

BUDESPRAY HFA METERED DOSE INHALER

Budesonide (100mcg, 200mcg)

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What *Budespray* is used for

Budespray is indicated only for treatment of bronchial asthma.

How *Budespray* works

Budespray possesses a high local anti-inflammatory action. It works directly in the lungs to make breathing easier by reducing the irritation and swelling of the airways. After a single dose of orally inhaled *Budespray*, improvement of the lung function is achieved within a few hours.

Budespray has also been shown to decrease airway reactivity to histamine and methacholine in hyper-reactive patients.

Before you use *Budespray*

When you must not use it

Do not use *Budespray* if you are hypersensitive to Budesonide.

Pregnancy and lactation

The administration of *Budespray* during pregnancy requires that the benefits for the mother be weighed against the risk for the foetus. There is no information regarding the passage of *Budespray* into breast milk.

Tell your doctor before using *Budespray* if you are pregnant, planning to get pregnant or breastfeeding.

Before you start to use it

Tell your doctor or pharmacist if you have:

- liver impairment
- lung tuberculosis (bacterial infection)
- fungal and viral infections in the airways

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy from a pharmacy, supermarket or health food shop without a prescription. These include CYP3A4 inhibitors such as ketoconazole and itraconazole (to treat fungal infection).

How to use *Budespray*

How much to use

Adults:

200-1,600 mcg daily, in 2-4 divided doses. For maintenance treatment, use twice daily, morning and evening.

Children aged 2 – 7 years:

200 - 400 micrograms, in 2-4 divided doses.

Children aged above 7 years:

200 - 800 micrograms in 2-4 divided doses. The dose should be reduced to the minimum needed to maintain good asthma control.

Safety and efficacy of budesonide inhalation suspension have not been established in children younger than 1 year of age.

When to use it

Use as directed by your doctor or pharmacist.

How long to use it

Continue taking *Budespray* for as long as your doctor recommends.

If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Taking large amount of the medicine over a short period may cause suppression of hypothalamic-pituitary-adrenal (HPA) axis function (stress response system).

Systemic effects may occur, particularly at high doses prescribed for prolonged periods.

Possible systemic effects include:

- Adrenal suppression
- Growth retardation in children and adolescents
- Decrease in bone mineral density
- Cataract
- Glaucoma (increased pressure inside the eye).

While you are using it

Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists that are treating you that you are taking *Budespray*.

Tell your doctor immediately if you become pregnant while taking this medication.

Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give *Budespray* to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Use of corticosteroids may lead to suppression of growth in children and adolescents. Children receiving prolonged therapy with orally inhaled budesonide should be monitored periodically for possible adverse effects on growth and development.

You are advised to rinse your mouth with water after each dosing to reduce the risk of oral fungal infection.

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Side effects

Like all medicines, *Budespray* can cause side effects, although not everybody gets them. Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Common side effect include:

- Mild irritation in the throat
- Candida infection in the oropharynx
- Hoarseness
- Coughing

Rare side effect include:

- Nervousness, restlessness, depression, behavioural disturbances
- Immediate and delayed hypersensitivity reactions including rash, contact dermatitis (itchy rash caused by a substance that comes into contact with your skin), urticaria (a red, raised, itchy rash), angioedema (swelling of the deeper layers of the skin) and bronchospasm (narrowing of the airways).
- Skin bruising

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers →Reporting).

Storage and Disposal of *Budespray*

Storage

Keep out of the reach and sight of children.

Store below 30°C.

Do not store any medicine in the bathroom, or near a sink, or on a window sill.

Do not leave it in the car especially on hot days. Heat and dampness can destroy medicines.

Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

Budespray 100 HFA Inhaler is a suspension aerosol for inhalation, in propellant HFA-134a, supplied in a pressurised container. On visual examination there should be no sign of physical damage, or leakage. Colour of suspension is white.

Budespray 200 HFA Inhaler is a suspension aerosol for inhalation, in propellant HFA-134a, supplied in a pressurised container. On visual examination there should be no sign of physical damage or leakage. Colour of suspension is white.

Ingredients

Active ingredient

Budesonide

Inactive ingredient

Tetrafluoroethane (HFA-134a
Propellant)

MAL numbers:

Budespray 100 HFA Inhaler
MAL10110020AZ

Budespray 200 HFA Inhaler
MAL10110021AZ

Manufacturer

MEDISPRAY LABORATORIES PVT
LTD
344/345 Kundaim Inhl. Estate Goa,
403115, INDIA

Product Registration Holder

PAHANG PHARMACY SDN. BHD.
Lot 5979 Jalan Teratai, 5 ½ Mile Off
Jalan Meru, 41050 Klang, Selangor
MALAYSIA

Date of revision

29/12/2015

Serial Number

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