Intal® Forte CFC-Free Inhaler

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Intal Forte CFC-Free Inhaler?

Intal Forte CFC-Free Inhaler contains the active ingredient sodium cromoglycate. Intal Forte CFC-Free Inhaler is used to treat asthma and can be used before exercise.

For more information, see Section 1. Why am I using Intal Forte CFC-Free Inhaler? in the full CMI.

2. What should I know before I use Intal Forte CFC-Free Inhaler?

Do not use if you have ever had an allergic reaction to Intal Forte CFC-Free Forte Inhaler or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed.

For more information, see Section 2. What should I know before I use Intal Forte CFC-Free Inhaler? in the full CMI.

3. What if I am taking or using other medicines?

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

More information can be found in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Intal Forte CFC-Free Inhaler?

The usual starting dose is two puffs four times each day.

More instructions can be found in Section 4. How do I use Intal Forte CFC-Free Inhaler? in the full CMI. Instructions on how to use and clean the inhaler can be found in Section 4. How do I use Intal Forte CFC-Free Inhaler? in the full CMI.

5. What should I know while using Intal Forte CFC-Free Inhaler?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are using Intal Forte CFC-Free Inhaler. If you have an Asthma Action Plan that you have agreed with your doctor, always follow it closely. Tell your doctor straight away if your asthma symptoms get worse. Tell your doctor if you become pregnant or plan to become pregnant. Tell your doctor if you are breastfeeding or plan to breastfeed. 	
Things you should not do	 Do not stop using this medicine suddenly or lower the dosage unless your doctor tells you to. Do not use Intal Forte CFC-Free Inhaler to relieve acute attacks of asthma. Do not take any other medicines for your breathing problems without checking with your doctor. 	
Driving or using machines	Be careful before you drive or use any machines or tools until you know how Intal Forte CFC-Free Inhaler affects you.	
Looking after your medicine	 Store below 30°C. Do not refrigerate or freeze. Store in a cool dry place away from moisture, heat or sunlight. 	

For more information, see Section 5. What should I know while using Intal Forte CFC-Free Inhaler? in the full CMI.

6. Are there any side effects?

Less serious side effects include sore throat, cough, difficulty breathing and wheezing. Serious side effects include an allergic reaction. Symptoms include dizziness, light-headed, wheezing, difficulty breathing or shallow breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Intal® Forte CFC-Free Inhaler

Active ingredient: sodium cromoglycate

Consumer Medicine Information (CMI)

This leaflet provides important information about using Intal Forte CFC-Free Inhaler. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Intal Forte CFC-Free Inhaler.

Where to find information in this leaflet:

- 1. Why am I using Intal Forte CFC-Free Inhaler?
- 2. What should I know before I use Intal Forte CFC-Free Inhaler?
- 3. What if I am taking or using other medicines?
- 4. How do I use Intal Forte CFC-Free Inhaler?
- 5. What should I know while using Intal Forte CFC-Free Inhaler?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Intal Forte CFC-Free Inhaler?

Intal Forte CFC-Free Inhaler contains the active ingredient sodium cromoglycate. Intal Forte CFC-Free Inhaler is an anti-allergic medicine. These medicines help to lower your allergic response to substances or triggers, such as house dust mites or smoke, which could lead to asthma symptoms.

Intal Forte CFC-Free Inhaler is inhaled into the lungs for the treatment of asthma.

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

Intal Forte CFC-Free Inhaler can be used before exercise. This should prevent asthma symptoms, such as wheeze, cough, and breathlessness.

Intal Forte CFC-Free Inhaler will not relieve the symptoms of an asthma attack that has already started.

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

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

2. What should I know before I use Intal Forte CFC-Free Inhaler?

Warnings

Do not use Intal Forte CFC-Free Inhaler if:

- you are allergic to sodium cromoglycate, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions
- use or take any medicines for any other condition

 have allergies to any medicines, or other substances, foods, preservatives, or dyes

Ask your doctor to write an asthma management plan for you before you begin to use Intal Forte CFC-Free Inhaler. You should discuss this plan regularly with your doctor to check your treatment.

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

3. What if I am taking or using other medicines?

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

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

Tell your doctor if you are using or taking a steroid medicine, such as:

- Budesonide
- Fluticasone
- Beclometasone
- Prednisolone

Your doctor may wish to lower the amount of steroid you are taking.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Intal Forte CFC-Free Inhaler.

4. How do I use Intal Forte CFC-Free Inhaler?

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

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.

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

How much to use

Follow the instructions provided and use Intal Forte CFC-Free Inhaler until your doctor tells you to stop.

The usual starting dose is two puffs twice daily. If you have more severe asthma or in more challenging times, the dose may be increased to four puffs four times each day. Your doctor may have prescribed a higher dose.

When to use Intal Forte CFC-Free Inhaler

Your doctor or pharmacist will discuss your individual dosing schedule with you.

 Intal Forte CFC-Free Inhaler should be used 5 to 10 minutes before exercise. This should prevent symptoms such as wheezing, cough or breathlessness.

Intal Forte CFC-Free Inhaler should be used every day even if you have no signs of asthma.

How to use Intal Forte CFC-Free 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 2 days, there is no need to prime it again.

If your inhaler has not been used for 3 to 7 days, you will need to prime it with 2 sprays.

