AERONIDE

Budesonide
Suspension for Inhalation

Name of the medicinal product
AERONIDE

Qualitative and quantitative composition
Active constituent:
Each dose contains budesonide 200 mcg

Pharmaceutical form
Suspension for inhalation.

Pharmacological properties
Pharmacotherapeutic group: Inhalation drugs for obstructive airway diseases.

ATC-code R03B A02

Budesonide is a glucocorticosteroid with a high local anti-inflammatory effect. Budesonide undergoes an extensive degree (=90%) of biotransformation in the liver to metabolites of low glucocorticosteroids. The glucocorticosteroid activity of the major metabolites, 6-beta-hydroxy-budesonide and 16-alfa-hydroxy-prednisolone, is less than 1% of that of budesonide.

Budesonide has shown anti-anaphylactic and anti-inflammatory effects in provocation studies in animals and patients, manifested as decreased bronchial obstruction in the immediate as well as the late allergic reaction.

Budesonide has also been shown to decrease airway reactivity to histamine and methacholine in hyperreactive patients. Therapy with inhaled budesonide has effectively been used for prevention of exercise-induced asthma. After a single dose, improvement ofthe lung function is achieved within a few hours.

Full effect of budesonide, as for other glucocorticosteroids, is however not achieved until after a couple of days. About 10% of the dose is deposited in the lungs. Of the fraction whichis swallowed, 90% is inactivated at first passage through the liver. The maximal plasma concentration after inhalation of 1 mg budesonide is less than 0.01 mcmol/L and is reached within 30 minutes.

Therapeutic indications
Bronchial asthma

Posology and method of administration
The dosage of AERONIDE is individual. When treatment with inhaled glucocorticosteroids is started, during periods of severe asthma and while reducing or discontinuing oral glucocorticosteroids the dosage should be:

Adults: 200 - 1200 mcg daily, divided into 2 - 4 administrations.

The maintenance dose is individual and should be the lowest possible. Administration twice daily at 200 - 400 mcg (morning and evening) is usually sufficient.

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The dosage can be increased up to 1200 mcg in severe asthma.

In patients in whom an increased therapeutic effect is desired, in general an increase of the AERONIDE dose is to be recommended in preference to combination treatment with oral corticosteroids on account of the lower risk of systemic side effects.

PATIENTS-NOT DEPENDENT ON ORAL STEROIDS:
A therapeutic effect is usually reached within 10 days. In patients with excessive mucus secretion in the bronchi, a short (about 2 weeks) additional oral corticosteroid regimen can be given initially.

PATIENTS-DEPENDENT ON ORAL STEROIDS:
When transfer from oral steroids to AERONIDE is initiated, the patient must be in a relatively stable condition. For 10 days, a high dose of AERONIDE is given in combination with the previously used oral steroid. After that the oral dose is gradually reduced (with for example 2.5 mg prednisolone or the equivalent each month) to the lowest possible level. In many cases, it is possible to completely substitute the oral steroid with AERONIDE.

Note
It is important that the inhaler is used correctly. The medication from AERONIDE is delivered to the lungs as the patient inhales and therefore it is important to instruct the patient to breathe in forcefully and deeply through the mouthpiece.
The patient may not taste or feel any medication when using AERONIDE due to the small amount of drug dispensed.
The patient should be instructed to rinse the mouth out with water after each dosing occasion.

Contraindications
History of Hypersensitivity to budesonide.

Undesirable effects
Mild irritation in the throat, coughing and hoarseness. Candida infection in the oropharynx has been reported. Coughing can usually be prevented by inhaling a beta-2-agonist, 5-10 minutes before inhalation of AERONIDE.

Immediate and delayed hypersensitivity reactions such as skin reactions (e.g. urticaria, rash, dermatitis), bronchospasm, angioedema and anaphylactic reaction may in rare cases occur in association with local corticosteroid therapy.

Psychiatric symptoms such as nervousness, restlessness and depression have been observed with budesonide as well as with other glucocorticosteroids.

