roposed packaging material		
Code	BRICASMA TURBUHALER 0.5 mg-PI-01.01	
Submission	☐NDA ☐Renewal ☒Variation change detail no.: MU-131610-159730	
Code of previous version	N/A	
Changes	Risk of SABA Monotherapy	
Reference	☒CDS version: 4.0 (Doc ID-003307686) ☐CPIL version:	☐SmPC country/version/date: ☐GRL approval:
Name & Date	ADR (03 May 2023)	

Bricasma® Turbuhaler® 0.5 mg/dose
terbutaline sulfate
Inhalation powder

Qualitative and quantitative composition
Each dose contains terbutalin sulfate 0.5 mg.

Pharmaceutical form
Inhalation powder

Therapeutic indication
Bronchial asthma, chronic bronchitis, emphysema and other lung diseases where bronchospasm is a complicating factor.

Posology and method of administration
Dosage of inhaled terbutaline via BRICASMA TURBUHALER should be individualized.

BRICASMA TURBUHALER should, as initially therapy, be used as required rather than regularly.

Adult and children over 12 years:
0.25 mg – 0.50 mg as required or, when used as regular maintenance therapy, every 6 hours. In severe cases the single dose may be increased to 1.5 mg. The total dose in 24 hours should not exceed 2 mg.

Children 7-12 years:
0.25 mg – 0.5 mg as required or, when used as regular maintenance therapy, every 6 hours. In severe cases the single dose may be increased to 1.0 mg. The total dose in 24 hours should not exceed 2 mg.

The medication from BRICASMA TURBUHALER is delivered to the lung as patient inhales and therefore it is important to instruct the patient to breathe in forcefully and deeply through the mouthpiece. When prescribing BRICASMA TURBUHALER to young children it is necessary to ascertain that they can follow the instructions for use.

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

Instruction 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 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

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

For detailed instructions please refer to the reverse of this leaflet

Contraindications
Hypersensitivity to terbutaline.

Special warning and precautions for use
Irrespective of asthma severity, having uncontrolled asthma is an important risk factor for exacerbations. Prescription of three or more SABA (short acting β_2 agonist) inhalers in a year is associated with an increased risk of severe exacerbations and mortality. The risk increases with the number of inhalers prescribed.

In mild asthma patients, there is an increased risk of severe exacerbations associated with over-reliance on SABA monotherapy.

Patients who are prescribed regular anti-inflammatory therapy should be advised to continue taking their anti-inflammatory medication even when symptoms decrease and they do not require BRICASMA.

BRICASMA should be used with caution if susceptibility to sympathomimetic amines is likely to be increased, for instance in patients with hyperthyroidism not yet under adequate control.

If a previously effective dosage regimen no longer gives the same symptomatic relief, the patient should seek medical care as soon as possible as this-could be the sign of worsening of underlying condition and warrants reassessment of the asthma therapy.

As for all β_2-agonists caution should be observed in patients with thyrotoxicosis. Cardiovascular effects may be seen with sympathomimetic drugs, including BRICASMA. There is some evidence from post-marketing data and published literature of myocardial ischaemia associated with beta agonists.

Patients with underlying severe heart disease (e.g. ischaemic heart disease, arrhythmia or severe heart failure) who are receiving BRICASMA should be warned to seek medical advice if they experience chest pain or other symptoms of worsening heart disease. Attention should be paid to assessment of symptoms such as dyspnoea and chest pain, as they may be of either respiratory or cardiac origin.

Due to the hyperglycemic effects of β_2-agonists, additional blood glucose controls are recommended initially in diabetic patients. Additional blood glucose tests are recommended

for asthmatic patient with concomitant diabetes starting on BRICASMA TURBUHALER therapy, due to the risk of hyperglycaemia with β_2-agonist. β_2 stimulants have successfully been used in the acute treatment of severe ischemic heart failure.

Due to the positive inotropic effect of β_2-agonists, this drug should not be used with hypertrophic cardiomyopathia.

However these drugs have an arrhythmogenic potential which must be considered in the treatment the individual lung patient.

Terbutaline is not indicated and should not be used for the management of preterm labor. Serious adverse reactions have been reported following administration of terbutaline sulfate to women in labor.

These reports have included transient hypokalemia, pulmonary edema (sometimes after delivery), and hypoglycaemia in the mother and/ neonatal child. Maternal death has been reported with terbutaline sulfate and other drugs of this class.

There have been rare reports of seizures occurring in patients receiving terbutaline, which do not recur when the drug is discontinued and have not been explained on any other basis.

