

Vannair[®] 100/6 and Vannair[®] 200/6

Budesonide/formoterol, 100/6 or 200/6 micrograms per dose.

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some of the common questions people ask about **Vannair**. It does not contain all the information that is known about **Vannair**. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor will have weighed the risks of you taking **Vannair** against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Vannair is used for

Vannair is used to treat the inflammation caused by asthma. It also widens the airways so that you find it easier to breathe. To get the best effect, you should use **Vannair** as prescribed by your doctor, even when you have no symptoms.

Vannair is also used to treat Chronic Obstructive Pulmonary Disease (COPD). COPD (which includes chronic bronchitis and emphysema) is a long term lung disease. There is often permanent narrowing and persistent inflammation of the airways. Symptoms may include difficulty in breathing (breathlessness or wheezing), coughing and increased sputum. **Vannair** when used as prescribed will help to control your COPD symptoms (i.e. breathing difficulties).

Vannair contains the medicines budesonide and formoterol, which have different ways of treating your condition.

Budesonide acts directly on your airways to reduce and prevent this inflammation.

Formoterol works by opening your airways, making it easier for you to breathe. This effect starts within 1-3 minutes after inhaling the medicine and lasts for up to 12 hours. When you breathe in through the mouthpiece of the inhaler, your breath carries the medicine to your lungs. See the **Vannair** instructions in the pack.

Asthma: Using **Vannair** regularly will help prevent asthma attacks and make it easier to breathe normally. It is not used to treat an asthma attack.

COPD: **Vannair** when used as prescribed will help to control your COPD symptoms (i.e. breathing difficulties).

Your doctor will have explained to you why you are being treated with **Vannair**, when you should use your **Vannair** and how many doses you should take.

Vannair is not addictive. **Vannair** is available only with a doctor's prescription.

Before you use Vannair

When you must not use it

Do not use Vannair to treat an asthma attack.

Do not use Vannair if you are pregnant or breast feeding unless your doctor says to do so.

Ask your doctor about the risks and benefits involved.

Do not use Vannair after the use by (expiry) date printed on the pack. It may have no effect at all, or worse, an entirely unexpected effect if you take it after the expiry date.

Do not use Vannair if the packaging is torn or shows signs of tampering.

Vannair has been prescribed for your asthma. Do not use it to treat any other complaints unless your doctor tells you to. Do not lend your Vannair inhaler to anyone else even if their symptoms seem similar to yours.

You must tell your doctor if:

1. you have any allergies to

- Formoterol, budesonide, apafurane (HFA 227), povidone K25 or macrogol (polyethylene glycol) 1000.

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If you have an allergic reaction, you may get a skin rash, hay fever or an asthma attack.

2. you have any of these medical conditions

- thyroid problems
- diabetes
- heart problems
- tuberculosis
- low potassium blood levels.

It may not be safe for you to take **Vannair** if you have any of these conditions.

You should tell your doctor if you have any of the following symptoms, which could be signs of chest infection: fever or chills, increased mucus production or change in mucus colour, increased cough or increased breathing difficulties.

Taking other medicines

You must tell your doctor if you are taking any other medicines, including

- medicines used to treat heart problems or high blood pressure
- medicines for glaucoma, including eye drops
- medicines used to treat fungal infections
- medicines used to treat depression
- any other medicine that you buy at the chemist, supermarket or health food shop.

These medicines may be affected by **Vannair**, or may affect how well it works.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

If you have not told your doctor about any of these things, tell him/her before you take Vannair.

Special warnings

You must contact your doctor as soon as possible if you need to use your rescue medicine inhaler more often than usual to control your airway disease. **Do not increase the dose of Vannair without talking to your doctor.** Always carry your rescue medicine with you.

You should always be very careful with the use of medicines if you are pregnant or breastfeeding. If you do become pregnant while using **Vannair** you should contact your doctor as soon as possible.

Using Vannair

Your doctor will have explained why you are being treated with **Vannair** and told you what dose to take. **Follow carefully all directions given to you by your doctor.** They may differ from the information contained in this leaflet.

Vannair produces a fine spray that follows your breath into your lungs. Make sure you know how to use your inhaler properly.

Each pack of **Vannair** contains an instruction leaflet that tells you the correct way to use it. Please read this carefully. If you are unsure about how to use your inhaler, ask your doctor or pharmacist. **Be sure to rinse your mouth out with water after using Vannair each time.** If you don't you are more likely to develop thrush in your mouth.

ASTHMA

Vannair 100/6

Usual doses for adults and adolescents 12 years and older: 2 inhalations once or twice daily. Your doctor may prescribe doses up to a maximum of 4 inhalations daily.

Usual doses for children (6 years and older): 2 inhalations twice daily. Maximum daily dose: 4 inhalations.

