HFA-134a placebo inhaler group.

Adverse reactions reported by less than 2% and at least 2 or more of the adolescent and adult patients receiving levosalbutamol inhaler and by a greater proportion than receiving HFA-134a placebo inhaler include cyst, flu syndrome, viral infection, constipation, gastroenteritis, myalgia, hypertension, epistaxis, lung disorder, acne, herpes simplex, conjunctivitis, ear pain, dysmenorrhea, hematuria, and vaginal moniliasis. There were no significant laboratory abnormalities observed in these studies.

Pediatric Patients 4 to 11 Years of Age

Adverse reaction information concerning levosalbutamol inhaler in children is derived from a 4-week, randomized, double-blind trial of levosalbutamol inhaler, a marketed albuterol HFA inhaler, and an HFA-134a placebo inhaler in 150 children aged 4 to 11 years with asthma. Table 3 lists the adverse reactions reported for levosalbutamol inhaler in children at a rate of 2% or greater and more frequently than for placebo.

Table 3: Adverse Reaction Incidence (% of Patients) in a 4-Week Clinical Trial in Children 4-11 Years of Age*

Body System	Preferred Term	Levosalbutamol inhaler 90 mcg (n=76)	Racemic Albuterol HFA 180 mcg (n=39)	Placebo (n=35)
Body as a Whole	Accidental injury	9%	10%	6%
Digestive System	Vomiting	11%	8%	6%
Respiratory System	Bronchitis	3%	0%	0%
	Pharyngitis	7%	13%	6%

* This table includes all adverse reactions (whether considered by the investigator to be related or unrelated to drug) from the trial that occurred at a rate of 2% or greater in the group treated with levosalbutamol HFA and more frequently than in the HFA-134a placebo inhaler group.

The incidence of systemic beta-adrenergic adverse reactions (e.g., tremor, nervousness) was low and comparable across all treatment groups, including placebo.

Post-marketing Experience

In addition to the adverse reactions reported in clinical trials, the following adverse reactions have been observed in post-approval use of levalbuterol inhalation solution. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. These events have been chosen for inclusion due to their seriousness, their frequency of reporting, or their likely beta-mediated mechanism: angioedema, anaphylaxis, arrhythmias (including atrial fibrillation, supraventricular tachycardia, extrasystoles), asthma, chest pain, cough increased, dysphonia, dyspnea, gastrooesophageal reflux disease (GERD), metabolic acidosis, nausea, nervousness, rash, tachycardia, tremor, urticaria.
In addition, levosalbutamol inhaler, like other sympathomimetic agents, can cause adverse reactions such as hypertension, angina, vertigo, central nervous system stimulation, sleeplessness, headache, and drying or irritation of the oropharynx.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product

Overdose

The expected symptoms with overdosage are those of excessive beta-adrenergic receptor stimulation and/or occurrence or exaggeration of any of the symptoms listed under *Undesirable Effects,* e.g., seizures, angina, hypertension or hypotension, tachycardia with rates up to 200 beats/minute, arrhythmias, nervousness, headache, tremor, dry mouth, palpitation, nausea, dizziness, fatigue, malaise, and sleeplessness. Hypokalemia also may occur. As with all sympathomimetic medications, cardiac arrest and even death may be associated with the abuse of levosalbutamol inhaler. Treatment consists of discontinuation of levosalbutamol inhaler together with appropriate symptomatic therapy. The judicious use of a cardioselective beta-receptor blocker may be considered, bearing in mind that such medication can produce bronchospasm. There is insufficient evidence to determine if dialysis is beneficial for overdosage of levosalbutamol inhaler.

Incompatibility

NA

Shelf-Life

24 Months

Storage

Store below 30°C. Do not freeze.

Packaging Information

Levolin Inhaler (CFC FREE) is available in canister containing 200 metered dose.

Last Updated: *May 2015*

Cipla

21048082

Cipla

Levosalbutamol Inhaler
50 mcg

Levolin
inhaler
with
dose indicator

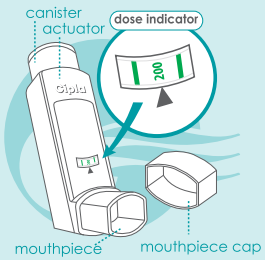
patient information leaflet

please read this leaflet completely before use

CFC-FREE

ABOUT YOUR LEVOLIN INHALER

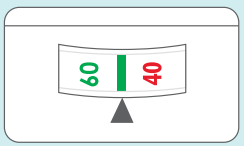
PARTS OF THE INHALER



Your **LEVOLIN** inhaler now comes with a dose indicator. It shows the number of puffs in the inhaler. As you use the inhaler, the dose indicator will countdown and indicate the number of puffs remaining.

