1.3.2 PATIENT INFORMATION LEAFLET (APPROVED)

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S 4**

Vannair® 80:4,5 Inhaler

Vannair® 160:4,5 Inhaler

Budesonide:formoterol fumarate dihydrate

Budesonide and formoterol fumarate dihydrate (hereafter referred to as formoterol).

Read all of this leaflet carefully before you start taking VANNAIR

- Keep this leaflet. You may need to read it again. This leaflet contains information about VANNAIR and how to use and clean the device. You may find that you need to clean your inhaler regularly (at least weekly). Please follow cleaning the instructions at the end of this leaflet.
- If you have further questions, please ask your doctor or pharmacist.
- VANNAIR has been prescribed for you personally and you should **not** share your medicine with other people. It may harm them, even if their symptoms are similar to yours.

What is in this leaflet

1. What VANNAIR is and what it is used for
2. What you need to know before you take VANNAIR
3. How to take VANNAIR
4. Possible side effects
5. How to store VANNAIR
6. Contents of the pack and other information.

1. What VANNAIR is and what it is used for

VANNAIR is a pressurised inhalation suspension (an aerosol spray allowing you to inhale the medication) containing the medicines budesonide and formoterol which have different ways of treating your airway disease (asthma or Chronic Obstructive Pulmonary Disease [COPD]). Asthma and COPD are caused by a type of chronic inflammation in the airways. Budesonide reduces and prevents this inflammation. Formoterol widens your airways and makes it easier for you to breathe. You should notice this within a short period of time after you have inhaled the medicine into your lungs and the effect lasts for up to 12 hours.

When you breathe in through the mouthpiece of the inhaler, the medicine is delivered directly into your lungs where it is needed (see "Instructions for use" at the end of this leaflet for the correct way to use your inhaler).

Each inhaler, after initial priming (2 puffs into the air the first time you use it), contains 120 puffs of budesonide and formoterol. Each inhaler is individually wrapped in a foil pouch containing a desiccant. Throw away the desiccant (in a place where it cannot harm children or pets) once the package is opened and the inhaler removed.

2. What you need to know before you take VANNAIR

Do not use VANNAIR

If you have had any unusual reactions to budesonide, formoterol, apaflurane (HFA 227), macrogol 1000, povidone K25 (which are the ingredients in VANNAIR) or to any other medicines.

Warnings and precautions

Before taking VANNAIR tell your doctor, pharmacist or other health care professional:

- If you currently have or have had, a heart disorder such as irregular heartbeat, high blood sugar (diabetes mellitus), problems with your thyroid (thyrotoxicosis) or low potassium in your blood (hypokalaemia).
- If you are already taking any other medicines including those you have bought without a prescription.
- If you are already taking medicines for allergy, high blood pressure, heart conditions, fungal infections, depression and also some types of eye drops.

VANNAIR has been prescribed for your airway disease (asthma or COPD). Never lend your VANNAIR to someone else, even if they have the same symptoms as you.

Other medicines and VANNAIR

Always tell your healthcare proffesional if you are taking any other medicine. (This includes complementary or traditional medicines.)

- If you are taking ketoconazole (medicine for fungal infections) for longer than 2 weeks, it can increase the amount of the budesonide component of VANNAIR in the body.
- Quinidine, disopyramide, procainamide, phenothiazines, antihistamines, monoamine oxidase inhibitors and tricyclic antidepressants can increase the risk of irregular heartbeat.
- Some medicines for high blood pressure, heart conditions, fungal infections, depression and some eye drops may alter the effect of VANNAIR if you use them at the same time.

Pregnancy, breastfeeding and fertility

Before you start using VANNAIR, tell your doctor if you are pregnant, trying to become pregnant or if you are breastfeeding. If you become pregnant while using VANNAIR, you should tell your doctor as soon as possible. You should not stop taking the medicine without discussing this with your doctor.

If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other health care professional for advice before using VANNAIR.

Driving and using machines

VANNAIR is not expected to affect your ability to drive or to operate any tools or machines.

3. How to take VANNAIR

Do not share medicines prescribed for you with any other person.

