# Symbicort Turbuhaler 320/9 μg/dose

*budesonide/formoterol*

**Inhalation powder**

## Composition

Each delivered dose (the dose that leaves the mouthpiece) contains: budesonide 320 micrograms/inhalation and formoterol fumarate dihydrate 9 micrograms/inhalation.

Symbicort Turbuhaler 320/9 micrograms/inhalation delivers the same amount of budesonide and formoterol as the corresponding Turbuhaler monoproducts, i.e. budesonide 400 micrograms/inhalation (metered dose) and formoterol 12 micrograms/inhalation (metered dose) alternatively labelled as 9 micrograms/inhalation (delivered dose).

Excipient: Lactose monohydrate 491 micrograms per dose.

## Therapeutic indications

**Asthma**

Symbicort is indicated in the regular treatment of asthma where use of a combination (inhaled corticosteroid and long-acting $beta_2$-agonist) is appropriate:

- patients not adequately controlled with inhaled corticosteroids and "as needed" inhaled short-acting $beta_2$-agonists

or

- patients already adequately controlled on both inhaled corticosteroids and long-acting $beta_2$-agonists.

**COPD**

Symptomatic treatment of patients with severe COPD ($FEV_1$ <50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators.

## Posology and method of administration

**Asthma**

Symbicort is not intended for the initial management of asthma. The dosage of the components of Symbicort is individual and should be adjusted to the severity of the disease. This should be considered not only when treatment with combination products is initiated but also when the maintenance dose is adjusted. If an individual patient should require a combination of doses other than those available in the combination inhaler, appropriate doses of $beta_2$-agonists and/or corticosteroids by individual inhalers should be prescribed.

**Recommended doses:**

***Adults (18 years and older):*** 1 inhalation twice daily. Some patients may require up to a maximum of 2 inhalations twice daily.

**Adolescents (12-17 years):** 1 inhalation twice daily.

Patients should be regularly reassessed by their prescriber/health care provider, so that the dosage of Symbicort remains optimal. The dose should be titrated to the lowest dose at which effective control of symptoms is maintained. When control of symptoms is maintained with the lowest recommended dosage, then the next step could include a test of inhaled corticosteroid alone.

In usual practice when control of symptoms is achieved with the twice daily regimen, titration to the lowest effective dose could include Symbicort given once daily, when in the opinion of the prescriber, a long-acting bronchodilator would be required to maintain control.

**Children (6 years and older):** A lower strength is available for children 6-11 years.

Symbicort 320/9 micrograms/inhalation should be used as Symbicort maintenance therapy only. Lower strengths are available for the Symbicort maintenance and reliever therapy regimen.

**COPD**
***Recommended doses:***
***Adults:*** 1 inhalation twice daily.

**General information**
***Special patient groups:*** There are no special dosing requirements for elderly patients. There are no data available for use of Symbicort in patients with hepatic or renal impairment. As budesonide and formoterol are primarily eliminated via hepatic metabolism, an increased exposure can be expected in patients with severe liver cirrhosis.

**Instructions for correct use of Turbuhaler:**
Turbuhaler is inspiratory flow-driven, which means that when the patient inhales through the mouthpiece, the substance will follow the inspired air into the airways.

**Note:** It is important to instruct the patient
- to carefully read the instructions for use/handling written at the end of this leaflet.
- to breathe in forcefully and deeply through the mouthpiece to ensure that an optimal dose is delivered to the lungs.
- never to breathe out through the mouthpiece.
- to replace the cover of the Symbicort Turbuhaler after use.
- to rinse their mouth out with water after inhaling the maintenance dose to minimise the risk of oropharyngeal thrush.

The patient may not taste or feel any medication when using Turbuhaler due to the small amount of drug dispensed.

## Contraindications

Hypersensitivity (allergy) to budesonide, formoterol or lactose (which contains small amounts of milk proteins).

