

Tilade[®]

CFC-Free Inhaler (TIE-laid)

nedocromil sodium (ned-oh-crow-mill so-dee-u m)

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Tilade CFC-Free Inhaler.

It does not contain all the information that is known about Tilade CFC-Free. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Tilade CFC-Free against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What Tilade CFC-Free is used for

Tilade CFC-Free is inhaled into the lungs for the preventive treatment of mild to moderate asthma.

Asthma is a disease where the lining of the lungs becomes inflamed (red and swollen), making it difficult to breathe. This may be due to an allergy to house dust mites, pollens, smoke, air-borne pollution or other irritants.

Tilade CFC-Free is used to prevent bronchial asthma due to allergy, exercise, cold air or irritants, in both adults and children over two years of age.

Tilade CFC-Free works by reducing the inflammation of the airways which occurs in asthma.

With regular use, Tilade CFC-Free will help prevent asthma symptoms from occurring.

Tilade CFC-Free will not relieve the symptoms of an asthma attack once the attack has started.

You should follow your doctor's advice and prescribed treatment to get relief from a sudden asthma attack.

Your doctor may have prescribed Tilade CFC-Free for another reason.

Ask your doctor if you have any questions about why Tilade CFC-Free has been prescribed for you.

This medicine is only available with a doctor's prescription.

There is no evidence that Tilade CFC-Free is addictive.

This product contains HFA-227, a non-ozone depleting propellant gas, which has been introduced as a replacement for the environmentally damaging chlorofluorocarbons (CFC's). This product contains no CFC's.

Before you use Tilade CFC-Free

When you must not use it

Do not use Tilade CFC-Free if you have an allergy to Tilade CFC-Free or any of the ingredients listed at the end of this leaflet.

If you have an allergic reaction you may get a skin rash, have difficulty in breathing, get symptoms of hayfever or feel faint.

Do not use Tilade CFC-Free after the expiry date (EXP) printed on the pack.

If you use this medicine after the expiry date has passed, it may not work as well.

Do not use Tilade CFC-Free if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start using Tilade CFC-Free, contact your doctor or pharmacist.

Before you use it

Ask your doctor to write an asthma management plan for you before you begin to use Tilade CFC-Free.

Tilade CFC-Free is only one part of a general plan to help you manage your asthma.

You should discuss this plan regularly with your doctor to check your treatment.

As part of your asthma management plan you will probably need to take another sort of medicine called a "reliever" to relieve the symptoms of an asthma attack which has started.

If you need treatment for a sudden asthma attack, use the "reliever" medicine your doctor has prescribed for you.

Tell your doctor or pharmacist if you have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.

Tell your doctor or pharmacist if you are breast-feeding or plan to breast-feed.

Tilade CFC-Free is not known to be harmful in pregnancy or while breast-feeding.

However, if you are pregnant or breast-feeding, you should discuss with your doctor the risks and benefits involved, before using Tilade CFC-Free.

Taking other medicines

Tell your doctor or pharmacist if you are using any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Tilade CFC-Free can be used with most other medicines which are used to prevent or treat asthma.

How to use Tilade CFC-Free

If you are not sure how to use an inhaler, ask your doctor or pharmacist.

Children should only use their inhaler on medical advice and with the help of an adult.

If the inhaler is new, it should be primed by pressing the inhaler 4 times before using. If the inhaler is not used for more than 3 days, prime it with 2 puffs before using.

It is important to use Tilade CFC-Free inhaler exactly as your doctor or pharmacist has told you.

How much to use

Your doctor will tell you how many puffs to take each day. The usual

dose is two puffs two to four times daily. Take Tilade CFC-Free only as prescribed by your doctor and follow his or her directions carefully.

Do not use it more often than prescribed.

How to use it

It is important that these instructions are followed closely to make sure the correct dose of Tilade CFC-Free reaches your lungs.

- 1. Remove the cap from the plastic mouthpiece.**



- 2. Shake the inhaler well.**
- 3. Hold the inhaler well away from your mouth. Breathe out slowly. DO NOT BREATHE OUT THROUGH THE INHALER. It will clog the inhaler valve.**



- 4. Place the inhaler in your mouth and close your lips around it. While breathing in slowly and deeply, press the metal canister firmly and continue to breathe in.**



- 5. Remove the inhaler from your mouth. Hold your breath for 10 seconds, or for as long as is comfortable. Then breathe out slowly.**



- 6. Wait 1 minute then repeat steps 2 to 5 if another puff is required.**
- 7. After use, replace the cap on the mouthpiece.**

This is one of several acceptable inhalation techniques for aerosols.