Always take VANNAIR exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

- VANNAIR produces a fine spray that follows your breath into your lungs. Make sure you know how to use your inhaler properly.
- Before you start using VANNAIR for the first time, it is important that you read the information "Instructions for use" at the end of this leaflet and follow the instructions carefully.

- The dosage of VANNAIR is individualised. It should be taken regularly, even when you have no symptoms. Your doctor will adjust your medicine to the lowest dose that controls your asthma or COPD. Follow your doctor's directions carefully. The directions may be different from the information contained in this leaflet.
- Take your VANNAIR regularly even when you have no symptoms.
- If you have the impression that the effect of VANNAIR is too strong or too weak, talk to your doctor or pharmacist.
- Do not increase the dose of VANNAIR without talking to your doctor.
- **Tell 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.**
- Young children may have difficulties in handling VANNAIR. It is therefore necessary to make sure that the child can follow the instructions for use.
- **Do not use VANNAIR to treat a severe asthma attack. Use your emergency rescue medicine inhaler in this case.**

Remember: Always rinse your mouth out with water after each dosing occasion!

PLEASE NOTE: The VANNAIR inhaler must not be taken apart. The VANNAIR canister must only be used with the VANNAIR actuator and, the VANNAIR actuator must not be used with any other inhalation product.

If you take more VANNAIR than you should

It is **important** to use only the number of puffs your doctor has prescribed. If you use more than the recommended dose you will increase the risk of side effects.

The most common symptoms and signs that may occur after overdosage are: trembling, headache and 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.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take VANNAIR

Do not take a double dose to make up for the forgotten individual dose. Just take the next dose as prescribed.

4. Possible Side effects

VANNAIR can have side effects.

Not all side effects reported for VANNAIRare included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking VANNAIR, please consult health care provider for advice.

Contact your doctor if any of the following side effects bother you or if any other unusual effects bother you.

Frequent:

- Irritation in the throat,
- Coughing,
- Hoarseness,
- Thrush (fungal infection in the mouth and throat),
- Headache,
- Trembling [and]
- Rapid heartbeat.
- Pneumonia in COPD patients

Less frequent:

- Sleep difficulties
- Restlessness and nervousness,
- Dizziness,
- Nausea,
- Muscle cramps and agitation,
- Skin rash,
- Itching,
- Spasm in the airways,



- Irregular heartbeats,
- Skin bruising,
- Severe allergic reactions,
- High blood sugar levels,
- Facial swelling,
- Depression,
- Behavioural disturbances
- Chest pain.

Should your general health worsen or if you experience any untoward effects while taking VANNAIR please consult your doctor, pharmacist or other health care professional for advice.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects you can help provide more information on the safety of VANNAIR

5. How to store VANNAIR:

Store at or below 30 °C.



Store all medicines out of reach of children.

Always replace the mouthpiece cover after using VANNAIR.

Once you have removed the inhaler from the foil wrapper, you must use the product within 3 months of opening it. Do not use VANNAIR after the shelf-life expiry date. Once the foil wrapper is opened and the inhaler is removed, mark/write the use by date immediately on the inhaler label.

Return all unused medicine to your pharmacist. Always be sure to dispose of your used VANNAIR responsibly, since some of the medicine will remain inside it. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Do not tamper with the inhaler. The canister is pressurised, please do not puncture or burn it, even when empty.

6. Contents of the pack and other information

6.1 What VANNAIR contains

VANNAIR contains a suspension that can be inhaled. The active ingredients are budesonide and formoterol.

The other ingredients are apaflurane (HFA 227), macrogol (polyethylene glycol) 1000 and povidone K25.

There are 2 strengths of VANNAIR:

VANNAIR 80:4,5 µg (micrograms)/puff: Each single puff contains 80 µg budesonide and 4,5 µg formoterol.

VANNAIR 160:4,5 µg (micrograms)/puff: Each single puff contains 160 µg budesonide and 4,5 µg formoterol.

6.2 What VANNAIR looks like and contents of the pack

VANNAIR consists of a canister, actuation counter, shield component and actuator. The actuation counter is attached to the base of the canister, then fitted into a plastic actuator with a white mouthpiece and a grey dust cap. VANNAIR is a pressurised container, comprising an internally coated aluminium canister, sealed with a metering valve and fitted into a plastic actuator.