## Special warning and precautions for use

It is recommended that the dose is tapered when the treatment is discontinued and should not be stopped abruptly.

If patients find the treatment ineffective, or exceed the highest recommended dose of Symbicort, medical attention must be sought. Increasing use of rescue bronchodilators indicates a worsening of the underlying condition and warrants a reassessment of the asthma therapy. Sudden and progressive deterioration in control of asthma or COPD is potentially life threatening and the patient should undergo urgent medical assessment. In this situation, consideration should be given to the need for increased therapy with corticosteroids, e.g. a course of oral corticosteroids, or antibiotic treatment if an infection is present.

Patients should be advised to have their rescue inhaler available at all times.

Patients should be reminded to take their Symbicort maintenance dose as prescribed, even when asymptomatic.

Once asthma symptoms are controlled, consideration may be given to gradually reducing the dose of Symbicort. Regular review of patients as treatment is stepped down is important. The lowest effective dose of Symbicort should be used (see section Posology and method of administration).

Patients should not be initiated on Symbicort during an exacerbation, or if they have significantly worsening or acutely deteriorating asthma.

Serious asthma-related adverse events and exacerbations may occur during treatment with Symbicort. Patients should be asked to continue treatment but to seek medical advice if asthma symptoms remain uncontrolled or worsen after initiation with Symbicort.

As with other inhalation therapy, paradoxical bronchospasm may occur, with an immediate increase in wheezing after dosing. Symbicort should then be discontinued; treatment should be re-assessed and alternative therapy instituted if necessary.

Systemic effects may occur with any inhaled corticosteroid, particularly at high doses prescribed for long periods. These effects are much less likely to occur with inhalation treatment than with oral corticosteroids. Possible systemic effects include adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract and glaucoma.

It is recommended that the height of children receiving prolonged treatment with inhaled corticosteroids is regularly monitored. If growth is slowed, therapy should be re-evaluated with the aim of reducing the dose of inhaled corticosteroid. The benefits

of the corticosteroid therapy and the possible risks of growth suppression must be carefully weighed. In addition consideration should be given to referring the patient to a paediatric respiratory specialist.

Limited data from long-term studies suggest that most children and adolescents treated with inhaled budesonide will ultimately achieve their adult target height. However, an initial small but transient reduction in growth (approximately 1 cm) has been observed. This generally occurs within the first year of treatment.

Potential effects on bone density should be considered, particularly in patients on high doses for prolonged periods that have coexisting risk factors for osteoporosis. Long-term studies with inhaled budesonide in children at mean daily doses of 400 micrograms (metered dose) or in adults at daily doses of 800 micrograms (metered dose) have not shown any significant effects on bone mineral density. No information regarding the effect of Symbicort at higher doses is available.

If there is any reason to suppose that adrenal function is impaired from previous systemic steroid therapy, care should be taken when transferring patients to Symbicort therapy.

The benefits of inhaled budesonide therapy would normally minimise the need for oral steroids, but patients transferring from oral steroids may remain at risk of impaired adrenal reserve for a considerable time. Patients who have required high dose emergency corticosteroid therapy in the past or prolonged treatment with high doses of inhaled corticosteroids may also be at risk. Additional systemic corticosteroid cover should be considered during periods of stress or elective surgery.

To minimise the risk of oropharyngeal candida infection, the patient should be instructed to rinse their mouth out with water after inhaling the maintenance dose.

Concomitant treatment with itraconazole, ritonavir or other potent CYP3A4 inhibitors should be avoided (see section Interactions). If this is not possible the time interval between administration of the interacting drugs should be as long as possible.

Symbicort should be administered with caution in patients with thyrotoxicosis, phaeochromocytoma, diabetes mellitus, untreated hypokalaemia, hypertrophic obstructive cardiomyopathy, idiopathic subvalvular aortic stenosis, severe hypertension, aneurysm or other severe cardiovascular disorders, such as ischaemic heart disease, tachyarrhythmias or severe heart failure.