Terbutaline sulfate is a sympathomimetic amine and such should be used with caution in patients with cardiovascular disorders (including arrythmias, coronary insufficiency and hypertension), in patients with hyperthyroidism or diabetes mellitus, history of seizures, or in patients who are unusually responsive to sympathomimetic amines.

Potentially serious hypokalemia may result from β_2-agonist therapy. Particular caution is recommended in acute severe asthma as the associated risk may be augmented by hypoxia. The hypokalemic effect may be potentiated by concomitant treatments (see *Interactions with other medicinal products and other forms of interaction)*. It is recommended that serum potassium levels are monitored in such situations. Patients susceptible to hypokalemia should be monitored because transient early falls in serum potassium levels have been reported with β_2-agonists.

Immediate hypersensitivity reactions and exacerbation of bronchospasm have been reported after terbutaline administration.

Safety and effectiveness in children below the age of 12 have not been established.

Interactions with other medicinal products and other forms of interaction
Beta-receptor blocking agents (including eye-drops) especially those which are non-selective may partly or totally inhibit the effect of beta-receptor stimulants.

Halogenated anaesthetics
Halothane anaesthesia should be avoided during β_2-agonists treatment, since it increases the risk of cardiac arrhythmias. Other halogenated anesthetics should be used cautiously together with β_2-agonists.

Potassium depleting agents and hypokalaemia
Owing to the hypokalaemic effect of beta-agonists, concurrent administration with Bricasma of serum potassium depleting agents known to exacerbate the risk of hypokalaemia, such as diuretics, methyl xanthines and corticosteroids, should be administered cautiously after careful evaluation of the benefits and risks with special regard to the increased risk of cardiac arrhythmias arising as a result of hypokalaemia (see Special warnings and precuaitons for use). Hypokalaemia also predisposes to digoxin toxicity

Pregnancy and lactation
No teratogenic effects have been observed in patients or in animals. However, caution is recommended during the first trimester of pregnancy.

Terbutaline passes over to breast milk. Caution should be exercised when this drug is administered to a nursing woman.

Transient hypoglycemia has been reported in newborn preterm infants after maternal β_2-agonist treatment.

Effect on ability to drive and use machines
BRICASMA TURBUHALER does not affect the ability to drive.

Undesirable effects
The intensity of the adverse reactions depends on dosage and route of administration. An initial dose titration will often reduce the adverse reactions. Most of the adverse reactions are characteristic of sympathomimetic amines. The majority of these effects have reversed spontaneously within the first 1-2 weeks of treatment.

Frequency Classification	**Adverse Drug Reaction**	
	System Organ Class (SOC)	Preferred term (PT)
Very common ≥1/10	Nervous system disorders	Tremor, headache
Common <1/10 and ≥1/100	Cardiac disorders	Tachycardia, palpitations
	Musculoskeletal and connective tissue disorders	Tonic muscle cramps
	Metabolism and nutrition disorders	Hypokalaemia

Frequency Classification	Adverse Drug Reaction	
	System Organ Class (SOC)	Preferred term (PT)
Rare <1/1000 and ≥1/10.000, Frequenty unknown*	Cardiac disorders	Cardiac arrhythmias, e.g. atrial fibrillation, supraventricular tachycardia and extrasystoles myocardial ischemia
	Gastrointestinal disorders	Nausea
	Psychiatric disorders	Sleep disturbances and behavioural disturbances, such as agitation, hyperactivity and restlessness
	Skin and subcutaneous tissue disorders	Urticaria and exanthema

* Reported spontaneously in post-marketing data and therefore frequency regarded as unknown

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions:

Pusat Farmakovigilans: Direktorat Pengawasan Keamanan, Mutu dan Ekspor Impor Obat Narkotika, Psikotropika, Prekursor, dan Zat Adiktif Badan Pengawas Obat dan Makanan Republik Indonesia
Address: Jl. Percetakan Negara No. 23, Jakarta Pusat, 10560
Email: pv-center@pom.go.id
Phone: +62-21- 4244691 Ext. 1079
Website: http://e-meso.pom.go.id/

Overdose
There is a potential for progressive accumulation of dry powder in the mouthpiece of the Bricasma Turbuhaler that could be released if dropped (for example, from a table) towards the end of inhaler life. To minimize unnecessary systemic exposure to terbutaline, the patients should be advised to, when possible, rinse their mouth after each use.

