Avacort HFA 200mg Metered Dose Inhaler

Budesonide 200 mcg per puff

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What Avacort is used for:

The name of your medicine is Avacort HFA 200mcg Metered Dose Inhaler (called 'Avacort' in this leaflet). Avacort contains a medicine called Budesonide, a glucocorticosteroid, which is a type of steroid. Each puff will contain 200mcg of Budesonide.

How Avacort works:

Avacort works by reducing and preventing swelling and inflammation of the lungs.

Before you use Avacort

When you must not use it:

Do not take this medicine and tell your doctor if:

- You are allergic (hypersensitive) to Budesonide or any of the other ingredients of Avacort
- You have tuberculosis (TB)
- You have a cold or chest infection
- You have liver problems

Before you start to use it:

Check with your doctor or pharmacist before taking this medicine :

- If you are pregnant or planning to become pregnant.
- If you are breast feeding.
- If you have liver problems.
- If you are taking any steroid medicines

Taking other medicines:

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Avacort and certain other medicines may interact with each other.

Especially tell your doctor if you are taking:

- Alcoholic drinks.
- CYP3A4 Inhibitors, e.g. Ketoconazole and Itraconazole
- Oestrogens and contraceptive steroids
- Steroids

How to use Avacort

How much to use?:

The usual dose given by your doctor is one puff in the morning and one puff in the evening. But this may be be increased by your doctor, depending on your conditions.

Hence, always take Avacort as directed by your doctor. Your doctor may change your dose if needed.

When to use it?:

Avacort can be taken the morning and in the evening, with or without food.

How long to use it?:

The time period for taking Avacort depends on your doctor's instruction. Hence, follow your doctor's instruction.

If you forget to use it:

If you miss a dose, take it as soon as you remember. If it is close to your next dose, do not take the missed dose. Just take the next dose at your regular time.

If you take too much (overdose):

If you took too much Avacort, call your doctor or the Poison Control Center, or go to the nearest hospital emergency room right away.

While you are using Avacort

Things you must do:

- If you are using Avacort for the first time, please read paragraph 'Preparing your Avacort Inhaler' below.
- Take your dose at same time of the day
- Never take more doses instructed by your doctor.
- Keep taking Avacort even if you feel better until the treatment is finished, or your doctor stopped the treatment.

If you experience any side effects, or have any further questions on the use of this product, ask your doctor or pharmacist.

Things you must not do:

Do not stop taking your medication without consulting your doctor.

Things to be careful of:

- Do not use Avacort to treat asthma symptoms.
- If you have liver problems, the dose will be lowered. You may have more frequent tests to see how your liver is working.
- Pregnancy and breast-feeding: ask your doctor or pharmacist for advice before taking any medicine if you think you might be or if you are pregnant or if you are breastfeeding.

Side effects

Like all medicines, Avacort can cause side effects, although not everybody gets them:

Common side effect is thrush, ie. fungal infection of the mouth and throat, possible side effects are allergic reaction, rash, urticaria and dermatitis (inflammation) of the skin, sleep disorders, and difficulty in breathing.

User may also experience anxiety or depression and behavorial changes (mostly in children).

If any of the above happens, stop taking Avacort and see your doctor immediately.

You may also 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 npra.moh.gov.my
(Public → Reporting Medicinal Problems / Side Effects / AEFI).

Preparing your Avacort Inhaler

Before using your new Avacort HFA 200mcg Metered Dose Inhaler for the first time, or if you have not used your inhaler for more than 7 days, or it it has been dropped, you need to prime it for use as follows:

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- Remove the dust cap from the plastic adapter. Check that the mouthpiece is clean and not blocked. Shake the inhaler vigorously, so that the contents of the aerosol canister are properly mixed.
- Press the canister twice to release two puffs into the air.
- Your inhaler is now ready for use.

How to use your inhaler

Avacort HFA 200mcg Metered Dose Inhaler is used by breathing the medicine contained in the inhaler in through your mouth. It is important that you do not rush your inhaler. At first, you may need to practise using the inhaler in front of the mirror. Any mist coming from the top of the inhaler or from the mouthpiece may mean that you have not inhaled the medicine properly. Young children may need help from their parents or carers to use the inhaler. Every time you need to take an inhalation, follow the instructions below:

1. Remove the dust cap from the plastic adapter. Check that the mouthpiece is clean and not blocked. Shake the inhaler vigorously, so that the contents of the aerosol canister are properly mixed before each use.
2. Hold you inhaler upright. Breathe out as far as possible.
3. Place the mouthpiece between your lips. Do not breathe out through your inhaler at any time. Do not chew or bite on the mouthpiece. Start to breathe in slowly and deeply through your mouth. Keep breathing in and press the canister firmly to release a puff from your inhaler. You may need to use both hands to release a puff from your inhaler. Keep breathing in for a short while after pressing the canister.
4. Hold your breath for about 10 seconds or for as long as is comfortable. Take out and hold your inhaler away from your mouth. Then breathe out slowly. If you are to take a second puff, wait at least half a minute. Then shake the inhaler vigorously and repeat steps 2, 3 and 4.
5. After use, replace the dust cap on the plastic adapter. Store your inhaler so that it is sitting upright on its plastic base.
6. Rinse your mouth with water and spit it out.

Using inhaler with a Nebu Chamber spacer device

A Nebu chamber spacer device may be provided to you by your doctor or obtained from a pharmacy. Ask to ensure that it is the suitable one for your inhaler, when receiving it.

It is a device fixed to the inhaler to assist you in inhaling the required dose.

The mouthpiece of your inhaler fits directly into one end of the Nebu Chamber spacer device, and the other end to your mouth.

When a child is using the Nebu Chamber spacer device, it is important to hold and support the spacer device in the child's mouth and to ensure that the child breathe through the space device properly.

A facemask is provided for young children who cannot breathe through the mouthpiece of the spacer device.

Cleaning your inhaler

Clean the inhaler once a week. Remove the dust cap and the aerosol canister. Clean the plastic actuator and dust cap with a dry cloth or tissue. Then, replace the aerosol canister and dust cap. Do not put the inhaler into water.

Storage and disposal of Avacort

Storage:

- Keep out of the reach and sight of children.
- Store in the original pack in a dry place at or below 30^0C.
- Store in the position as indicated by the arrow with wordings 'KEEP UPRIGHT' on the box.
- After use, always replace the dust cap.
- Do not use Avacort after the expiry date refers to the last day on the carton. 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 helps to protect the environment.

Warning: The canister contains a pressurized liquid. Do not expose to temperature higher than 50^0C. Do not pierce the canister. The canister should not be broken, puncture or burnt, even when it seems to be empty.

Product Description

What it looks like:

Avacort HFA 200mcg Metered Dose Inhaler is a one-piece aluminum pressurized container, containing liquid under pressure, with no foreign or unpleasant odor, administered via a 50 µl metering valve.

Ingredients in Avacort

Active ingredients: One metered dose contains 200 micrograms of budesonide.

Inactive ingredients:
It contains ethanol, polyethylene glycol and Propellant HFA134a.

Manufacturer:

Synmosa Biopharma Corporation, Synmosa Plant,
No. 6, Kuang Yeh 1st Road, Hu-Kao Hsiang, Hsin-Chu Ind. Park, Hsin Chu Hsien, Taiwan, R.O.C

Product Registration holder:

Nano Medic Care Sdn Bhd
No. 1-6 & 1-12, 1st floor, Jalan Indah 2, Taman Indah,
84000 Muar, Johor, Malaysia

Malaysia Registration No.: MAL

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