Caution should be observed when treating patients with prolongation of the QTc-interval. Formoterol itself may induce prolongation of the QTc-interval.

The need for, and dose of inhaled corticosteroids should be re-evaluated in patients with active or quiescent pulmonary tuberculosis, fungal and viral infections in the airways.

Potentially serious hypokalaemia may result from high doses of $beta_2$-agonists. Concomitant treatment of $beta_2$-agonists with drugs which can induce hypokalaemia or potentiate a hypokalaemic effect, e.g. xanthine derivatives, steroids and diuretics,

may add to a possible hypokalaemic effect of the $beta_2$-agonist. Particular caution is recommended in unstable asthma with variable use of rescue bronchodilators, in acute severe asthma as the associated risk may be augmented by hypoxia and in other conditions when the likelihood for hypokalaemia adverse effects is increased. It is recommended that serum potassium levels are monitored during these circumstances.

As for all $beta_2$-agonists, additional blood glucose controls should be considered in diabetic patients.

Symbicort Turbuhaler contains lactose (<1 mg/inhalation). This amount does not normally cause problems in lactose intolerant people. The excipient lactose contains small amounts of milk proteins, which may cause allergic reactions.

## Interactions

The metabolic conversion of budesonide is impeded by substances metabolized by CYP P450 3A4 (e.g. itraconazole, ritonavir). The concomitant administration of these potent inhibitors of CYP P450 3A4 may increase plasma levels of budesonide. The concomitant use of these drugs should be avoided unless the benefit outweighs the increased risk of systemic side effects.

Beta-adrenergic blockers can weaken or inhibit the effect of formoterol. Symbicort should therefore not be given together with beta-adrenergic blockers (including eye drops) unless there are compelling reasons.

Concomitant treatment with quinidine, disopyramide, procainamide, phenothiazines, antihistamines (terfenadine), monoamine oxidase inhibitors and tricyclic anti-depressants can prolong the QTc-interval and increase the risk of ventricular arrhythmias.

In addition L-Dopa, L-thyroxine, oxytocin and alcohol can impair cardiac tolerance towards $beta_2$-sympathomimetics.

Concomitant treatment with monoamine oxidase inhibitors including agents with similar properties such as furazolidone and procarbazine may precipitate hypertensive reactions.

There is an elevated risk of arrhythmias in patients receiving concomitant anaesthesia with halogenated hydrocarbons.

Concomitant use of other beta-adrenergic drugs can have a potentially additive effect.

Hypokalaemia may increase the disposition towards arrhythmias in patients who are treated with digitalis glycosides.

Budesonide and formoterol has not been observed to interact with any other drugs used in the treatment of asthma.

## Pregnancy and lactation

For Symbicort or the concomitant treatment with formoterol and budesonide, no clinical data on exposed pregnancies are available. Data from an embryo-fetal development study in the rat, showed no evidence of any additional effect from the combination.

There are no adequate data from use of formoterol in pregnant women. In animal studies formoterol has caused adverse effects in reproduction studies at very high systemic exposure levels (see section Preclinical safety data).

Data on approximately 2000 exposed pregnancies indicate no increased teratogenic risk associated with the use of inhaled budesonide. In animal studies glucocorticosteroids have been shown to induce malformations (see section Preclinical safety data). This is not likely to be relevant for humans given recommended doses.

Animal studies have also identified an involvement of excess prenatal glucocorticoids in increased risks for intrauterine growth retardation, adult cardiovascular disease and permanent changes in glucocorticoid receptor density, neurotransmitter turnover and behaviour at exposures below the teratogenic dose range.

During pregnancy, Symbicort should only be used when the benefits outweigh the potential risks. The lowest effective dose of budesonide needed to maintain adequate asthma control should be used.