In rare cases signs or symptoms of systemic glucocorticosteroid effect, including hypofunction of the adrenal gland and reduction of growth velocity, may occur with inhaled glucocorticosteroids, probably depending on dose, exposure time, concomitant and previous steroid exposure, and individual sensitivity.

Special warnings and special precautions for use
During transferal from oral steroid therapy to AERONIDE the patient may regain earlier symptoms, e.g. rhinitis, eczema and pain in muscles and joints. In these cases, a temporary increase in the dose of oral steroids is sometimes necessary. A general, insufficient steroid effect should be suspected if, in rare cases, symptoms such as tiredness, headache, nausea and vomiting should occur.

Acute exacerbations of asthma may need complementary treatment with a short oral steroid regimen.

To minimize oropharyngeal thrush and systemic effects, the patient should rinse the mouth out with water after each dosing occasion.

Special care is needed in patients with lung tuberculosis and fungal and viral infection in the airways.

Decreased liver function may affect the ability to eliminate budesonide. This may be clinically relevant in patients with severely compromised liver function.

Long-term studies show that children and adolescents treated with inhaled budesonide 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.

Pregnancy and lactation
Pregnancy
Administration during pregnancy should be avoided unless there are compelling reasons. In pregnant animals, administration of budesonide causes abnormalities of foetal development. The relevance of this finding to man has not been established.

Lactation
Budesonide is excreted in breast milk. However, at therapeutic doses of AERONIDE no effects on the suckling child are anticipated. AERONIDE can be used during breast feeding.

Interaction with other medicaments and other forms of interaction
The kinetics of budesonide was investigated in healthy subject without and with cimetidine, 1000 mg daily. After a 4 mg oral dose the values for C_{max} (nmol/L) and systemic availability (%) of budesonide without and with cimetidine (3.3 vs 5.1 nmol/L and 10 vs 12% respectively) indicated a slight inhibitory effect on hepatic metabolism of budesonide caused by cimetidine. This should be of little clinical importance.

Overdose
Acute overdosage with AERONIDE, even in excessive doses, is generally not a clinical problem.

Incompatibilities
Not applicable.

Shelf life
24 months.
The shelf life after first usage is 3 months.

Special precautions for storage
- Do Not Freeze
- Keep in tight containers, protected from the light. Store below 30°C.

Nature and contents of container
Available pack: AERONIDE is supplied in the following packs as a pressurized aluminum canister sealed with a metering valve, actuator and dust cap packaged 1 canisters, 1 canisters with Aerohaler within a paper box.

List of Excipient
Alcohol
Oleic acid
Heptafluoropropane and Tetrafluoroethane Combination

HARUS DENGAN RESEP DOKTER

Manufactured by
Inpac Pharma Co.Ltd
2,4 Soi Anamai-Ngamcharoen 24, Thakham, Bangkhuntian,
Bangkok 10150, Thailand

Imported by
PT Tempo Scan Pacific Tbk. Cikarang,
Bekasi - Indonesia

Packaging
Box, 1 canister @ 200 doses + Aerohaler (Reg. No.)
Box, 1 canister @ 200 doses (Reg. No.)

The parts of your inhaler:

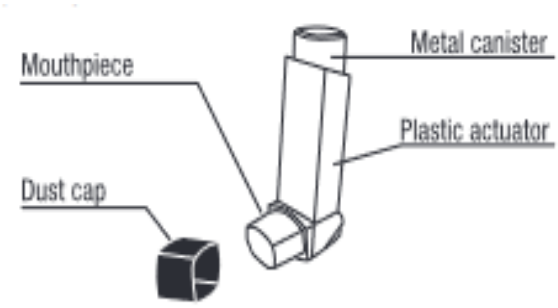

Figure 1.

There are 2 main parts to your inhaler—the metal canister that holds the medicine and the plastic actuator that sprays the medicine from the canister *(see Figure 1).*
- The inhaler also has a dust cap that covers the mouthpiece of the actuator.
- Do not use the actuator with a canister of medicine from any other inhaler.
- And do not use with an actuator from any other inhaler.