Too frequent administration, as with other sympathomimetic agents, may cause nausea, headaches, changes in blood pressure, anxiety, tension, insomnia, tremor. The symptoms and sign are those characteristic of excessive symphatetic stimulation.

Possible symptoms and sign: Headache, anxiety, tremor, nausea, tonic muscle cramps, palpitation, tachycardia and cardiac arrhythmia. A fall in blood pressure sometimes occurs.

Laboratory findings: Hyperglycaemia and lactacidosis sometimes occur. $ß_2$-agonist may cause hypokalemia as a result of redistribution of potassium.

Treatment of overdose: Usually no treatment is required.
If it can be suspected that significant amounts of terbutaline sulfate have been swallowed, the following measures should be considered:
Gastric lavage, activated charcoal. Determine of acid-base balance, blood sugar and electrolytes. Monitor of heart rate and rhythm and blood pressure. Metabolic changes should be corrected. A cardio-selective ß-blocker (e.g. metoprolol) is recommended for the treatment of arrhythmias causing a hemodynamic deterioration. The ß-blocker should be used with care because of the possibility of inducing bronchial obstruction.

If the $ß_2$-mediated reduction in peripheral vascular resistance significantly contributes to the fall in blood pressure, a volume expander should be given.

Mild and moderate cases: Reduce the dose. Then increase the dose more slowly until the broncholytic effect is insufficient.

Pharmacodynamic properties
Pharmacotherapeutic group: selective β_2-agonist, terbutaline, ATC code: R03A C03.

BRICASMA is a sympathomimetic bronchodilator with a degree of selective B_2 stimulant activity on the respiratory system, Terbutaline is an adrenergic agonist which predominantly stimulates β_2-receptors, thus producing relaxation of bronchial smooth muscle, inhibition of the release of endogenous spasmogens, inhibition of oedema caused by endogenous mediators and increased mucociliary clearance.

Inhaled terbutaline acts within a few minutes and has a duration for up to 6 hours.
About 10% of the dose is deposited in the lungs. Terbutaline is metabolized mainly by conjugation with the sulphuric acid and excreted as the sulfate conjugate. No active metabolites are formed. BRICASMA TURBUHALER contains pure terbutaline sulfate and is free from propellants lubricants, preservatives, carrier substances or other additives. BRICASMA TURBUHALER is breath actuated and hence there is no need to coordinate the release of the dose and the inhalation as with a pressurized inhaler. When inhaling, the substance follows the inspired air into the airways.

Pharmacokinetic properties
The absolute pulmonary bioavailability is about 16% of the delivered dose at a normal inhalation flow rate. Following administration of a single 1.5 mg dose (3 inhalations of 0.5 mg), maximum plasma concentration (C_{max}) of terbutaline of 12 nmol/L was achieved around 1.3 hours post-dose (t_{max}); the area under the plasma concentration-time curve (AUC) was 89 nmol*h/L and elimination half-life ($t_{1/2}$) was about 12 hours. Terbutaline is mainly metabolised by conjugation with sulphuric acid and excreted as the sulphate conjugate. No active metabolites are formed.

List of excipients
Lactose monohydrate (which may contain milk protein residue).

Special precautions for storage
Do not store above 30^{o}C.

Should be stored with the cover tightened.

HARUS DENGAN RESEP DOKTER

Pack Size
Box of 1 TURBUHALER 120 doses @ 0.5 mg (Reg. No.: DKI1851303467A1)

Manufactured by:
AstraZeneca AB, Sodertalje, Sweden

Imported by:
PT AstraZeneca Indonesia
Cikarang, Bekasi – Indonesia

Date of revision text:
Approval date:
ANGEL Doc-ID: Doc ID-005037268

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 (Figure 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.

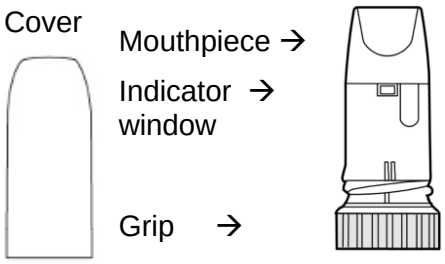

Figure 1

How to prepare a new inhaler for use

Before using Turbuhaler **for the first time** you need to prepare the inhaler for use.

1. Unscrew and lift off the cover.
2. Hold the inhaler upright with the red grip downwards (Figure 2). Do not hold the mouthpiece when you turn the grip. **Turn the grip as far as it will go in one direction and then back again in the opposite direction as far as it will go**. It does not matter which way you turn first. During this procedure you will hear a click.