Each inhaler is individually wrapped in a foil laminate pouch containing a desiccant. Throw away the desiccant (in a place where it cannot harm children or pets) once the package is opened and the inhaler removed.

Each inhaler delivers 120 puffs of budesonide/formoterol 80:4,5 or 160:4,5 µg after initial priming (release 2 puffs in the air the first time you use it).

The canister contains a white to off-white suspension.

Holder of certificate of registration

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VANNAIR 80:4,5: A39/21.5.1/0506

VANNAIR 160:4,5: A39/21.5.1/0507

Access to the corresponding Professional Information

TBD

INSTRUCTIONS FOR USE/HANDLING:

Please read all the following instructions carefully before using your inhaler.

Information about your VANNAIR inhaler:

- Your doctor, nurse or pharmacist should instruct you on the correct use of your inhaler.
- Your inhaler will already be assembled when you first receive it. Please do not take your inhaler apart. If it becomes loose, then place it back and continue to use it as instructed.
- Before starting to use your VANNAIR inhaler, remove it from the foil wrapper. Throw away the wrapper as well as the drying agent, which is inside the wrapper. If the drying agent has leaked out of its packet, do not use the inhaler.
- After you have taken the inhaler out of its foil wrapper, you should use it within 3 months. Write the use by date (3 months from opening the wrapper) on the inhaler label to remind you when to stop using the inhaler.
- The parts of your inhaler are shown in the picture (Figure 1).

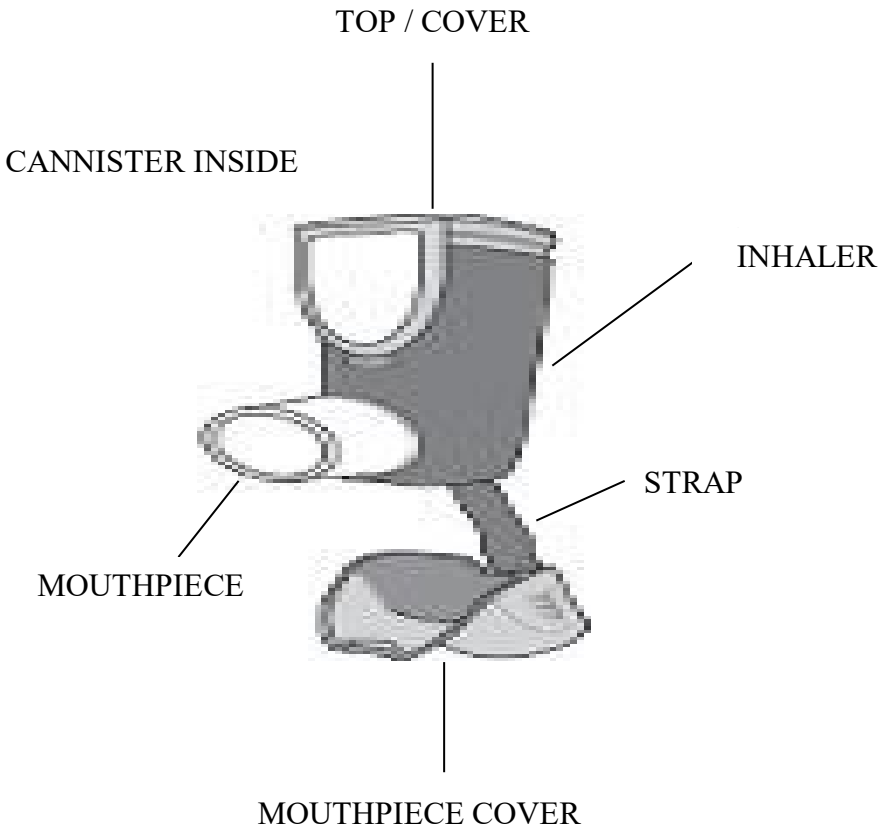


Figure 1

Preparing your VANNAIR inhaler:

You need to prepare your inhaler for use in the following situations:

- If you are using your new VANNAIR inhaler for the first time.
- If you have not used it for more than 7 days.
- If it has been dropped.