Budesonide is excreted in breast milk. However, at therapeutic doses no effects on the nursing child are anticipated. It is not known whether formoterol passes into human breast milk. In rats, small amounts of formoterol have been detected in maternal milk. Administration of Symbicort to women who are breastfeeding should only be considered if the expected benefit to the mother is greater than any possible risk to the child.

## Effects on ability to drive and use machines

Symbicort has no or negligible influence on the ability to drive and use machines.

## Undesirable effects

Since Symbicort Turbuhaler contains both budesonide and formoterol, the same pattern of undesirable effects as reported for these substances may occur. No increased incidence of adverse reactions has been seen following concurrent administration of the two compounds. The most common drug related adverse reactions are pharmacologically predictable side-effects of $beta_2$-agonist therapy, such as tremor and palpitations. These tend to be mild and usually disappear within a few days of treatment. In a 3-year clinical trial with budesonide in COPD, skin bruises and

pneumonia occurred at a frequency of 10% and 6%, respectively, compared with 4% and 3% in the placebo group ($p<0.001$ and $p<0.01$, respectively).

Adverse reactions, which have been associated with budesonide or formoterol, are given below, listed by system organ class and frequency. Frequency are defined as: very common (≥1/10), common (≥1/100) and <1/10), uncommon (≥1/1 000 and < 1/100), rare (≥1/10 000 and < 1/1000) and very rare (<1/10 000).

| | | |
|---|---|---|
| Cardiac disorders | Common | Palpitations |
| | Uncommon | Tachycardia |
| | Rare | Cardiac arrhythmias, e.g. atrial fibrillation, supraventricular tachycardia, extrasystoles |
| | Very rare | Angina pectoris |
| Endocrine disorders | Very rare | Signs or symptoms of systemic glucocorticosteroid effects, e.g. adrenal suppression, growth retardation, decrease in bone mineral density, cataract and glaucoma |
| Gastrointestinal disorders | Uncommon | Nausea |
| Immune system disorders | Rare | Immediate and delayed hypersensitivity reactions, e.g. exanthema, urticaria, pruritus, dermatitis, angioedema and anaphylactic reaction |
| Infections and infestations | Common | Candida infections in the oropharynx |
| Metabolic and nutrition disorders | Rare | Hypokalemia |
| | Very rare | Hyperglycemia |
| Musculoskeletal, connective tissue and bone disorders | Uncommon | Muscle cramps |
| Nervous system disorders | Common | Headache, tremor |
| | Uncommon | Dizziness |

| | | |
|---|---|---|
| | Very rare | Taste disturbances |
| Psychiatric disorders | Uncommon | Agitation, restlessness, nervousness, sleep disturbances |
| | Very rare | Depression, behavioural disturbances (mainly in children) |
| Respiratory, thoracic and mediastinal disorders | Common | Mild irritation in the throat, coughing, hoarseness |
| | Rare | Bronchospasm |
| Skin and subcutaneous tissue disorders | Uncommon | Bruises |
| Vascular disorders | Very rare | Variations in blood pressure |

As with other inhalation therapy, paradoxical bronchospasm may occur in very rare cases (see section Special warning and precautions for use).

Systemic effects of inhaled corticosteroids may occur particularly at high doses prescribed for prolonged periods. These may include adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract and glaucoma (see section Special warning and precautions for use).

Treatment with beta$_2$-agonists may result in an increase in blood levels of insulin, free fatty acids, glycerol and ketone bodies.

The excipient lactose contains small amounts of milk proteins. These may cause allergic reactions.

## Overdose

An overdose of formoterol would likely lead to effects that are typical for beta$_2$-adrenergic agonists: tremor, headache, palpitations. Symptoms reported from isolated cases are tachycardia, hyperglycaemia, hypokalaemia, prolonged QTc-interval, arrhythmia, nausea and vomiting. Supportive and symptomatic treatment may be indicated. A dose of 90 micrograms administered during three hours in patients with acute bronchial obstruction raised no safety concerns.