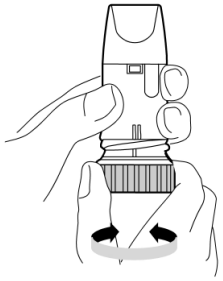

Figure 2

The inhaler is now ready for use, and **you should not repeat this procedure again.** To take a dose, please continue according to the instructions below.

How to use BRICASMA Turbuhaler

To administer one dose, simply follow the instructions below.

1. Unscrew and lift off the cover.
2. **Hold the inhaler upright** with the red grip downwards (Figure 2). Do not hold the mouthpiece when you turn the grip. To load the inhaler with a dose **turn the grip as far as it will go in one direction, and then back again in the opposite direction as far as it will go.** It does not matter which way you turn first. During this procedure you will hear a click.
3. Hold the inhaler away from your mouth. **Breathe out.** Do **not** breathe out **through** the mouthpiece.
4. Place the mouthpiece gently between your teeth, close your lips and **inhale forcefully and deeply through the device** (Figure. 3). Do not chew or bite on the mouthpiece.
5. **Remove the inhaler from your mouth, before breathing out.**

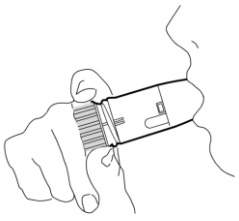

Figure 3

6. If more than one dose has been prescribed, repeat steps 2-5.
7. **Replace the cover** by screwing it back on tightly.
8. **Rinse your mouth out with water after inhaling your prescribed dose.**

NOTE!
Never breathe out through the mouthpiece.
Always replace the cover properly after use.

As the amount of the powder dispensed is very small, you may not be able to taste it after inhalation. However, you can still be confident that the dose has been inhaled if you have followed the instructions.

Do not try to remove the mouthpiece since it is fixed to your Turbuhaler and must not be taken off. The mouthpiece can be rotated but do not twist it unnecessarily. Do not use your Turbuhaler if it has been damaged or tf the mouthpiece has come apart from your Turbuhaler.

If you by mistake perform the loading procedure more than once before taking your dose, you will still only receive one dose. The dose indicator will however, register all the loaded doses.

The sound heard if you shake the inhaler is not produced by the medication but by a drying agent.

Cleaning
Clean the outside of the mouthpiece regularly (weekly) with a dry tissue.
Do not use water or other liquids for cleaning the mouthpiece.

How will I know when to replace my inhaler?

The dose indicator (Figure 4) tells you approximately how many doses are left in the inhaler, starting with 120 when full.

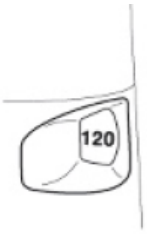

Figure 4

The indicator is marked in intervals of 10 doses. Therefore, it does not show the loading of each individual dose.

You should be reassured that Turbuhaler delivers the dose even if you may not notice a movement in the dose indicator.

For the last 10 doses, the background of the indicator is red. When the zero reaches the middle of the window (Figure 5), it is time for you to discard the inhaler.

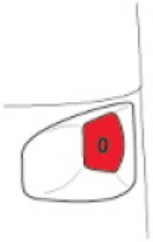

Figure 5

Please note that even when the dose indicator registers zero, it is still possible to turn the grip. However, the indicator stops moving and the zero remains the window.

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 you pharmacist for advice.

Proposed packaging material		
Code	BRICASMA TURBUHALER 0.5 mg/mL-PIL-01.01	
Submission	☐NDA ☐Renewal ☒Variation change detail no.: MU-131610-159730	
Code of previous version	N/A	
Changes	Risk of SABA Monotherapy	
Reference	☐CDS version: ☒CPIL version: 4-Oct-22	☐SmPC country/version/date: ☐GRL approval:
Name & Date	ADR, 18 May 2023	

Leaflet Informasi Pasien
Bricasma™ Turbuhaler™ 0.5 mg/Dosis
Terbutaline Sulphate
Serbuk Inhalasi

Bacalah seluruh isi leaflet dengan seksama sebelum Anda mulai menggunakan obat ini

- Simpanlah leaflet ini, Anda mungkin perlu membacanya kembali di kemudian hari
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakanlah pada dokter, perawat, ataupun apoteker Anda
- Obat ini telah diresepkan khusus untuk Anda. Dilarang memberikan obat ini untuk orang lain karena hal ini dapat membahayakan mereka, meskipun tanda dan gejala penyakit mereka sama dengan yang Anda alami.

