

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

BUDESONIDE 0,125 mg/mL RESPULES CIPLA

BUDESONIDE 0,25 mg/mL RESPULES CIPLA

BUDESONIDE 0,5 mg/mL RESPULES CIPLA

Active substance: Budesonide

Sugar free.

Read all of this leaflet carefully before you are given BUDESONIDE RESPULES CIPLA

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- BUDESONIDE RESPULES CIPLA 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 BUDESONIDE RESPULES CIPLA is and what is used for:
2. What you need to know before you receive BUDESONIDE RESPULES CIPLA
3. How to use BUDESONIDE RESPULES CIPLA

4. Possible side effects
5. How to store BUDESONIDE RESPULES CIPLA
6. Contents of the pack and other information.

1. What BUDESONIDE RESPULES CIPLA is and what it is used for

BUDESONIDE RESPULES CIPLA belongs to a group of steroids called glucocorticoids which can be used to reduce or prevent inflammatory reactions (inflammation) in the lungs. Your medicine is used for the treatment of asthma. It is used in patients where other types of inhalers, such as a pressurised inhaler or an inhaler containing a dry powder are unsatisfactory or inappropriate. This medicine may also be used for the treatment in hospitals of very serious cases of croup (a disease of the throat that may cause difficulty in breathing) in infants and children.

2. What you need to know before you use BUDESONIDE RESPULES CIPLA

Do not use BUDESONIDE RESPULES CIPLA

- if you are allergic to budesonide or any of the other ingredients of this medicine (listed in **section 6**).
- have or have had tuberculosis.
- If you have a fungal, viral or other infection of the airways, e.g., a cold or chest infection.

Warnings and precautions

Talk to your doctor or health care provider before using BUDESONIDE RESPULES CIPLA if you

- have or have had a liver disease or problems with your liver

Important information about your asthma symptoms

If you feel you are getting breathless or wheezy while using BUDESONIDE RESPULES CIPLA, you should continue to use BUDESONIDE RESPULES CIPLA but go to see your doctor as soon as possible, as you may need additional treatment.

Contact your doctor immediately if:

- o your breathing is getting worse, or you often wake up at night with asthma
- o 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.

Rash on the face after using the face mask. You can stop this from happening by washing your face after using the face mask.

Contact your doctor if you experience blurred vision or other visual disturbances.

If you are switching from corticosteroid tablets (such as prednisolone) to BUDESONIDE RESPULES CIPLA, you may feel generally unwell during the switch. It is also possible that you may get symptoms that were suppressed by the corticosteroid tablets, such as allergic rhinitis

(itchy, blocked or runny nose), eczema (dry, itchy skin), muscle and joint pain. You should talk to your doctor if this happens to you.

BUDESONIDE RESPULES CIPLA is not suitable for use in an attack of acute shortness of breath. The sudden attack of breathlessness should be treated with a short-acting bronchodilator medicine.

If you experience more wheezing and/or shortness of breath immediately after using BUDESONIDE RESPULES CIPLA, you should immediately stop using BUDESONIDE RESPULES CIPLA and seek medical advice. Inform your doctor immediately while taking this medicine.

To reduce your risk of getting oral thrush (white patches on the tongue or in the mouth), rinse your mouth with water (spit out the water – do not swallow it) and brush your teeth after using BUDESONIDE RESPULES CIPLA. Tell your doctor if you do get oral thrush.

Children and adolescents

Long term treatment with BUDESONIDE RESPULES CIPLA can slow down the normal growth of children and adolescents. If your child uses this medicine for a long time, it is normal that the doctor will want to monitor their height on a regular basis.

Other medicines and BUDESONIDE RESPULES CIPLA

Always tell your health care provider if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription (this includes all complementary or traditional medicines). Some medicines may increase the effects of BUDESONIDE RESPULES CIPLA and your doctor may wish to monitor you carefully if you are taking these medicines:

- Medicines for the treatment of a fungal infection such as ketoconazole or itraconazole
- Some medicines for HIV such as ritonavir or cobicistat-containing products
- Other steroid medicines.

Pregnancy and breastfeeding

Safety in pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist, or other health care provider for advice before taking this medicine. If you become pregnant whilst taking this medicine, you should tell your doctor as soon as possible.

Driving and using machines

Inhaled budesonide has no or negligible influence on the ability to drive and use machines.

It is not always possible to predict to what extent BUDESONIDE RESPULES CIPLA may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which BUDESONIDE RESPULES CIPLA affects you.

3. How to use BUDESONIDE RESPULES CIPLA

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

Always use BUDESONIDE RESPULES CIPLA exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

The solution in an ampoule must be put into a nebuliser and made into a fine mist before it can be breathed in. It is then inhaled through a face mask or mouthpiece. Instructions for using your nebuliser are given after this section.

Asthma

Your doctor will tell you how much to take. This will depend on how severe your asthma is. Your doctor may lower your dose as your asthma improves.

Initial Dose:

0,5 to 1 mg twice daily. In some cases, the dose may be further increased.