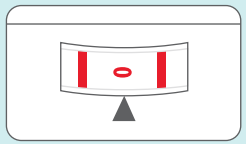
HOW TO KNOW THAT YOUR LEVOLIN INHALER IS GETTING OVER

When there are 40 puffs remaining, the colour of the numbers will change from green to red.



This indicates that fewer doses are remaining in the inhaler. You should now consider getting a new inhaler or ask your doctor if you need another one.

When the dose indicator displays '0', this means that there is no more medicine left in the inhaler & you need to discard the inhaler. Your inhaler may not feel empty & it may continue to operate, but you will not get the right amount of medicine, if you keep using it beyond '0'.



BEFORE USING YOUR LEVOLIN INHALER

1 Remove the cap from the mouthpiece & make sure that the mouthpiece is clean.

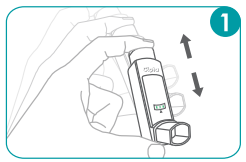
2 Hold the inhaler away from your face. Shake it well & release two puffs into the air.

3 Your **LEVOLIN** inhaler is now ready for use.

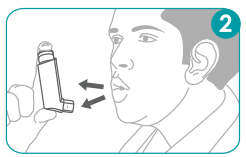
IF you have not used your inhaler for a week or more, shake well and release one puff into the air.

USING YOUR LEVOLIN INHALER

1 Sit or stand upright. Remove the mouthpiece cap & shake the inhaler well. Hold it upright as shown, with your thumb at the base below the mouthpiece. Place either one or two fingers on top of the canister.



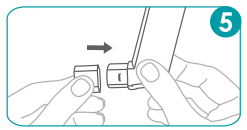
2 Breathe out fully, through your mouth.



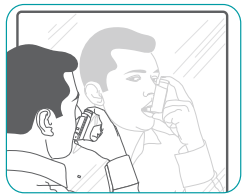
3 Place the mouthpiece of the inhaler in your mouth between your teeth & close your lips around it (do not bite it). **Start breathing in slowly through your mouth. Press down the canister firmly & fully to release one spray while continuing to breathe in slowly & deeply.**

4 Remove the inhaler from your mouth & hold your breath for 10 seconds, or for as long as is comfortable. Breathe out normally.

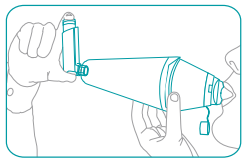
5 If another puff is required, wait for at least 1 minute. Shake inhaler well & repeat steps 2 to 4. After use, replace the mouthpiece cap firmly & snap it into position.



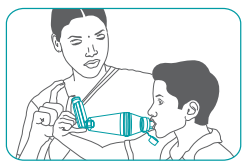
IMPORTANT:
Do not rush steps 2, 3 & 4. It is important that you start to breathe in slowly before releasing a puff.
To ensure correct use of the inhaler, use it in front of a mirror for the first few times. If you see 'mist' coming out from the top of the inhaler or the sides of your mouth, start again from step 1. This escaping mist indicates incorrect technique.



In case of difficulty in using the inhaler correctly, you may use it along with a spacer device.



FOR CHILDREN:
Parents must assist those children who need help in using the **LEVOLIN** inhaler correctly with/without a spacer.

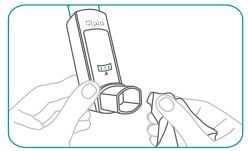


CLEANING YOUR LEVOLIN INHALER

It is important to keep your inhaler clean. Clean your inhaler atleast once a week.

1 Take the mouthpiece cap off. **DO NOT take the metal canister out of the actuator.**

2 Wipe the inside & the outside of the mouthpiece with a clean, dry cloth.



3 Replace the mouthpiece cap.

4 DO NOT wash or soak any part of the inhaler in water.

STORING YOUR LEVOLIN INHALER

Store below 30°C.
Do not freeze.

Keep the inhaler in an upright position, with the mouthpiece down.

DO NOT

- × *Spray the inhaler in your eyes.*
- × *Exceed the recommend ed dose.*
- × *Change/tamper with the numbers on the dose indicator.*
- × *Puncture or burn the inhaler even when empty as it is pressurized.*

Keep the inhaler out of the reach of children.

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