To prepare your inhaler for use, follow the instructions below:

1. Shake the inhaler well to mix the contents of the aerosol canister.
2. Remove the mouthpiece cover by pressing lightly on the bumps on the side. The strap on the mouthpiece cover will stay attached to the inhaler.
3. Hold the inhaler upright. Then press the counter (on the top of the inhaler) to release a puff into the air. You can use 1 or both hands, as shown in the pictures (Figure 2 and 3).



Figure 2

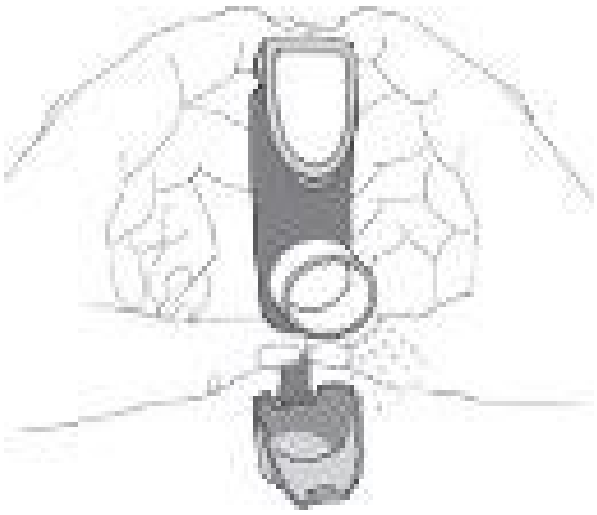


Figure 3

4. Release your finger(s) from the counter.
5. Wait for 10 seconds, shake well and then repeat steps 3 and 4.
6. Your inhaler is now ready for use.

How to take an inhalation:

Each time you need to take an inhalation, follow the instructions below:

1. Shake the inhaler well to mix the contents of the aerosol canister.

2. Remove the mouthpiece cover by pressing lightly on the bumps on the side. Check that the mouthpiece is not blocked.

3. Hold your inhaler upright in front of your mouth, using your thumb(s) at the base of the inhaler and your index finger(s) on the top. Breathe out gently.

4. Place the mouthpiece gently between your teeth. Close your lips (Figure 4).

5. Start to breathe in slowly and deeply through your mouth. Press the counter (on the top of the inhaler) firmly to release a puff. Keep breathing in for a short **w**hile after pressing the counter.



Figure 4

6. Continue to breathe in and hold your breath for approximately 10 seconds, or for as long as it is comfortable.

7. Before you breathe out, release your finger from the counter and remove the inhaler from your mouth. Keep the inhaler upright.

8. To take another inhalation, shake the inhaler well for 5 seconds and repeat steps 3 to 7.

9. Replace the mouthpiece cover. Always store your VANNAIR inhaler so that it stands upright on its red plastic base.

10. Rinse your mouth with water after your daily morning and or/evening doses and spit it out.

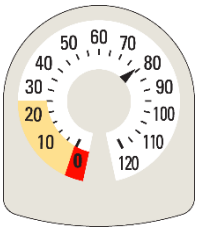
Cleaning your VANNAIR inhaler:

Your inhaler mouthpiece will need to be cleaned regularly, at least once a week and to do this you will need to:

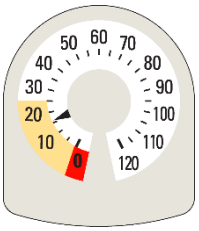
1. Remove the mouthpiece.
2. Wipe the inside and outside of the mouthpiece opening with a clean, dry cloth.
3. Replace the mouthpiece cover.
4. Do not put the inhaler in water.
5. Do not try to take the inhaler apart.

How will I know when to replace my VANNAIR inhaler?

READING THE COUNTER:



- The arrow on the counter on the top of the inhaler points to the number of inhalations (puffs) remaining in your inhaler.
- The counter will count down towards zero (‘0’) each time you release a puff of medicine (either when preparing your inhaler for use or when taking the medicine.



- When the arrow on the counter enters the yellow area, this means that there are about 20 puffs left.
- It is very important that you note the number of inhalations (puffs) remaining in your VANNAIR inhaler

by reading the counter. Discard VANNAIR after the counter reaches zero ('0'), indicating that you have used the number of inhalations on the product label and box. Your inhaler may not feel empty and it may continue to operate, but you will not get the right amount of medicine if you keep using it.

REMEMBER:

VANNAIR has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

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