Children	12 months to 6 years	6 years and older
Previous therapy	Recommended starting dose	
Bronchodilators alone	0,25 mg twice daily	0,25 to 0,5 mg twice daily
Inhaled corticosteroids	0,25 mg twice daily	0,25 to 0,5 mg twice daily
Oral corticosteroids	0,5 mg twice daily	0,25 to 1 mg twice daily

Maintenance dose	0,25 to 0,5 mg twice daily
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Dose of BUDESONIDE RESPULES CIPLA may be increased based on the individual patient requirements.

Maintenance dose: The maintenance dose is individual. After the desired effect has been obtained, the maintenance dose may be gradually reduced to the smallest amount necessary to control symptoms.

Croup

The recommended dose for infants and children is 2 mg a day. This may be given as a single dose or as two 1 mg doses separated by 30 minutes.

Dosage table:

Dosage in mg	Volume of BUDESONIDE RESPULES CIPLA				
	0,125 mg / mL (1 ampoule = 0,25 mg / 2mL)		0.25 mg/mL (1 ampoule = 0,5 mg / 2mL)		0.5 mg / mL (1 ampoule = 1mg / 2mL)
0.25 mg	2 mL (1 ampoule)				
0.5 mg*	4 mL (2 ampoules)	or	2 mL (1 ampoule)		
0.75 mg**	2 mL	plus	2 mL		

Dosage in mg	Volume of BUDESONIDE RESPULES CIPLA				
	0,125 mg / mL (1 ampoule = 0,25 mg / 2mL)		0.25 mg/mL (1 ampoule = 0,5 mg / 2mL)		0.5 mg / mL (1 ampoule = 1mg / 2mL)
	(1 ampoule)		(1 ampoule)		
1 mg***			4 mL (2 ampoules)	or	2 mL (1 ampoule)
1.5 mg****			2 mL (1 ampoule)	plus	2 mL (1 ampoule)
2 mg					4 mL (2 ampoules)

* **Either** Two ampoules of BUDESONIDE 0.25 mg / 2 mL RESPULES CIPLA **or** one ampoule of BUDESONIDE 0.5 mg / 2 mL RESPULES CIPLA

** One ampoule of BUDESONIDE 0.25 mg / 2 mL RESPULES CIPLA **plus** one ampoule of BUDESONIDE 0.5 mg / 2 mL RESPULES CIPLA

*** **Either** 2 ampoules of BUDESONIDE 0.5 mg / 2 mL RESPULES CIPLA **or** one ampoule of BUDESONIDE 1 mg / 2 mL RESPULES CIPLA

**** One ampoule of BUDESONIDE 0.5 mg / 2 mL RESPULES CIPLA **plus** one ampoule of BUDEFLAM 1 mg / 2 mL RESPULES CIPLA

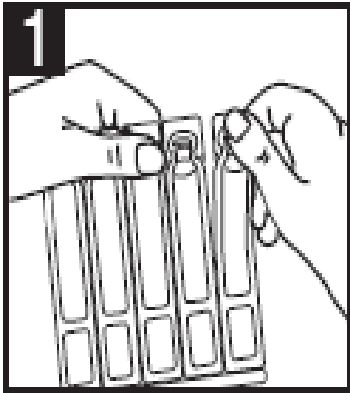
Your doctor will tell you how long your treatment with BUDESONIDE RESPULES CIPLA will last.
If you have the impression that the effect of BUDESONIDE RESPULES CIPLA is too strong or too weak, tell your doctor or pharmacist.

Instructions for use

Your medicine must be used with a jet nebuliser. The “mist” produced is then inhaled through a mouthpiece or face mask. Ultrasonic nebulisers should not be used with this medicine.

To take your medicine follow these steps:

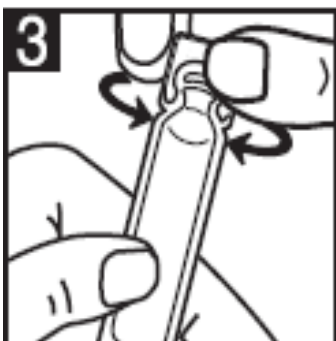
1. Break off a single ampoule from the strip, leaving the rest in the foil sachet (see diagram 1 below).



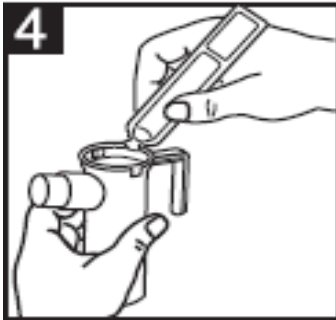
2. Shake the ampoule gently using a circular motion as shown in Figure 2.



3. Open the ampoule by twisting off the top (see diagram 3 below).



4. Place the open end of the ampoule firmly inside the nebuliser cup (reservoir). Squeeze slowly to put the liquid in the cup as shown in Figure 4. and dispose of the empty ampoule carefully.