If your inhaler has not been 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.

After using Intal Forte CFC-Free Inhaler

Cleaning instructions

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

Intal Forte CFC-Free Inhaler does not contain chlorofluorocarbons (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.

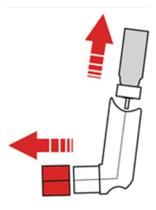
Therefore, it is very important to keep Intal Forte CFC-Free Inhaler clean and dry to prevent build-up of excess powder in the mouthpiece.

Your mouthpiece must be regularly cleaned and dried.

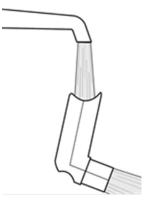
For best results wash the mouthpiece every night to prevent the build-up of excess powder which can cause blockage.

Follow the instructions below:

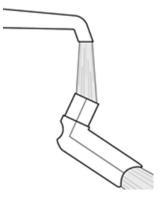
1. Remove the red cap and the metal canister from the mouthpiece before washing.



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.



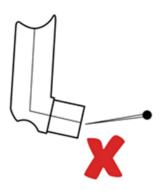
6. Before replacing the canister into the mouthpiece make sure that the white rubber cap firmly sits onto the metal canister.



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

IMPORTANT:

Never try to unblock the mouthpiece with a pin as this will damage the inhaler.



Never wash the metal canister.

Do not remove the white rubber cover from 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 and red cap, then following steps 2 to 7 above.

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

If you forget to use Intal Forte CFC-Free Inhaler

Intal Forte CFC-Free Inhaler should be used regularly at the same times each day.

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

If you use too much Intal Forte CFC-Free Inhaler

If you think that you have used too much Intal Forte CFC-Free Inhaler, you may need urgent medical attention.

You should immediately:

phone the Poisons Information Centre

(by calling 13 11 26 for Australia),

(by calling 0800 764 766 for New Zealand), or

contact your doctor, or go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Intal Forte CFC-Free Inhaler?

Things you should do

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

Continue using Intal Forte CFC-Free Inhaler for as long as your doctor tells you to.

Visit your doctor regularly to check on your asthma condition.

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

If you are taking or using a steroid your doctor may decide to lower the amount taken. Follow your doctor's instructions carefully. Tell your doctor straight away if your asthma symptoms get worse.

Remind any doctor, dentist or pharmacist you visit that you are using Intal Forte CFC-Free Inhaler.

Call your doctor straight away if you:

- · become pregnant or intend to become pregnant.
- are breastfeeding or plan to breastfeed.

Things you should not do

- Do not stop using this medicine or lower the dosage unless your doctor tells you to.
- Do not take any other medicines for your breathing problems without checking with your doctor.
- Do not use Intal Forte CFC-Free Inhaler to relieve acute attacks of asthma. If you become wheezy or tight in the chest before your next dose of Intal Forte CFC-Free Inhaler is due, use a 'reliever puffer' in the usual way.
- Do not give Intal Forte CFC-Free Inhaler to anyone else, even if they have the same condition as you.
- Do not use Intal Forte CFC-Free Inhaler to treat any other complaints unless your doctor tells you to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Intal Forte CFC-Free **Inhaler** affects you.

Looking after your medicine

Store below 30°C. Do not refrigerate or freeze.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example:

- Do not store it in the bathroom or near a sink,
- Do not store it in the car or on window sills.

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

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
 sore throat cough narrowing of the airways swelling with fluid in tissues headache stomach pain diarrhoea painful joints sore muscles skin rashes wheezing difficulty breathing 	Speak to your doctor if you have any of these less serious side effects and they worry you. These effects are usually mild.

Serious side effects

Serious side effects	What to do
Worsening of asthma symptoms	Call your
Allergic reaction related Symptoms include:	doctor straight away, or go straight to the
 dizziness light-headed swelling of lips, face, throat, or tongue difficulty swallowing difficulty breathing wheezing tightness in the chest hives, skin rash or itching 	Emergency Department at your nearest hospital if you notice any of these serious side effects.

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

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

Reporting side effects

After you have received medical advice for any side effects you have experienced, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Intal Forte CFC-Free Inhaler contains

Active ingredient (main ingredient)	Each puff contains 5 mg of sodium cromoglycate	
Other ingredients (inactive ingredients)	PovidoneMacrogol 600Apaflurane	

Do not take this medicine if you are allergic to any of these ingredients.

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

What Intal Forte CFC-Free Inhaler looks like

Intal Forte CFC-Free Inhaler is supplied in a canister containing 112 puffs (Aust R 67820).

Each pack contains an additional mouthpiece to assist in the cleaning and maintenance of Intal Forte CFC-Free Inhaler.

Who distributes Intal Forte CFC-Free Inhaler

Intal Forte CFC-Free Inhaler is distributed in Australia by:

sanofi aventis Australia pty Itd

12-24 Talavera Road

Macquarie Park, NSW 2113

Freecall No: 1800 818 806

Intal Forte CFC-Free Inhaler is distributed in New Zealand by:

sanofi-aventis new zealand limited

Level 8,

56 Cawley Street,

Ellerslie, Auckland 1051 Freecall No: 0800 283 684

Intal Forte CFC-Free Inhaler is made in the United Kingdom.

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