If your doctor or pharmacist has suggested another method, you should use that method.

Good inhaler technique is essential and should be checked frequently.

When to use it

It is important that you continue taking Tilade CFC-Free, even when you are feeling well, to achieve the best result from this medication.

If you are not sure when to use it, ask your doctor or pharmacist.

If you forget to use it

If you forget to use your Tilade CFC-Free inhaler, just take the next dose when it is due, and then go back to using your medicine as you would normally.

Do not use a double dose to make up for the dose that you missed.

If you are not sure what to do, ask your doctor or pharmacist.

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

How long to use it

Tilade CFC-Free helps control your condition. Therefore you must use Tilade CFC-Free every day. Continue using the medicine for as long as your doctor or pharmacist tells you.

Do not stop using it unless your doctor or pharmacist tells you to - even if you feel better.

If you take too much (overdose)

Excessive inhalation of the aerosol should be avoided as large doses of the propellants may be hazardous.

In the case of accidental overdose immediately ask your doctor or Poisons Information Centre (Australia telephone 13 11 26 or New Zealand telephone 0800 764 766) for advice.

While you are using it

Things you must do

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

Continue using Tilade CFC-Free for as long as your doctor or pharmacist tells you.

Visit your doctor regularly to check on your asthma condition.

Good inhaler technique is very important and should be checked by your doctor regularly. Your doctor or pharmacist may suggest you use a spacer device to help you.

Tell any other doctors, dentists and pharmacists who are treating you that you are using Tilade CFC-Free.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are using Tilade CFC-Free.

If you become pregnant, while using Tilade CFC-Free, tell your doctor or pharmacist.

Things you must not do

Do not take any other medicines for your breathing problems without checking with your doctor.

Do not give Tilade CFC-Free to anyone else, even if they have the same condition as you.

Do not use Tilade CFC-Free to treat any other complaints unless your doctor or pharmacist tells you to.

Do not stop using Tilade CFC-Free or lower the dosage, without checking with your doctor or pharmacist.

Do not use Tilade CFC-Free to relieve acute attacks of asthma. If you become wheezy or tight in the chest, use a 'reliever puffer' in the usual way.

Side Effects

All medicines have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor or pharmacist has weighed the risks of using this medicine against the benefits they expect it will have for you.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Tilade CFC-Free.

It helps most people with asthma, but it may have unwanted side effects in a few people.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- fever
- headache
- nausea
- vomiting
- stomach upset or stomach pains

These side effects are usually mild and short-lived.

The following side effects can occur with any inhaled medicine:

- cough, sore throat
- unpleasant taste in your mouth
- breathing difficulties

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

Other side effects not listed above may occur in some people.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

If you get any side effects, do not stop using Tilade CFC-Free without first talking to your doctor or pharmacist.

After using it

Cleaning Instructions

This pack contains an extra mouthpiece which can be used while the other mouthpiece is being dried after washing.

Tilade does not contain CFC, which harms the environment, and contributes to the depletion of the ozone layer. The propellant used is more environmentally friendly and is in keeping with our responsibility to support the phasing out of all CFC-containing products. Unfortunately, this propellant tends to result in some blockage in the mouthpiece which can only be prevented by daily cleaning and drying of the mouthpiece. It is therefore very important to keep Tilade CFC-Free inhaler clean and dry to prevent the build up of excess powder in the mouthpiece which can then be difficult to remove and cause blockage to occur.

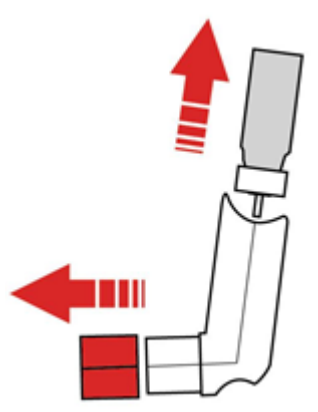
YOUR MOUTHPIECE MUST BE REGULARLY CLEANED AND DRIED.

FOR BEST RESULTS WASH MOUTHPIECE EVERY NIGHT

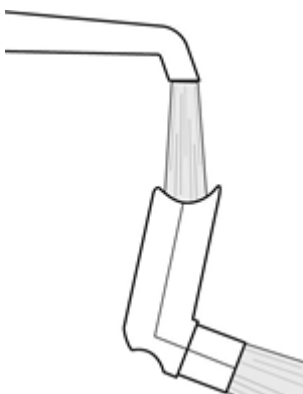
TO PREVENT BUILD UP OF EXCESS POWDER WHICH CAN CAUSE A BLOCKAGE.