5. Connect one end of the cup to the mouthpiece or face mask and the other end to the air pump.
6. Gently shake the cup once more then turn on the nebuliser. Breathe in the “mist” calmly and deeply using the mouthpiece or face mask.
7. When no more mist comes out of the mouthpiece or face mask, your treatment is complete.
8. Rinse your mouth with water (spit out the water – do not swallow it) and brush your teeth.
If you have used a face mask, you should also wash your face well. It is important to do this as it can reduce the risk of some side effects associated with this medicine.
9. You should clean the nebuliser after each use. Wash the nebuliser container and mouthpiece or face mask in warm water using a mild detergent in accordance with the manufacturer’s instructions. The nebuliser should then be rinsed well and dried by connecting the nebuliser container to the air pump.

It is important that you always follow the manufacturer’s instructions that come with the nebuliser.

If you are not sure about how to use the nebuliser, talk to your doctor or pharmacist.

If you use more BUDESONIDE RESPULES CIPLA than you should

In the event of overdosage, contact your doctor or pharmacist as soon as possible. If neither is available, contact the nearest hospital or poison centre,

Remember to take the pack and any remaining ampoules with you. It is important that you take your dose as stated on the pharmacist's label or as advised by your doctor. You should not increase or decrease your dose without seeking medical advice.

If you forget to use BUDESONIDE RESPULES CIPLA

Do not take a double dose to make up for a forgotten dose. Simply take your next dose on time.

If you stop using BUDESONIDE RESPULES CIPLA

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

4. Possible side effects

BUDESONIDE RESPULES CIPLA can have side effects.

Not all side effects reported for BUDESONIDE RESPULES CIPLA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BUDESONIDE RESPULES CIPLA, please consult your health care provider for advice.

If any of the following happens, stop taking / using BUDESONIDE RESPULES CIPLA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Signs of an allergic reaction which may include the following: swelling of your face, particularly around your mouth (with possible swelling of the lips, tongue, eyes and ears), rash, itching, contact dermatitis (a skin problem), hives and bronchospasm (tightening of the muscles in the airways which causes wheezing).
- Sudden wheezing and/or shortness of breath after inhaling your medicine.

Note: These are all very serious side effects. If you have them, you may have had a serious reaction to BUDESONIDE RESPULES CIPLA. 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:

- Cataracts (clouding of the lens in the eye), depression or feeling anxious, muscle spasms, trembling and shaking, blurred vision.
- Increased cough or increased breathing difficulties.
- Soreness and/or irritation in the mouth (including oral thrush), a mild sore throat, coughing or a hoarse voice, pneumonia (infection of the lung) in COPD patients.

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

Tell your doctor if you notice any of the following:

Less frequent side effects:

- a slowing of the rate of growth of children and adolescents.
- an effect on the adrenal gland (a small gland next to the kidney).

- bruising of the skin
- aggression
- increased motor activity (difficulty to stay still)
- sleeping problems
- over-excited or irritable (these effects are more likely to occur in children)
- loss of voice
- hoarse voice (in children)

Side effects with unknown frequency:

- glaucoma (increased pressure in the eye)
- feeling restless
- nervous

These effects are much less likely to happen with inhaled corticosteroids than with corticosteroid tablets.

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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website, or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of BUDESONIDE RESPULES CIPLA.

5. How to store BUDESONIDE RESPULES CIPLA

Store at or below 30 °C.

Store all medicines out of reach of children.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

Do not use this medicine after the expiry date which is stated on the carton and foil sachet after Exp. The expiry date refers to the last day of that month.

Store the ampoules in their foil sachet and their original carton in order to protect from light and moisture.

Once you have opened a single ampoule it should be used within 12 hours. After this time, the ampoule and any remaining contents should be thrown away.

Once a foil sachet has been opened, the ampoules inside should be used within 3 months (it is a good idea to mark the opening date on the foil sachet to help you remember).

6. Contents of the pack and other information

What BUDESONIDE RESPULES CIPLA contains

The active substance is budesonide.

The other ingredients are citric acid monohydrate (E330), edetate disodium, Polysorbate 80 (E433), sodium chloride, sodium citrate (Dihydrate) (E331), and water for Injection.

What BUDESONIDE RESPULES CIPLA looks like and contents of the pack

Your medicine comes in the form of plastic ampoules containing 2 mL of a white to off-white suspension to be nebulised (made into a fine mist for inhalation).

The ampoules are packed in strips of 5 inside a foil sachet, 4 such sachets are then packed into a carton.

1's pack: Carton containing Triple laminated pouch having 1 respule of 2 mL

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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This leaflet was last revised in

First authorisation: 18 March 2025

Latest renewal: Not applicable

Registration number

BUDEFLAM 0,125 mg / mL RESPULES: 57/21.5.1/0001

BUDEFLAM 0,25 mg / mL RESPULES: 57/21.5.1/0002

BUDEFLAM 0,5 mg / mL RESPULES: 57/21.5.1/0003

Access to the corresponding Professional Information

To access corresponding Professional Information and translated Patient Information Leaflet, scan the QR Code below.

PLACE HOLDER:

The QR Code to be generated and included after approval.