How to Use Your Inhaler

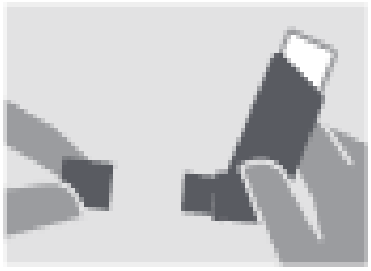

Figure 2.

Testing your inhaler

1. When using the inhaler for the first time, test that it is working. Remove the mouthpiece cover by gently squeezing the sides with your thumb and forefinger and pull apart.
2. To make sure that it works, shake it well, point the mouthpiece away from you and press the canister to release a puff into the air. If you have not used the inhaler for a week or more, release two puffs of medicine into the air

Using your inhaler

It is important to start to breathe as slowly as possible just before using your inhaler.

Figure 3.

1. Stand or sit upright when using your inhaler.
2. Remove the mouthpiece cover (as shown in the Figure 3). Check inside and outside to make sure that the mouthpiece is clean and free of objects.
3. Shake the inhaler 4 or 5 times to ensure that any loose objects are removed and that the contents of the inhaler are evenly mixed.
4. Hold the inhaler upright with your thumb on the base, below the mouthpiece.

Figure 4

Breathe out as far as is comfortable. Do not breathe in again yet.

5. Place the mouthpiece in your mouth between your teeth. Close your lips around it. Do not bite.

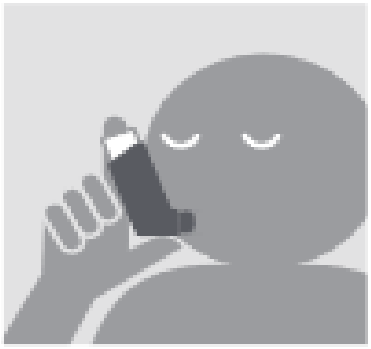

Figure 5.

6. Breathe in through your mouth. Just after starting to breathe in, press down on the top of the canister to release a puff of medicine. Does this while still breathing in steadily and deeply.

Figure 6.

7. Hold your breath, take the inhaler from your mouth and your finger from the top of the inhaler. Continue holding your breath for a few seconds, or as long as is comfortable.

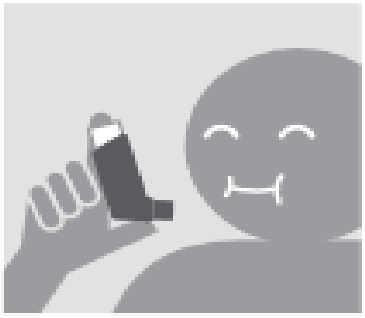

Figure 7.

8. If your doctor has told you to take two puffs, wait about half a minute before you take another puff by repeating steps 3 to 7.
9. After use always replace the mouthpiece cover straight away to keep out dust. Replace the cover by firmly pushing and clicking into position.

Cleaning your inhaler

To stop your inhaler blocking, it is important to clean it at least once a week.
To clean your inhaler:

- Remove the mouthpiece cover.
- Do not remove the metal canister from the plastic casing at any time.
- Wipe the inside and outside of the mouthpiece and the plastic casing

with a dry cloth or tissue.

- Replace the mouthpiece cover.
- Do not put the metal canister in water.

Special precautions for disposal and other handling
Handling precaution:

- Keep out of reach of children. Avoid spraying in eyes.
- Contents under pressure: Do not puncture. Do not use or store near heat or open flame.
- Exposure to temperatures above 50^0C may cause bursting. Never throw container into fire or incinerator.
- Store the inhaler with the mouthpiece down. For best results, the inhaler should be at room temperature before use. SHAKE WELL BEFORE EACH SPRAY.
- It does not contain chlorofluorocarbons (CFCs) as the propellant.