Follow Instructions Below

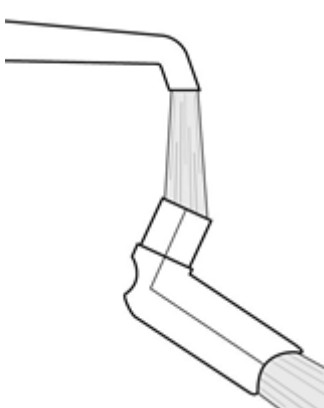
1. Remove cap and metal canister from mouthpiece before washing.



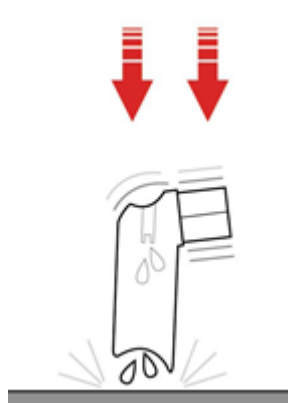
2. Wash the plastic mouthpiece in hand-hot water through the top for a minute.



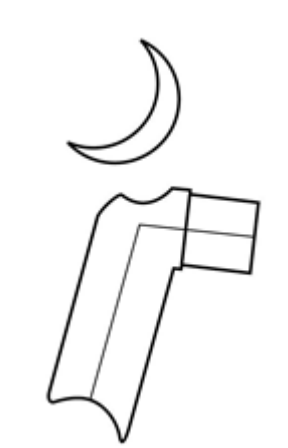
3. Wash through the bottom for a minute.



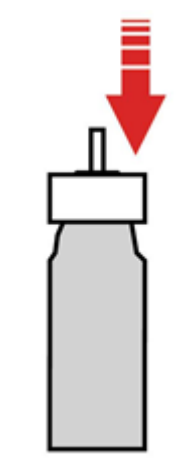
4. Shake out excess water from inside by tapping the mouthpiece on a hard surface.



5. Leave overnight or as long as possible to dry thoroughly. In humid conditions you may need to leave the mouthpiece to dry for a longer period of time.



6. Before replacing the canister into the mouthpiece make sure that the white rubber cap firmly sits onto the metal canister.

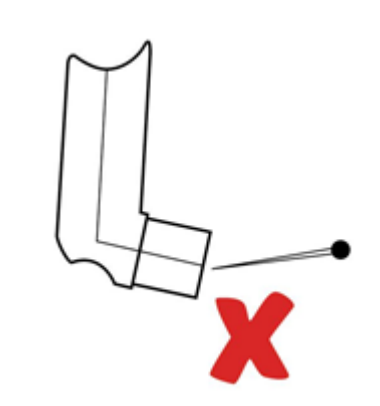


7. When the mouthpiece is completely dry replace the metal canister.

IMPORTANT:

Never try to unblock the mouthpiece with a pin - this will

damage the inhaler. Never wash the metal canister.



If the inhaler is blocked you may wish to take the added step of soaking the mouthpiece in hot water for 20 minutes after removing the canister, then following steps 2 - 7 above.

For further instructions please call Australia 1800 818 806 or New Zealand 0800 283 684.

Storage

Keep your inhaler in a cool dry place where the temperature stays below 30°C. Do not freeze. Protect from light.

Do not leave Tilade CFC-Free in the car on hot days or on window sills.

Heat, light and dampness can destroy some medicines.

Do not store Tilade CFC-Free or any other medicine in the bathroom or near a sink or stove.

Keep Tilade CFC-Free where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above ground is a good place to store medicines.

Disposal

If your doctor or pharmacist tells you to stop using Tilade CFC-Free or it has passed its expiry date, ask your pharmacist what to do with any that are left over.

Do not puncture the container or throw it into a fire.

Product description

What it looks like

Tilade CFC-Free Inhaler is supplied in a canister containing 112 puffs and an additional mouthpiece.

Ingredients

Active ingredient:

- 2mg nedocromil sodium per puff

Inactive ingredients:

- 1,1,1,2,3,3,3-heptafluoropropane
- povidone
- macrogol 600
- menthol.

Tilade CFC-Free does not contain any chlorofluorocarbons (CFCs).

Sponsor

Distributed in Australia by:

sanofi-aventis australia Pty Ltd

12-24 Talavera Road

Macquarie Park, NSW 2113

Freecall No: 1800 818 806

Distributed in New Zealand by:

sanofi-aventis new zealand limited

Level 8, James & Wells Tower

56 Cawley Street

Ellerslie

Auckland

Freecall No: 0800 283 684

Tilade CFC-Free is made in the United Kingdom.

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