1. What Intal is and what it is used for

Intal® CFC-Free Inhaler 5mg Pressurised inhalation, suspension
sodium cromoglicate SANOFI

In this leaflet:
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1. What Intal is and what it is used for

Intal CFC-Free Inhaler (called Intal in this leaflet) contains a medicine called sodium cromoglicate. This belongs to a group of medicines called anti-allergics.

It works by having an effect deep in the air passages of your lungs. It also lowers your response when you are exposed to substances to which you are allergic.

Intal is used to help prevent asthma attacks and may be called a ‘preventer’.

- Intal will not help an asthma attack that has already started
- You will need to use a different inhaler, called a ‘reliever’, for these attacks (see ‘Using a ‘reliever’ inhaler in Section 3’)

2. Before you use Intal

Do not use this medicine and tell your doctor if:
- You are allergic (hypersensitive) to sodium cromoglicate or any of the other ingredients of Intal (listed in Section 6: Further information).
- Signs of an allergic reaction include: a rash, swelling or breathing problems, swelling of your lips, face, throat or tongue

Do not use this medicine if the above applies to you. If you are not sure, talk to your doctor or pharmacist before using Intal.

3. How to use Intal

Always use Intal exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Using this medicine
- It is important to use this medicine every day, even if you have no signs of asthma
- This medicine is taken by breathing in through your mouth (see ‘How to use your inhaler’ below)
- You may need to use Intal for several weeks for it to work best
- Your asthma may get worse if you have an infection, are unwell or come into contact with anything to which you are allergic. If this happens, talk to a doctor straight away
- If you are using a steroid as well as Intal, your doctor may decide to lower the amount of steroid taken or gradually stop the steroid altogether
- If your steroid treatment has been reduced or stopped and your asthma then gets worse you must tell your doctor straight away. They may wish to increase or re-start the steroid treatment.

Pregnancy and breast-feeding
Talk to your doctor before using this medicine if you are pregnant, might become pregnant or think you may be pregnant.

If you are breast-feeding, talk to your doctor or pharmacist before using Intal.

4. Possible side effects

How much to use (adults, elderly and children)
- The starting dose is two puffs (inhalations) four times each day
- Taking puffs at meal times and at bedtime may help you to remember to use it
- If your asthma gets better, your doctor may suggest that you lower your daily dose to one puff four times each day
- Sometimes when your asthma is bad or when you come into contact with anything to which you are allergic, your doctor may change how much you use. Your dose may be increased to two puffs six to eight times each day

Using a ‘reliever’ inhaler
- If your doctor has advised you to use a ‘reliever’ inhaler at the same time as Intal, it is best to use your ‘reliever’ inhaler before using your Intal Inhaler. This will open the airways and allow the Intal to get down into them better
- Keep your ‘reliever’ inhaler at all times in case of a sudden attack or if your asthma gets worse. Talk to your doctor if it takes more puffs than usual from your ‘reliever’ inhaler to control your symptoms

How to use your Intal Inhaler (An adult should help small children use their inhaler properly)
1. Open
Remove the mouthpiece cover and check that the mouthpiece is clean.
2. Shake
Shake the inhaler well (at least 5 times).
- If your doctor has told you to take 2 puffs each time you use your inhaler:
  - Wait for one minute after the first puff. Then repeat steps 3 to 4 once more
3. Inhale
- Hold the inhaler upright with your thumb on the base
- Hold the inhaler well away from your mouth
- Breathe out as far as is comfortable
- DO NOT breathe out through the inhaler. This is to stop moisture from collecting and blocking the spray
Important things to make sure you are using the inhaler properly

- Practice in front of a mirror or with a nurse, pharmacist or doctor from time to time. If you see a mist escaping from your mouth or around the sides of the canister you need to try to use your inhaler better.
- Be sure to have your lips closed properly around the mouthpiece
- Be sure to start breathing in before pressing the canister
- Adults should supervise the use of Intal in small children.

If you or a child use more Intal than you should, talk to a doctor as soon as possible.

If you forget to use Intal

If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop using Intal

Keep using Intal until your doctor tells you to stop. Do not stop using Intal just because you feel better. If you stop, your illness may get worse.

When your doctor says that you can stop using Intal, your dose will be lowered gradually over a week.

How to clean

It is very important to keep the plastic body of the inhaler clean. This helps to stop the build-up of powder. Clean the plastic body at least twice a week. No harm will come from washing the plastic body and mouthpiece cover every day.

1. Remove
   - Remove the metal canister and put it in a safe place
   - Take off the mouthpiece cover

2. Wash
   - Wash the plastic body of the inhaler thoroughly in hand hot water from both ends

3. Dry
   - Shake off any water that is left and leave to dry in a clean warm place overnight
   - When completely dry, put the metal canister back into the plastic body of the inhaler. Then replace the mouthpiece cover.
   - If the metal canister will not slide easily into the plastic mouthpiece, press the white rubber cover firmly back down onto the metal canister
   - Use the second Intal Inhaler you have been given while the other inhaler is drying

4. Possible side effects

Like all medicines, Intal can cause side effects, although not everybody gets them.

Stop using Intal and see a doctor or go to a hospital straight away if:

- You have an allergic reaction to Intal. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You have a bad attack of wheezing, difficulty breathing or tightness in the chest (something called bronchospasm). People who are allergic to Intal can also experience these side effects. If this happens, do not use your Intal Inhaler. Use your ‘reliever’ inhaler instead and contact a doctor straight away. The doctor may decide to stop your treatment with Intal
- Lung problems including inflammation of the lungs. This means you may have a lung infection called ‘eosinophilic pneumonia’. Signs include:
  - Feeling unwell or less hungry, a high temperature (fever) lasting 2 to 3 days
  - Difficulty breathing, shortness of breath and cough

Talk to your doctor or pharmacist if any of the side effects gets serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet:

- Sore throat - drinking water after you use your inhaler may help this
- Coughing
- Headache
- Sneezing, runny or blocked nose

If you have any further questions on the use of this product, ask your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Intal

Keep this medicine in a safe place where children cannot see or reach it.

Do not use Intal Inhaler after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

Do not refrigerate or freeze. The aerosol inhaler canister is pressurised. Protect the aerosol from heat or direct sunlight, do not puncture or incinerate even when it is empty.

Medicines should not be disposed of via the household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information

What Intal Inhaler contains

- The active substance is sodium cromoglicate. Each puff (inhalation) contains 5mg of sodium cromoglicate
- The other ingredients are polyvidone K30, polyethylene glycol (PEG) 600, apafurane HFA 227 - a non ozone depleting propellant
- You have a bad attack of wheezing, difficulty breathing or tightness in the chest (something called bronchospasm). People who are allergic to Intal can also experience these side effects. If this happens, do not use your Intal Inhaler. Use your ‘reliever’ inhaler instead and contact a doctor straight away. The doctor may decide to stop your treatment with Intal

What Intal Inhaler looks like and contents of the pack

- Intal is a metered dose inhaler supplied in an aluminium can fitted with a metering valve which delivers 112 actuations. Each actuation contains 5mg of sodium cromoglicate
- Each can of Intal comes with a plastic adaptor (inhaler) with a dust-cap

Marketing Authorisation Holder and Manufacturer

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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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