Informasi di leaflet ini:

Bricasma Turbuhaler mengandung zat aktif berupa terbutaline sulphate.

- Bricasma Turbuhaler 0.5 mg/dosis mengandung 120 dosis. Dalam satu aktuasi (inhalasi) mengandung 0.5 mg terbutaline sulphate

Bricasma Turbuhaler mengandung laktosa

1. BRICASMA TURBUHALER DAN KEGUNAANNYA

BRICASMA TURBUHALER merupakan sediaan serbuk inhalasi yang mengandung terbutaline sulphate.

BRICASMA TURBUHALER digunakan untuk memperlebar saluran pernafasan sehingga dapat mempermudah Anda untuk bernafas. Obat akan masuk ke dalam paru-paru saat Anda bernafas melalui *mouthpiece* inhaler.

BRICASMA TURBUHALER dapat meredakan gejala sesak napas pada pasien penderita asma dan kondisi serupa lainnya secara cepat.

2. HAL YANG PERLU DIKETAHUI SEBELUM MENGGUNAKAN BRICASMA TURBUHALER

Jangan gunakan Bricasma Turbuhaler:

- Jika Anda alergi dengan terbutaline sulphate atau laktosa

Sebelum pengobatan Anda dengan Bricasma Turbuhaler dimulai:

- Beritahu dokter jika anda pernah mengalami reaksi yang tidak biasa pada penggunaan Bricasma (terbutaline) atau laktosa atau obat lainnya
- Pada beberapa kasus, Bricasma Turbuhaler harus digunakan dengan perhatian khusus. Oleh karena itu selalu beritahu dokter tentang masalah kesehatan Anda lainnya, terutama jika Anda memiliki riwayat gangguan jantung, ritme jantung tidak teratur, angina, diabetes atau gangguan fungsi tiroid (hipertiroidisme)
- Anda harus selalu memberitahu dokter Anda terkait semua obat yang Anda gunakan, termasuk obat yang Anda beli tanpa resep dokter. Lihat bagian "Penggunaan obat lain"
- Bricasma Turbuhaler diresepkan khusus untuk kondisi Anda sekarang. Jangan gunakan Bricasma Turbuhaler untuk kondisi lain kecuali dokter memberitahu Anda. Jangan pernah berikan obat Anda kepada orang lain.

Kehamilan

Sebelum menggunakan Bricasma Turbuhaler, beritahu dokter jika Anda hamil atau berencana untuk hamil. Jika anda dalam kondisi hamil, Anda harus selalu berhati-hati dengan obat yang Anda gunakan. Bricasma tidak menunjukkan efek berbahaya ketika digunakan oleh wanita hamil. Namun, jika Anda hamil saat menggunakan Bricasma Turbuhaler, Anda harus memberitahu dokter Anda sesegera mungkin.

Menyusui

Sebelum menggunakan Bricasma Turbuhaler, beritahu dokter jika Anda sedang menyusui. Jika anda dalam kondisi menyusui, Anda harus selalu berhati-hati dengan obat yang Anda gunakan. Bricasma tidak menunjukkan efek berbahaya ketika digunakan oleh wanita menyusui.

Mengemudi dan Menjalankan Mesin

Bricasma Turbuhaler tidak mempengaruhi kemampuan mengemudi ataupun menjalankan mesin.

Informasi Penting Mengenai Laktosa pada Bricasma Turbuhaler

Bricasma Turbuhaler mengandung laktosa. Laktosa dapat mengandung sisa protein susu dalam jumlah sedikit. Pada pasien dengan hipersensitivitas pada protein susu, laktosa dapat menimbulkan reaksi alergi.

Penggunaan Obat Lain

Anda harus selalu memberitahu dokter Anda mengenai **semua** obat yang Anda gunakan, termasuk obat yang Anda beli tanpa resep.

Beta-blockers (beberapa obat-obatan untuk tekanan darah tinggi, kondisi jantung dan beberapa obat tetes mata) dapat mengurangi atau menghambat efek Bricasma jika digunakan secara bersamaan. Diperkirakan juga terdapat efek pada keseimbangan garam dalam darah (rendahnya kadar kalium) ketika Bricasma digunakan bersamaan dengan obat-obat tertentu lainnya. Biasanya, kondisi ini jarang terjadi, namun dalam beberapa kasus dapat berefek pada ritme jantung.

Halogenated anaesthetics

Anda harus menghindari *halothane anaesthesia* (obat-obatan yang digunakan untuk bius pada operasi) selama menggunakan obat-obatan golongan β2-agonis karena dapat meningkatkan resiko aritmia jantung.

