

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

INOXAB 200

Budesonide 200 µg

Sugar free

Read all of this leaflet carefully before you start taking INOXAB 200

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **INOXAB 200** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What **INOXAB 200** is and what it is used for
2. What you need to know before you take **INOXAB 200**
3. How to take **INOXAB 200**
4. Possible side effects
5. How to store **INOXAB 200**
6. Contents of the pack and other information

1. What INOXAB 200 is and what it is used for

INOXAB 200 is an inhaler used for the prevention of the symptoms of asthma. When you breathe in through the mouthpiece of the inhaler, your breath carries the medicine to your lungs. **INOXAB 200** acts directly on your airways to reduce inflammation. This helps to improve your asthma condition and to prevent asthma attacks from occurring.

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2. What you need to know before you take INOXAB 200

Do not take INOXAB 200:

- if you are hypersensitive (allergic) to budesonide or any of the other ingredients of **INOXAB 200**. listed in section 6.1.
- if you have a lung infection.
- if you have a cold or chest infection or any problems with your breathing.
- if you have or have ever had tuberculosis (TB).

Warnings and precautions

Talk to your doctor or pharmacist before taking **INOXAB 200**

Your doctor or pharmacist will instruct you on the correct use of your **INOXAB 200** inhaler. Each pack of **INOXAB 200** contains an instruction leaflet that tells you the correct way to use it. Please read this carefully.

It is important to use **INOXAB 200** every day even if you have no asthma symptoms at the time. Your breathing may improve within 2 days. However it can take up to 4 weeks for the medicine to have its full effect.

Be sure to rinse your mouth out with water after every time you use **INOXAB 200**. This is to help reduce the chance of developing thrush in your mouth. This water should not be swallowed.

INOXAB 200 can affect the adrenal gland (a small gland next to the kidney). Report to your doctor any side effects that you think might be caused by **INOXAB 200** as your adrenal glands begin to produce much less hormone than usual. In some cases, they stop producing the hormone altogether. Symptoms may include.

- Unusual fatigue and muscle weakness
- Dizziness when standing
- Nausea, vomiting and/or diarrhea
- Loss of appetite
- Stomachache
- Weight loss

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- Dark tanning of the skin
- Craving for salt

If you feel you are getting breathless or wheezy while using **INOXAB 200**, you should stop using **INOXAB 200** and see your doctor as soon as possible, as you may need additional treatment.

Contact your doctor immediately if:

- Your breathing is getting worse or you often wake up at night with asthma
- Your chest starts to feel tight in the morning or your chest tightness lasts longer than usual.

These signs could mean that your condition is not being properly controlled and you may need different or additional treatment immediately.

Inhaled corticosteroids such as **INOXAB 200** can affect the normal production of steroid hormones in your body, particularly if you use high doses for a long time, for example 400 micrograms or more daily for several years. The effects include:

- Cushing's syndrome with a collection of signs and symptoms which may include high blood pressure, abdominal obesity but with thin arms and legs, reddish stretch marks, a round red face, a fat lump between the shoulders, weak muscles, weak bones, acne, and fragile skin that heals poorly
- a slowing of the rate of growth of children and adolescents.
- changes in bone mineral density (thinning of the bones).
- cataracts or glaucoma (increased pressure in the eye), sleeping problems, anxiety, depression, aggressiveness, increased motor activity (difficulty to stay still) and irritable.

These effects are more likely to occur in children.

Inform your doctor if you have liver disease.

You should tell your doctor if you have any of the following symptoms, which could be signs of chest infection: fever or chills, increased mucus production or change in mucus colour, increased cough or increased breathing difficulties.

If you have been prescribed **INOXAB 200** and still are using "steroid" tablets, your doctor may gradually (over a period of weeks or months) reduce your dose of tablets. You may even be able to eventually

stop using the tablets. If your medicine is changed from “steroid” tablets to **INOXAB 200** you may temporarily regain symptoms which may have bothered you earlier, e.g. weakness or pain in muscles and joints. If any of these symptoms bother you, or symptoms such as headache, tiredness, nausea or vomiting occur, contact your doctor.