Vannair 200/6

Usual doses for adults and adolescents 12 years and older: 2 inhalations once or twice daily. Your doctor may prescribe doses up to a maximum of 4 inhalations daily.

Always take the number of inhalations that your doctor tells you to take.

If you have an Asthma Action Plan that you have agreed with your doctor, follow it closely at all times.

COPD

Vannair 200/6

Usual doses for adults: 2 inhalations twice a day. Your doctor may prescribe doses up to a maximum of 4 inhalations daily.

Your doctor should tell you the best way to manage your symptoms and any exacerbations. This may include additional medicines (such as “reliever” medicines) to use when you have sudden attacks of breathlessness.

If you are using more inhalations of your reliever medicine or you are wheezing or breathless more than usual tell your doctor.

If your COPD gets worse, your doctor may give you some additional medicines (such as oral corticosteroids or antibiotics).

If you forget to take it

If you miss a dose, it is not necessary to make up for the dose you have missed. Just take it when the next dose is due.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

While you are using Vannair

Take your Vannair regularly for your asthma, even if you feel well.

See your doctor regularly to make sure that your asthma is not getting worse. Your Vannair dose will be changed (up or down) by your doctor depending on your condition.

Things you must not do

Do not stop taking Vannair for your asthma unless you have discussed it with your doctor.

Do not use **Vannair** to relieve asthma attacks.

Do not increase the dose of Vannair without talking to your doctor. You must contact your doctor as soon as possible if you need to use your rescue medicine inhaler more often than usual to control your airway disease. Always carry your rescue medicine with you.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Vannair. Ask them to answer any questions you may have.

Usually you do not feel any side effects when you use **Vannair**. However, be sure to tell your doctor if any of the following side effects bother you or if any other unusual effects bother you:

Common side effects

- mild irritation in the throat
- coughing
- hoarseness
- thrush (fungal infection in mouth and throat)
- headache
- trembling
- rapid heartbeat
- pneumonia in patients with COPD

Less common side effects

- sleep difficulties
- restlessness, nervousness and anxiety
- dizziness
- vomiting / nausea
- muscle cramps

Rare side effects

- skin rash and bruising
- itching
- irregular heartbeats
- facial swelling
- spasm in the airways
- high blood sugar levels
- depression
- chest pain
- behavioural symptoms

Important: This leaflet alerts you to some of the situations when you should call your doctor. Other situations, which cannot be predicted, may arise. Nothing in this leaflet should stop you from calling your doctor or pharmacist with any questions or concerns you have about using **Vannair**.

Tell your doctor if you notice anything else that is making you feel unwell or bothering you.

Overdose

Use only the number of inhalations your doctor has prescribed. Using more will increase the risk of side effects.

The most common symptoms and signs that may occur after overdosage are:

- trembling
- headache
- rapid heartbeat

If you use too much **Vannair** over a longer period (months) it is possible that you may get side effects related to budesonide. **If you think this may have happened to you or if any of the above mentioned symptoms bother you, please discuss it with your doctor or pharmacist.**

Please telephone your doctor or the National Poisons Information Centre Ph: 0800 POISON (0800 764 766) or go to Accident and Emergency at your nearest hospital immediately if you think that you or anyone else may have taken too much Vannair, even if there are no signs of discomfort or poisoning.

After using it

Cleaning

The Vannair mouthpiece must be wiped with a clean dry tissue and must never get wet.

Clean your inhaler at least once a week. It is important to keep your inhaler clean and dry.

Full instructions on the right way to use and clean the inhaler are inside each pack.

Storage

Vannair should be kept below 30°C. Always replace the mouthpiece cover after using the inhaler.

Discard Vannair 3 months after removing from the foil overwrap. Once the foil overwrap is opened and the inhaler is removed, write the use by date immediately on the canister label.

Do not store Vannair or any other medicine in the bathroom or near a sink. Heat and dampness can destroy some medicines.

Keep Vannair where young children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not leave Vannair in the car on hot days.

Disposal

Do not tamper with the inhaler. The canister is pressurised, do not puncture or burn it, even when it is empty. Ask your pharmacist what to do with any Vannair you have left over if your doctor tells you to stop taking it, or you find that the expiry date has passed.

Product description

Vannair is a pressurised metered dose inhaler, comprising of an internally coated aluminium can, sealed with a metering valve and fitted into a red plastic actuator.

Vannair contains budesonide and formoterol fumarate dihydrate as the active ingredients. The other ingredients are Apaflurane (HFA 227), Povidone K25 and Macrogol (polyethylene glycol) 1000.

Vannair contains 120 doses.

Vannair 100/6: Each inhalation contains budesonide equivalent to 100 micrograms metered dose and formoterol equivalent to 6 micrograms metered dose.

Vannair 200/6: Each inhalation contains budesonide equivalent to 200 micrograms metered dose and formoterol equivalent to 6 micrograms metered dose.

The inhaler is made of plastic parts.

Marketed by:

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