Penggunaan halogenated anesthetic lainnya harus digunakan secara hati-hati apabila digunakan bersamaan dengan golongan β2- agonis.

3. CARA MENGGUNAKAN BRICASMA TURBUHALER

Dosis Bricasma Turbuhaler bersifat individual. Ikuti petunjuk dokter secara seksama karena informasi yang diberikan oleh dokter dapat berbeda dengan informasi yang terdapat di dalam leaflet.

Sebelum menggunakan Bricasma Turbuhaler untuk pertama kali, penting untuk membaca informasi **"Cara menggunakan Turbuhaler"** dan mengikuti petunjuk yang diberikan secara seksama.

Anak-anak dapat mengalami kesulitan saat menggunakan turbuhaler. Penting untuk memastikan anak-anak dapat mengikuti petunjuk penggunaan secara benar.

Bricasma Turbuhaler harus digunakan sesuai kebutuhan, bukan untuk penggunaan harian. Jika Anda juga diresepkan obat anti-inflamasi harian untuk asma (seperti kortikosteroid inhalasi atau antagonis leukotriene), Anda harus melanjutkan penggunaannya walaupun Anda sudah tidak membutuhkan penggunaan Bricasma Turbuhaler.

Penggunaan Bricasma Turbuhaler saja untuk penanganan asma tanpa terapi tambahan lainnya (seperti kortikosteroid inhalasi) dapat meningkatkan resiko serangan asma berat.

Segera cari pertolongan medis jika gejala asma Anda (kesulitan bernapas, mengi, atau dada sesak) memburuk atau jika Anda sangat kesulitan bernapas untuk berbicara, makan, ataupun tidur.

Penggunaan harian Bricasma Turbuhaler secara berlebihan harus dihindari karena dapat meningkatkan resiko serangan asma yang dapat mengancam nyawa atau bahkan bersifat fatal. Anda mungkin memerlukan obat tambahan untuk mengontrol asma Anda. Segera hubungi dokter jika Anda membutuhkan Bricasma Turbuhaler dengan dosis lebih tinggi dari biasanya untuk mengatasi gangguan pernapasan Anda.

Dosis umum untuk dewasa dan anak diatas 12 tahun: 1 inhalasi (0,5 mg) sesuai kebutuhan. Jika diperlukan, penggunaan hingga 3 inhalasi (1,5 mg) dapat dilakukan pada waktu bersamaan. Anda seharusnya tidak boleh menggunakan lebih dari 4 inhalasi (2 mg) dalam jangka waktu 24 jam.

Dosis umum untuk anak usia 7-12 tahun: 1 inhalasi (0,5 mg) sesuai kebutuhan. Jika diperlukan, penggunaan hingga 2 inhalasi (1 mg) dapat dilakukan pada waktu bersamaan. Anak-anak seharusnya tidak boleh menggunakan lebih dari 4 inhalasi (2 mg) dalam jangka waktu 24 jam.

Anda biasanya akan mendapatkan efek Bricasma Turbuhaler dalam waktu beberapa menit. Efek Bricasma Turbuhaler bertahan hingga 6 jam.

Jika Anda menggunakan Bricasma Turbuhaler Lebih dari yang Seharusnya
Gunakan jumlah dosis (inhalasi) sesuai yang diresepkan dokter. Penggunaan secara berlebihan akan meningkatkan resiko efek samping.

Tanda dan gejala paling umum yang dapat muncul setelah penggunaan secara berlebihan (overdosis):

- Mual
- Sakit kepala
- Denyut jantung cepat atau tidak teratur
- Kram otot
- Gugup, gelisah, gemetaran
- Pusing atau rasa kantuk yang tidak biasa

Hubungi dokter Anda jika gejala diatas mengganggu Anda.

Jika Anda lupa menggunakan Bricasma Turbuhaler
Bricasma Turbuhaler harus digunakan sesuai kebutuhan, bukan digunakan secara rutin. Namun, jika Anda telah diresepkan pengobatan secara rutin dan Anda lupa menggunakannya, gunakanlah saat Anda ingat. Jika Anda ingat pada waktu penggunaan dosis berikutnya, tunggu hingga waktu penggunaan dosis berikutnya.

4. EFEK SAMPING YANG MUNGKIN TERJADI

Biasanya, Anda tidak akan merasakan efek samping saat menggunakan Bricasma Turbuhaler. Efek samping yang muncul biasanya ringan dan akan menghilang dengan sendirinya dalam waktu satu atau dua minggu pengobatan. Namun, pastikan Anda memberitahu dokter Anda jika terdapat efek samping berikut yang mengganggu atau berlanjut.