Other medicines and INOXAB 200

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.).

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Steroid medicines.
- Medicines used to treat fungal infections (such as itraconazole and ketoconazole).
- HIV medicines (such as ritonavir or cobicistat-containing products).

Using INOXAB 200 with food and drink

Do not use **INOXAB 200** while eating or drinking.

Pregnancy, breastfeeding and fertility

The corresponding professional information can be accessed at <https://macleodssaproducts.co.za/> or contact 011 682 1169.

Driving and using machines

INOXAB 200 may cause blurred vision. If symptoms are severe, the patient should not drive or operate machinery.

3. How to take INOXAB 200

Do not share medicines prescribed for you with any other person.

Always take **INOXAB 200** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

If you have the impression that the effect of **INOXAB 200** is too strong or too weak talk to your doctor or pharmacist.

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Shake the inhaler before use. The usual dose is:

In adults and children over 12 years of age: the dose can range from 200 micrograms up to 1600 micrograms each day. This is taken in divided doses, once or up to four times a day. When your asthma is under control the dose is usually lowered.

If you are using an inhaled bronchodilator in addition to **INOXAB 200** you should use the bronchodilator several minutes before the inhalation of **INOXAB 200** to minimise possible local side effects such as cough.

Rinse the mouth after each dosage administration.

Do not abruptly stop treatment with **INOXAB 200** without speaking to your doctor first.

If you inhale more INOXAB 200 than you should

In the event of overdose consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control centre.

If you forget to take INOXAB 200

If you forget to take a dose, skip the missed dose and take the next dose as usual. Do not take a double dose to make up for a forgotten dose.

If you stop taking INOXAB 200

Do not stop using **INOXAB 200** without consulting your doctor. If you stop using **INOXAB 200** abruptly, it may make your asthma worse.

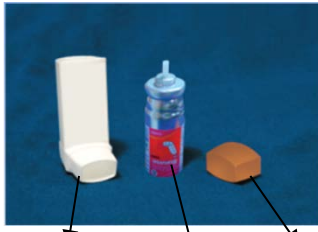
HOW TO USE YOUR INHALER CORRECTLY

PARTS OF THE INHALER

Plastic body



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Mouthpiece Canister Mouthpiece cover

Testing your inhaler

Before using your inhaler for the first time, or if it has not been used for a week or more, “test fire” it, i.e. release one puff into the air.



USING YOUR INHALER

1) Remove the mouthpiece cover, and check that the mouthpiece is clean.

Shake the inhaler well. Hold the inhaler upright as shown with your thumb on the base. Place either one or two fingers on top of the canister.



2) Breathe out gently, through your mouth.



3) Place the mouthpiece of the inhaler in your mouth between your teeth and close your lips around it (Do not bite it.)

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Start breathing in slowly through your mouth. As you breathe in, press down the canister to release one dose while continuing to breathe in steadily and deeply.



4) Remove the inhaler from your mouth and hold your breath for 10 seconds, or for as long as it is comfortable. Breathe out slowly.



5) If another dose is required wait for at least one minute. Repeat steps 2 to 4. After use, replace the mouthpiece cover.



Important do not rush steps 3 to 4. It is important that you start to breathe in as slowly as possible just before releasing the dose. Practice in front of mirror for the first few times. If you see “mist” coming from the top of the inhaler or the sides of your mouth, start again from step 1. This escaping mist indicates incorrect technique.



Cleansing

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It is essential to keep the plastic mouthpiece clean, to ensure proper functioning of the inhaler. Clean your inhaler at least once a week, as follows:

1) Gently pull the metal canister out of the plastic body of the inhaler. Remove the mouthpiece cover.