Acute overdosage with budesonide, even in excessive doses, is not expected to be a clinical problem. When used chronically in excessive doses, systemic glucocorticosteroid effects, such as hypercorticism and adrenal suppression, may appear.

If Symbicort therapy has to be withdrawn due to overdose of the formoterol component of the drug, provision of appropriate inhaled corticosteroid therapy must be considered.

## Pharmacodynamic properties

Pharmacotherapeutic group: Adrenergics and other drugs for obstructive airway diseases.

ATC-code: R03AK07

***Mechanisms of action and pharmacodynamic effects***

Symbicort contains formoterol and budesonide, which have different modes of action and show additive effects in terms of reduction of asthma exacerbations. The mechanisms of action of the two substances, respectively are discussed below.

***Budesonide***
Budesonide is a glucocorticosteroid which when inhaled has a dose-dependent anti-inflammatory action in the airways, resulting in reduced symptoms and fewer asthma exacerbations. Inhaled budesonide has less severe adverse effects than systemic corticosteroids. The exact mechanism responsible for the anti-inflammatory effect of glucocorticosteroids is unknown.

***Formoterol***
Formoterol is a selective beta$_2$-adrenergic agonist that when inhaled results in rapid and long-acting relaxation of bronchial smooth muscle in patients with reversible airways obstruction. The bronchodilating effect is dose-dependant, with an onset of effect within 1-3 minutes. The duration of effect is at least 12 hours after a single dose.

***Symbicort Turbuhaler***
***Asthma***
Clinical studies in adults have shown that the addition of formoterol to budesonide improved asthma symptoms and lung function, and reduced exacerbations. In two 12-week studies the effect on lung function of Symbicort was equal to that of the free combination of budesonide and formoterol, and exceeded that of budesonide alone. All treatment arms used a short-acting beta$_2$-agonist as needed. There was no sign of attenuation of the anti-asthmatic effect over time.

In a 12-week paediatric study 85 children aged 6-11 years were treated with a maintenance dose of Symbicort (2 inhalations of 80/4.5 micrograms/inhalation twice daily), and a short-acting beta$_2$-agonist as needed. Lung function was improved, and the treatment was well tolerated compared to the corresponding dose of budesonide Turbuhaler.

**COPD**
In two 12-month studies, the effect on lung function and the rate of exacerbation (defined as courses of oral steroids and/or course of antibiotics and/or hospitalisations) in patients with severe COPD was evaluated. Median $FEV_1$ at inclusion in the trials was 36% of predicted normal. The mean number of exacerbations per year (as defined above) was significantly reduced with Symbicort as compared with treatment with formoterol alone or placebo (mean rate 1.4 compared with 1.8-1.9 in the placebo/formoterol group). The mean number of days on oral corticosteroids/patient during the 12 months was slightly reduced in the Symbicort group (7-8 days/patient/year compared with 11-12 and 9-12 days in the placebo and formoterol groups, respectively). For changes in lung-function parameters, such as $FEV_1$, Symbicort was not superior to treatment with formoterol alone.

## Pharmacokinetic properties

**Absorption**
Symbicort Turbuhaler and the corresponding monoproducts have been shown to be bioequivalent with regard to systemic exposure of budesonide and formoterol, respectively. In spite of this, a small increase in cortisol suppression was seen after administration of Symbicort compared to the monoproducts. The difference is considered not to have an impact on clinical safety.

There was no evidence of pharmacokinetic interactions between budesonide and formoterol.

Pharmacokinetic parameters for the respective substances were comparable after the administration of budesonide and formoterol as monoproducts or as Symbicort Turbuhaler. For budesonide, AUC was slightly higher, rate of absorption more rapid and maximal plasma concentration higher after administration of the fixed combination. For formoterol, maximal plasma concentration was similar after administration of the fixed combination. Inhaled budesonide is rapidly absorbed and the maximum plasma concentration is reached within 30 minutes after inhalation. In studies, mean lung deposition of budesonide after inhalation via Turbuhaler ranged from 32% to 44% of the delivered dose. The systemic bioavailability is approximately 49% of the delivered dose.