Efek samping yang sangat umum terjadi (lebih dari 1 dari 10 orang)
- Gemetaran
- Sakit kepala

Efek samping yang umum terjadi (kurang dari 1 dari 10 orang)
- Denyut jantung cepat
- Kram otot
- Kadar kalium dalam darah dibawah kadar normal

Frekuensi tidak diketahui*
- Denyut jantung tidak teratur
- Mual (merasa sakit)
- Agitasi, gelisah atau gangguan tidur
- Bronkospasma (penyempitan otot saluran pernapasan yang menyebabkan mengi)**
- Reaksi alergi seperti kemerahan dan gatal

* Efek samping diobservasi dari laporan pasca pemasaran sehingga frekuensi tidak diketahui
**Obat untuk inhalasi dapat menyebabkan bronkospasma

Walaupun tidak diketahui secara pasti seberapa sering dapat terjadi, beberapa orang dapat mengalami nyeri dada (karena masalah jantung seperti angina). Beritahu dokter Anda jika Anda mengalami gejala-gejala tersebut saat Anda menggunakan Bricasma Turbuhaler, tetapi jangan berhenti menggunakan obat ini kecuali diberitahu oleh dokter Anda.

Anda juga harus menghubungi dokter Anda jika Anda merasakan efek tidak biasa lainnya saat menggunakan Bricasma Turbuhaler.

Jika anda merasakan efek samping yang tidak disebutkan dalam leaflet ini, harap beritahu dokter atau apoteker Anda.

5. CARA PENYIMPANAN BRICASMA TURBUHALER

Jauhkan dari jangkauan anak-anak.
Selalu pasang kembali penutup inhaler setelah menggunakan Bricasma Turbuhaler.

Jangan simpan pada suhu diatas 30°C.

Masa Pakai
Jangan gunakan Bricasma Turbuhaler setelah tanggal kedaluwarsa yang tertera pada inhaler dan dus.

Ingatlah untuk mengembalikan Bricasma Turbuhaler yang tidak terpakai pada apoteker Anda.

6. INFORMASI LEBIH LANJUT

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AstraZeneca AB
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Diimpor oleh:
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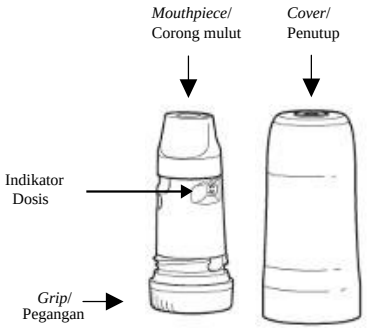
Cikarang, Bekasi – Indonesia

HARUS DENGAN RESEP DOKTER

Nomor Izin Edar	**: DKI1851303467A1**
Leaflet ini terakhir direvisi	**: 03 May 2023**
ANGEL Doc ID	**:**

Petunjuk pemakaian/penggunaan
Bacalah petunjuk lengkap berikut dengan seksama sebelum Anda mulai menggunakan obat Anda

Turbuhaler adalah inhaler dosis ganda yang memberikan sejumlah kecil serbuk per dosisnya (Gambar 1). Saat Anda menarik napas melalui Turbuhaler, serbuk di dalamnya ikut masuk ke paru-paru Anda. Oleh karena itu, penting bagi Anda untuk **menarik napas dengan kuat dan dalam** melalui *mouthpiece* turbuhaler.



Gambar 1

Bagaimana cara mengatur inhaler baru agar siap digunakan
Sebelum menggunakan Turbuhaler untuk **pertama kali**, Anda harus mengatur Inhaler agar siap digunakan.

Putar untuk membuka dan angkat penutupnya. Suara berderak akan terdengar saat Anda membuka penutupnya

Gambar 2

Pegang inhaler secara tegak lurus dengan *grip* berada di bawah (Gambar 2). Jangan memegang *mouthpiece* saat Anda memutar *grip*. **Putar *grip* ke satu arah sampai berbunyi, dan kemudian kembali lagi ke arah yang berlawanan sampai berbunyi.** Tidak masalah ke arah mana Anda memutarnya pertama kali. Saat melakukan prosedur ini Anda akan mendengar bunyi **klik**. Lakukan prosedur tersebut dua kali.

