

Intal® CFC-Free Inhaler

Sodium Cromoglycate

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about Intal CFC-Free.

It does not contain all the information that is known about Intal 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 Intal CFC-Free against the benefits he/she expects 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 Intal CFC-Free is used for

Intal CFC-Free is inhaled into the lungs for the treatment of 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, smoke, air-borne pollution or other irritants.

Intal CFC-Free is used to prevent bronchial asthma due to allergy, exercise, cold air or irritants, in both adults and children.

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

Intal 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.

Intal CFC-Free can also be used before exercise or before exposure to dust or other known asthma triggers, such as pollens or dust mite. This should prevent the symptoms (wheeze, cough, breathlessness) these triggers can cause.

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

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

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

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

Before you use Intal CFC-Free

When you must not use it

Do not use Intal CFC-Free if you have an allergy to Intal 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 Intal 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 or may be harmful.

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

If you are not sure whether you should start using Intal 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 Intal CFC-Free.

Intal 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 action 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.

Intal CFC-Free is not known to be harmful in pregnancy, however, it does pass into breast milk.

Therefore, if you are pregnant or breastfeeding you should discuss with your doctor the risks and benefits involved, before using Intal 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.

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

How to use Intal 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 your child has difficulty using the inhaler properly, ask your doctor or pharmacist for advice on the use of a spacer device. Young children may benefit from the use of a spacer with their inhaler.

If your inhaler is new, you will need to prime the inhaler by pressing the canister down 4 times before you use it. If you use your inhaler again within two days, there is no need to prime it again.

If your inhaler is not used for three to seven days, you will need to prime it with 2 sprays.

If your inhaler is not used for more than 7 days, you will need to prime it with 4 sprays.

Follow the instructions below:

1. Remove the cover from the mouthpiece, and shake the inhaler vigorously.
2. Holding the inhaler well away from your mouth, breathe out

gently (but not fully). To avoid condensation and blockage of the spray, DO NOT breathe out through the mouthpiece.

3. Place the mouthpiece in your mouth and close your lips around it. After starting to breathe in slowly and deeply through your mouth, press the metal canister firmly to release the powder, and continue to breathe in.
4. Remove the inhaler from your mouth and hold your breath for 10 seconds, or as long as is comfortable, before breathing out slowly.
5. If you are to take a second inhalation, you should wait at least one minute before repeating steps 2, 3 and 4. After use replace the cover on the mouthpiece.

Note - if you are using a spacer with the inhaler, be careful to follow the instructions provided with the spacer.

When to use it

The usual starting dose is two puffs four times a day. Some patients may require higher doses.

If you forget to use it

If you forget to use your Intal CFC-Free inhaler, use it as soon as you remember, and then go back to using your medicine as you would normally.

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

Intal CFC-Free helps control your condition. Therefore you must use Intal 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)

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have used too much Intal CFC-Free. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using Intal CFC-Free

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 Intal CFC-Free for as long as your doctor or pharmacist tells you.

Visit your doctor regularly to check on your asthma condition.

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

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

If you become pregnant, while using Intal 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 Intal CFC-Free to anyone else, even if they have the same condition as you.

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

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

Do not use Intal CFC-Free to relieve acute attacks of asthma. If you become wheezy or tight in the chest before your next dose of Intal CFC-Free is due, use a 'reliever puffer' in the usual way.

Things to be careful of

Be careful driving or operating machinery until you know how Intal CFC-Free affects you.

Side Effects

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

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

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

- sore throat
- cough
- difficulty breathing

These side effects are usually mild.

Rare side effects may include:

- swelling with fluid in tissues

- headache
- stomach pain
- diarrhoea
- painful joints
- sore muscles
- skin rashes

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

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

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

You may not experience any of them.

Storage

Keep your inhaler in a cool dry place where the temperature stays below 30 degrees C.

Do not leave Intal CFC-Free in the car on hot days or on window sills. Heat, light and dampness can destroy some medicines.

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

Keep Intal 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 Intal 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.

Intal CFC-Free description

What Intal CFC-Free looks like

Intal CFC-Free Inhaler is supplied in a canister containing 200 doses.

Ingredients

Each Intal CFC-Free dose contains 1mg sodium cromoglycate as the active ingredient.

Each Intal CFC-Free Inhaler also contains povidone, macrogol 600 and 1,1,1,2,3,3,3-heptafluoropropane.

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

After using Intal CFC-Free

Cleaning instructions

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

Intal CFC-Free does not contain CFC, which harms the environment, and contributes to the depletion of the ozone layer. A new propellant is used which is more environmentally friendly and is in keeping with our responsibility to support the phasing out of all CFC-containing products in Australia. Unfortunately, this new propellant tends to result in more blockage in the mouthpiece, which can only be prevented by daily cleaning and drying of the mouthpiece.

It is therefore, very important to keep Intal CFC-Free inhaler clean and dry to prevent build up of excess powder in the mouthpiece.

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 BLOCKAGE.

Follow Instructions Below

- 1. Remove blue cap and metal canister with white rubber cap from mouthpiece before washing.**

2. Wash the white plastic mouthpiece in hand-hot water through the top for a minute.
3. Wash through the bottom for a minute.
4. Shake out the excess water from inside by tapping the mouthpiece on a hard surface.
5. Leave overnight to dry thoroughly.
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
1800 818 806

Intal CFC-Free is made in the UK
and distributed in Australia by:
sanofi aventis Australia Pty Ltd
12-24 Talavera Road
Macquarie Park, NSW 2113

Freecall No: 1800 818 806

This leaflet was approved June 2008

Australian Registration Number:
AUST R 93909