Inhaled formoterol is rapidly absorbed and the maximum plasma concentration is reached within 10 minutes after inhalation. In studies the mean lung deposition of formoterol after inhalation via Turbuhaler ranged from 28% to 49% of the delivered dose. The systemic bioavailability is about 61% of the delivered dose.

**Distribution and metabolism**
Plasma protein binding is approximately 50% for formoterol and 90% for budesonide. Volume of distribution is about 4 L/kg for formoterol and 3 L/kg for budesonide. Formoterol is inactivated via conjugation reactions (active O-demethylated and deformylated metabolites are formed, but they are seen mainly as inactivated conjugates). Budesonide undergoes an extensive degree (approximately 90%) of biotransformation on first passage through the liver to metabolites of low glucocorticosteroid activity. The glucocorticosteroid activity of the major metabolites,

6-beta-hydroxy-budesonide and 16-alfa-hydroxy-prednisolone, is less than 1% of that of budesonide. There are no indications of any metabolic interactions or any displacement reactions between formoterol and budesonide.

**Elimination**
The major part of a dose of formoterol is transformed by liver metabolism followed by renal elimination. After inhalation, 8% to 13% of the delivered dose of formoterol is excreted unmetabolised in the urine. Formoterol has a high systemic clearance (approximately 1.4 L/min) and the terminal elimination half-life averages 17 hours.

Budesonide is eliminated via metabolism mainly catalysed by the enzyme CYP3A4. The metabolites of budesonide are eliminated in urine as such or in conjugated form. Only negligible amounts of unchanged budesonide have been detected in the urine. Budesonide has a high systemic clearance (approximately 1.2 L/min) and the plasma elimination half-life after i.v. dosing averages 4 hours.

The pharmacokinetics of budesonide or formoterol in children and patients with renal failure is unknown. The exposure of budesonide and formoterol may be increased in patients with liver disease.

## Preclinical safety data

The toxicity observed in animal studies with budesonide and formoterol, given in combination or separately, were effects associated with exaggerated pharmacological activity.

In animal reproduction studies, corticosteroids such as budesonide have been shown to induce malformations (cleft palate, skeletal malformations). However, these animal experimental results do not seem to be relevant in humans at the recommended doses. Animal reproduction studies with formoterol have shown a somewhat reduced fertility in male rats at high systemic exposure and implantation losses as well as decreased early postnatal survival and birth weight at considerably higher systemic exposures than those reached during clinical use. However, these animal experimental results do not seem to be relevant in humans.

## List of excipients

Lactose monohydrate (which contains milk proteins).

## Incompatibilities

Not applicable.

## Shelf-life

Please refer to expiry date on the outer carton.

## Special precautions for storage

Do not store above 30° C. Keep the container tightly closed.

## Pack size

Please refer to outer carton for pack size.

## Date of revision of text

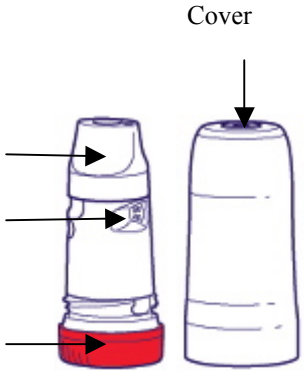
November 2008.

RITA.000-345-021.2.0

INSTRUCTIONS FOR USE/HANDLING
*Please read the complete instructions carefully before you start to take your medication*

Turbuhaler is a multidose inhaler from which very small amounts of powder are administered (Fig 1). When you breathe in through Turbuhaler the powder is delivered to your lungs. It is therefore important that **you inhale forcefully and deeply** through the mouthpiece.