Sekarang inhaler siap digunakan, dan **Anda tidak boleh mengulangi lagi prosedur di atas.** Untuk mengonsumsi satu dosis, silakan lanjutkan sesuai petunjuk di bawah ini.

CARA MENGGUNAKAN BRICASMA TURBUHALER

Untuk mengeluarkan satu dosis, cukup ikuti petunjuk di bawah ini.
1. Putar untuk membuka dan angkat penutupnya.

Suara berderak akan terdengar saat Anda membuka penutupnya.

2. **Pegang inhaler tegak lurus** dengan *grip* berada di bawah (Gambar 2). Jangan memegang *mouthpiece* saat Anda memutar *grip*. Untuk memuat satu dosis pada inhaler **putar *grip* ke satu arah sampai berbunyi, lalu kembali lagi ke arah yang berlawanan sampai berbunyi.** Tidak masalah ke arah mana Anda memutarnya pertama kali. Saat melakukan prosedur ini Anda akan mendengar bunyi **klik**.

3. Pegang inhaler menjauhi mulut Anda. **Embuskan napas. JANGAN mengembuskan napas ke *mouthpiece*.**

4. Posisikan *mouthpiece* di antara gigi Anda dengan hati-hati, rapatkan bibir Anda lalu **tarik napas dengan kuat dan dalam melalui turbuhaler** (Gambar 3). Jangan menggigit *mouthpiece.*

Gambar 3

5. **Lepaskan inhaler dari mulut Anda, lalu hembuskan napas**.

6. Jika diresepkan lebih dari satu dosis, ulangi langkah 2–5.

7. **Pasang kembali penutup inhaler** dengan memutarnya kembali dengan erat

8. **Berkumurlah dengan air setelah menghisap dosis yang diresepkan.**

CATATAN!

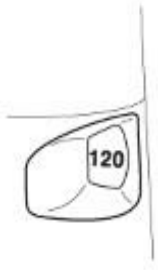
Jangan mengembuskan napas ke *mouthpiece*. Selalu pasang tutup dengan benar setelah digunakan.
Karena jumlah bubuk yang dikeluarkan sangat sedikit, Anda mungkin tidak dapat merasakannya setelah menghisapnya. Namun, yakinlah bahwa obat telah terhirup jika anda telah mengikuti petunjuk di atas.

Jangan melepaskan *mouthpiece* yang terpasang pada turbuhaler. *Mouthpiece* dapat diputar, tapi jangan memutar *mouthpiece* jika tidak diperlukan.
Jangan gunakan turbuhaler Anda jika ia sudah rusak atau jika *mouthpiece* terlepas dari turbuhaler.

Jika anda tidak sengaja melakukan prosedur pemuatan lebih dari satu kali sebelum Anda mengambil dosis, Anda tetap akan hanya menerima satu dosis. Namun, indikator dosis akan mencatat semua dosis yang dimuat. Suara yang terdengar jika Anda mengocok inhaler tidak dihasilkan oleh obat, tapi dihasilkan oleh zat pengering.

Pembersihan
Bersihkan bagian luar *mouthpiece* secara teratur (tiap minggu) dengan tisu kering.
Jangan menggunakan air untuk membersihkan *mouthpiece*.

Bagaimana cara saya tahu kapan mengganti inhaler saya?
Indikator dosis (Gambar 4) memberitahukan Anda kira-kira berapa banyak dosis yang tersisa di dalam inhaler, dimulai dengan 120 ketika terisi penuh.

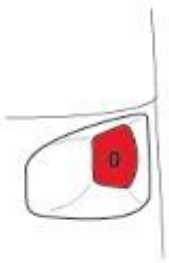


Gambar 4

Indikator ditandai dengan interval 10 dosis. Oleh karena itu, ia tidak menunjukkan pemuatan dari setiap dosis individu.

Anda harus yakin bahwa turbuhaler menghantarkan dosis meskipun Anda mungkin tidak melihat adanya perubahan pada indikator dosis.

Untuk 10 dosis terakhir, jendela indikator akan berwarna merah. Ketika angka nol berada di tengah jendela indikator (Gambar 5), saatnya bagi Anda untuk membuang inhaler.



Gambar 5

Harap diperhatikan meskipun indikator dosis menunjukkan angka nol, *grip*/pegangan masih dapat diputar. Namun, indikator dosis akan berhenti bergerak dan angka nol tetap akan berada pada jendela indikator

Pembuangan
Pastikan Anda membuang Turbuhaler bekas pakai secara bertanggung jawab / dengan cara yang disarankan karena sebagian obat masih tertinggal di dalamnya.