

INTAL™ Spincaps™

Powder for Inhalation

Sodium cromoglycate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Intal Spincaps.

It does not contain all the available information. 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 Spincaps against the benefits they expect it will have for you.

If you have any concerns about using this medicine, talk to your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Intal Spincaps are used for

The name of your medicine is Intal Spincaps. It contains the active ingredient sodium cromoglycate and is used with a Spinhaler device.

Sodium cromoglycate is a white powder inhaled into the lungs to reduce inflammation and prevent asthma including exercise-related asthma.

People with asthma have extra sensitive airways. The lining of the lungs becomes inflamed (red and swollen), making it harder to breathe. This may be due to an allergy to house dust mites, smoke, air-borne pollution or other irritants.

Intal Spincaps is a preventative medicine for adults and children

that requires regular usage for full benefit. By using Intal Spincaps regularly even when you feel well, asthma can be controlled and most attacks prevented.

Intal Spincaps will not relieve the symptoms of an asthma attack after the attack has started.

You should follow your doctor's advice and prescribed treatment in the event of a sudden asthma attack.

Your doctor may have prescribed Intal Spincaps for another reason. Ask your doctor if you have any questions about why Intal Spincaps has been prescribed for you.

Intal Spincaps is available only with a doctor's prescription.

There is no evidence that Intal Spincaps is addictive.

Before you use Intal Spincaps

When you must not use it

Do not use Intal Spincaps if you have an allergy to sodium cromoglycate.

Signs of an allergic reaction may include wheezing, shortness of breath, swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing, hives, itching or skin rash or fainting.

Do not use Intal Spincaps to treat an acute asthma attack.

Do not use Intal Spincaps after the expiry date printed on the pack.

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

Do not use Intal Spincaps if the packaging is torn or shows signs of tampering or if the Spincaps do not look quite right.

If you are not sure whether you should start using Intal Spincaps, talk to your doctor.

Before you start to use it

It is advisable to ask your doctor to write an asthma management plan for you before you start to use Intal Spincaps

Intal Spincaps is one part of a general plan for you to handle your asthma. Discuss and check your asthma plan regularly with your doctor.

Tell your doctor if you have any allergies to:

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

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

Your doctor will discuss the possible risks and benefits of using Intal Spincaps during pregnancy.

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

Your doctor will discuss the possible risks and benefits of using Intal Spincaps during breast-feeding.

Intal Spincaps are not known to be harmful in pregnancy; however, it

does pass into breast milk.

Therefore, if you are pregnant or breast-feeding, you should discuss with your doctor the risks or benefits involved before using Intal Spincaps.

Taking other medicines

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

Intal Spincaps can be used with other medicines which are used to prevent or treat asthma.

How to use Intal Spincaps

Intal Spincaps must be administered by means of a Spinhaler device which delivers the medicine directly to your lungs.

Intal Spincaps used for the treatment of asthma are not to be swallowed.

If you are not sure how to use Intal Spincaps or the Spinhaler device, ask your doctor or pharmacist.

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

Children should only use Intal Spincaps and the Spinhaler device on medical advice and with the help of an adult.

How much to use

Your doctor will tell you how many Intal Spincaps you will need to use each day. This depends on your condition, your potential exposure to trigger factors for your asthma and whether you are using/taking any other medicines.

How to use

How to load the Intal Spinhaler

First make sure your hands are clean and dry. Tear open the sachet and press out a Spincap through the foil.

Load the Spinhaler as follows:

1. Hold the Spinhaler upright with the mouthpiece pointing downwards; then unscrew the body.
2. Check that the propeller is on its spindle, then firmly push an Intal Spincap (coloured end downwards) into the cup of the propeller. Make sure that the propeller spins easily and then screw the body tightly back onto the mouthpiece.
3. Still holding the Spinhaler upright, slide the outer sleeve down as far as it will go and then back up again. This pierces the Spincap and makes the Spinhaler ready for use. This step may be repeated a second time for optimal piercing.

How to inhale Intal

1. Make sure the mouthpiece and the body of the Spinhaler are still tightly screwed together.
2. Breathe out, put the mouthpiece in your mouth and close your lips around it so that they are right up against the lip of the Spinhaler.
3. Tilt your head well back and breathe in as deeply as you can. This is very important.
4. Hold your breath for as long as comfortable, then take the Spinhaler right out of your mouth and breathe out.
5. Keep repeating this process until the Spincap is empty. Two or three attempts should be enough and it does not matter if a little powder is left.
6. If you have a little irritation in your throat afterwards, have a drink of water.

How to look after your Spinhaler

For best results, the parts of the Spinhaler must be kept free from any powder residue. Wash your Spinhaler in warm water once a week, taking care to remove the snap fit propeller first. Dry overnight in a warm place, clicking the propeller firmly back into place before re-using it. Always inspect your Spinhaler before use and be careful to remove any dust or other particles which may be inside before inhaling through it.

How long to use it

For people using Intal Spincaps to control asthma symptoms, Intal Spincaps must be used every day.

Continue using Intal Spincaps for as long as your doctor recommends.

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

If you forget to use it

If you forget to use your Intal Spincaps, 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 pharmacist or doctor.

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

If you use too much (overdose)

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

You may need urgent medical attention.

While you are using Intal Spincaps

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 Spincaps for as long as your doctor or pharmacist tells you to.

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 Spincaps.

If you are about to start on any new medicine, tell your doctor or pharmacist that you are using Intal Spincaps.

If you become pregnant while using Intal Spincaps, tell your doctor or pharmacist.

Tell your doctor if, for any reason, you have not used your medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor if you feel the medicine is not helping your condition.

Things you must not do

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

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not use Intal Spincaps to treat any other complaints unless your doctor tells you to.

Do not stop using Intal Spincaps, or lower the dose, without first checking with your doctor.

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

Do not let yourself run out of medicine over the weekend or on holidays.

Things to be careful of

Be careful driving or operating machinery until you know how Intal Spincaps affects you.

Side effects

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

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 any questions you may have.

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

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

- sore throat
- cough
- narrowing of the airways

These side effects are usually mild.

Rare side effects may include:

- headache
- stomach pain
- diarrhoea
- painful joints
- sore muscles
- skin rashes
- swelling with fluid in tissues

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using Intal Spincaps

Storage

Keep the Intal Spincaps in the blister pack until it is time to use them.

If you take the Spincaps out of the packet or the blister pack they will not keep as well.

Keep your Intal Spincaps in a cool dry place where it stays below 30°C.

Always keep your Spinhaler in its container. This will keep it clean and ready for use.

Do not store Intal Spincaps or any other medicine in the bathroom or near a sink.

Do not leave this medicine in the car on hot days or on a window sill.

Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

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

Disposal

If your doctor tells you to stop using Intal Spincaps or you find that they have passed their expiry date, ask your pharmacist what to do with any Intal Spincaps that are left over.

Product description

What it looks like

Intal Spincaps are available in packs of 100 cartridges with 10 individual packets each containing a blister strip of 10 Spincaps.

The Intal Spincaps are clear and yellow capsules marked SODIUM CROMOGLYCATATE 20 mg and containing a white powder.

Ingredients

Each Intal Spincap contains 20 mg of sodium cromoglycate only.

Sponsor

Intal Spincaps and the Intal Spinhaler are supplied in Australia by:

Amneal Pharma Australia Pty Ltd
12 River Street
South Yarra VIC 3141

Australian Registration Number

Intal Spincaps: AUST R 27760

This leaflet was prepared in July 2015