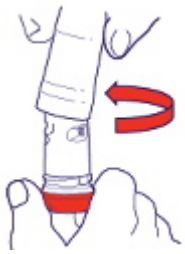
[k1][k2]




**Taking your medicine**

To take your medicine, just take these three simple steps:
Unscrew the lid of your Turbuhaler.

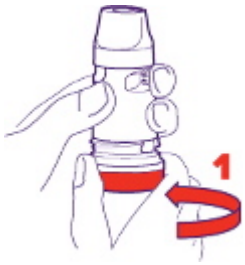
[k7]



**1 Twist**

**Holding it upright**, **twist** the red grip as far as it will go to the right direction.

[k8]




**2 Click**

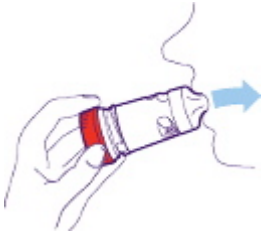
Then twist it back as far as it will go to the left direction.

*(Do this twice if it's the first time you've used it. Otherwise just do it once.)*

A **click** will tell you that your dose is loaded. Breathe out, then put the mouthpiece gently between your lips[k3].


**3 Inhale**

Close your lips over the mouthpiece. Take a big, deep **breath in**. Hold it for a few seconds. Then take the Turbuhaler out off your mouth before



you[k4] breathe out again.

If you've been prescribed more than one dose, just repeat the process, then put the lid back on tightly. It's as easy as that.

### Only one dose at a time

Don't worry if you click your Turbuhaler more than once. It can only ever give you one dose at a time.

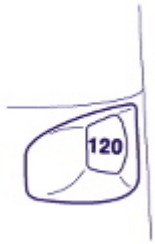
### You can't taste it, feel it or smell it

Your Turbuhaler only delivers a very small amount of medication that's taken straight to your lungs when you inhale.

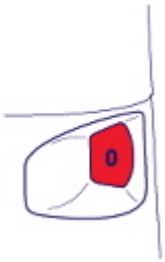
### The counter is small and moves slowly

There is a small dose indicator on one side of your Turbuhaler, which we meant to design it small to help keep your Turbuhaler compact. Because it's small, it doesn't indicate every dose you've taken, but moves around slowly to count every 10 doses.

### It tells you when it's empty




[k5][k6]You can see, at a glance, how many doses you have in your Turbuhaler. When it's full there are 60 or 120 doses. When the red background appears, you're down to your last 20 and when you see '0', you need a new Turbuhaler.




Any rattling you hear is a drying agent, not the medication. So this sound doesn't mean that there's any medicine left.

### Some important things to note

- Rinse your mouth with water after taking your daily doses and spit it out.

- Don't try to remove or twist the mouthpiece. It is fixed to your Turbuhaler and must not be taken off.
- Do not use your Turbuhaler if it has been damaged or if the mouthpiece has come apart from your Turbuhaler.

- Clean your Turbuhaler by wiping the outside

of the mouthpiece once a week with a dry tissue. Do not use water or other liquids.

- If you use more Symbicort Turbuhaler than you should, contact your doctor or pharmacist for advice. The most common symptoms that may occur if you use more than you should are trembling, headache or a rapid heart beat.

- If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose.

- Do not take a double dose to make up for a forgotten dose.

## Disposal

Always be sure to dispose of your used Turbuhaler responsibly/in the recommended way, since some of the medicine will remain inside it. Ask your pharmacist for advice.

**For further information please visit**
**www.symbicortturbuhaler.com**



AstraZeneca AB, Södertälje, Sweden

**THIS IS A MEDICAMENT**

*Medicament is a product, which affects your health and its consumption contrary to instructions is dangerous for you. Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.*

- *The doctor and the pharmacist are the experts in medicines, their benefits and risks.*
- *Do not by yourself interrupt the period of treatment prescribed.*
- *Do not repeat the same prescription without consulting your doctor.*
- *Keep all medicaments out of reach of children.*

*Council of Arab Health Ministers, Union of Arab Pharmacists.*