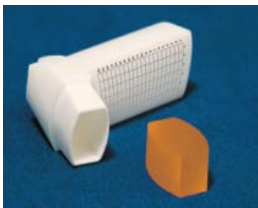
2) Immerse the plastic body and the mouthpiece cover in warm water. Do not put the metal canister in the water.



3) Next, rinse the plastic body and mouthpiece cover under running tap water.



4) Shake well to remove excess water. Leave to dry. Avoid the use of heat to dry the parts.



5) When the plastic body is dry, replace the canister and the mouthpiece cover correctly.

4. Possible side effects

INOXAB 200 can have side effects. Not all the side effects reported for **INOXAB 200** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **INOXAB 200**, please consult your doctor, pharmacist or healthcare professional for advice

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If any of the following happens, stop taking **INOXAB 200** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- severe rash or itching

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **INOXAB 200**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Bronchospasm (tightening of the muscles in the airways which causes wheezing).
- Mood changes (such as depression)
- Adrenal gland suppression with symptoms of :
 - Unusual fatigue and muscle weakness
 - Dizziness when standing
 - Nausea, vomiting and/or diarrhea
 - Loss of appetite
 - Stomachache
 - Weight loss
 - Dark tanning of the skin
 - Craving for salt
- Pneumonia (infection in the lungs). Tell your doctor if you have any of the following while taking budesonide they could be symptoms of a lung infection:
 - Fever or chills.
 - Increased mucus production, change in mucus colour.
 - Increased cough or increased breathing difficulties.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequently occurring side effects:

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- Thrush (a fungal infection) in the mouth. This is less likely if you rinse your mouth out with water after using your **INOXAB 200** inhaler.
- Sore throat, coughing, dryness of mouth and throat and a hoarse voice.

Less frequent side effects:

- Cushing's syndrome with a collection of signs and symptoms which may include high blood pressure, abdominal obesity but with thin arms and legs, reddish stretch marks, a round red face, a fat lump between the shoulders, weak muscles, weak bones, acne, and fragile skin that heals poorly
- A slowing of the rate of growth of children and adolescents.
- Changes in bone mineral density (thinning of the bones).
- Cataracts (clouding of the lens in the eye) or glaucoma (increased pressure in the eye)
- Sleeping problems, anxiety, depression, aggressiveness, increased motor activity (difficulty to stay still) and irritable. These effects are more likely to occur in children.
- Trembling and shaking, headache
- Muscle cramps
- Bruising of the skin, thinning of the skin, skin rash, itching, contact dermatitis (a skin problem), hives
- Loss of voice
- Muscle spasm
- Nausea, diarrhoea, bad taste
- Tiredness and thirst

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **INOXAB 200**.

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5. How to store INOXAB 200

Store at or below 30 °C. Avoid storage in direct sunlight or heat. The canister should not be punctured, broken or burnt even if it is apparently empty.

KEEP OUT OF THE REACH OF CHILDREN.

6. Contents of pack and other information

What INOXAB 200 contains

INOXAB 200 contains the active substance budesonide 200 µg.

The other ingredient is CFC-free propellant 1, 1, 1, 2-tetrafluoroethane (HFC-134a).

Sugar free.

What INOXAB 200 looks like and contents of the pack:

INOXAB 200 is a pressurised metered dose inhaler containing suspension aerosol filled in a 19 ml aluminium canister fitted with metered dispensing 50 µl nitrile valve crimped in place and a polypropylene actuator attached (brown coloured cap and white colour body) packed in an outer carton. There should be no sign of physical damage or leakage.

Holder of Certificate of Registration and Manufacturer

MACLEODS PHARMACEUTICALS SA (PTY) LTD

Office Block 1, Bassonia Estate Office Park (East),

1 Cussonia Drive, Bassonia Rock, Ext. 12,

Alberton, South Africa.

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Access to the corresponding Professional Information

The corresponding professional information can be accessed at <https://www.macleodspharma.com> or email macleodrsa@macleodspharma.com or contact 011 682 1169.

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