

Dispense with Patient's Instructions For Use available at: <https://www.sunpharma.com/usa/products>

Patient Information and Instructions for Use

Budesonide (bew DEH so nide) Inhalation Suspension 2 mL ampules containing 0.25 mg, 0.5 mg, or 1 mg

For inhalation only.

Do not swallow.

Only use budesonide inhalation suspension with a jet nebulizer machine that is connected to an air compressor. Do not use with an ultrasonic nebulizer.

Read the Patient Information that comes with budesonide inhalation suspension before your child starts using it and each time you get a refill. There may be new information. This information does not take the place of talking with your healthcare provider about your child's medical condition or treatment. If you have any questions about budesonide inhalation suspension, ask your healthcare provider or pharmacist.

What is budesonide inhalation suspension?

Budesonide inhalation suspension is an inhaled corticosteroid medicine. Budesonide inhalation suspension is a long-term maintenance medicine used to control and prevent asthma symptoms in children ages 12 months to 8 years.

Inhaled corticosteroids help to decrease inflammation in the lungs. Inflammation in the lungs can lead to asthma symptoms. Budesonide inhalation suspension helps reduce swelling and inflammation in the lungs, and helps keep the airways open to reduce asthma symptoms.

Budesonide inhalation suspension does not treat the sudden symptoms (wheezing, cough, shortness of breath, and chest pain or tightness) of an asthma attack. Always have a short-acting beta₂-agonist medicine (rescue inhaler) with you to treat sudden symptoms. If your child does not have an inhaled, short-acting bronchodilator, ask your healthcare provider to have one prescribed for your child.

It is not known if budesonide inhalation suspension is safe or effective in children younger than 12 months or older than 8 years.

Who should not use budesonide inhalation suspension?

Do not use budesonide inhalation suspension:

- **to treat sudden symptoms of asthma**
- **if your child is allergic to budesonide or any of the ingredients in budesonide inhalation suspension. See the end of this leaflet for a complete list of ingredients in budesonide inhalation suspension.**

What should I tell my healthcare provider before using budesonide inhalation suspension?

Before your child uses budesonide inhalation suspension, tell your healthcare provider if your child:

- has an allergy. See the section "Who should not use budesonide inhalation suspension? There is a complete list of ingredients in budesonide inhalation suspension at the end of this leaflet.
- has or recently had chicken pox or measles, or has recently been near anyone with chicken pox or measles.
- has or had tuberculosis of the respiratory tract.
- has certain kinds of infections that have not been treated, including:
 - o fungal infections
 - o bacterial infections
 - o viral infections
 - o parasitic infections
 - o herpes simplex infection of the eye (ocular herpes simplex)

Budesonide inhalation suspension may not be right for children who have had any of these types of infections.

- has decreased bone mineral density (bone strength). Your child is at risk for decreased bone mineral density if he or she:
 - o is inactive for a long period of time
 - o has a family history of osteoporosis
 - o does not eat well (poor nutrition)
 - o takes bone thinning medicines (such as anticonvulsant medicines or corticosteroids) for a long time.

- has an eye problem such as increased pressure in the eye, glaucoma or cataracts.
- has liver problems.
- is planning to have surgery.
- has any other medical conditions.
- is pregnant or plans to become pregnant. It is not known if budesonide inhalation suspension will harm your unborn baby.
- is breast-feeding or plans to breast-feed. Budesonide can pass into breast milk. You and your healthcare provider should decide if you will use budesonide inhalation suspension or breast-feed.

Tell your healthcare provider about all the medicine your child takes, including prescription and non-prescription medicines, vitamins, and herbal supplements.

Using budesonide inhalation suspension with certain other medicines may affect each other causing side effects. Especially tell your healthcare provider if your child takes:

- corticosteroids
- anti-seizure medicine (anticonvulsants)
- medicines that suppress the immune system (immunosuppressant)
- ketoconazole (Nizoral)
- certain medicines that can affect how your liver breaks down medicine

Ask your healthcare provider or pharmacist for a list of these medicines, if you are not sure.

Know the medicines your child takes. Keep a list of them and show it to your healthcare provider and pharmacist when your child gets a new medicine.

How should I use budesonide inhalation suspension?

- Use budesonide inhalation suspension exactly as prescribed by your healthcare provider. Your child must use budesonide inhalation suspension regularly for it to work.
- Budesonide inhalation suspension comes in three strengths. Your healthcare provider has prescribed the strength that is best for your child.
- Do not stop using budesonide inhalation suspension, and do not change your child's dose of budesonide inhalation suspension without talking to your healthcare provider.
- Budesonide inhalation suspension is for inhaled use only. Use budesonide inhalation suspension with a jet nebulizer connected to an air compressor set up with a mouthpiece or face mask. Do not use an ultrasonic nebulizer to give budesonide inhalation suspension.
- Do not mix budesonide inhalation suspension with other nebulizer medicines. If your child uses another medicine by inhalation to treat asthma, talk with your healthcare provider for instructions on when to use the other medicine.
- If your child misses a dose, just give the next regularly scheduled dose when it is due. Do not use budesonide inhalation suspension more often than has been prescribed.
- Improvement in the control of asthma symptoms with budesonide inhalation suspension can occur within 2 to 8 days. It may take up to 4 to 6 weeks before maximum improvement is seen.
- Make sure your child always has a short-acting beta₂-agonist medicine with him or her. Your child should use the short-acting beta₂-agonist medicine for breathing problems between doses of budesonide inhalation suspension or if a sudden asthma attack happens. Call your healthcare provider right away if:
 - o the short-acting rescue medicine does not work as well for relieving asthma symptoms.
 - o your child needs to use the short-acting rescue medicines more often than usual.
 - o your child's breathing problems worsen with budesonide inhalation suspension
- Rinse your child's mouth with water and have him or her spit the water out after each budesonide inhalation suspension treatment. Do not swallow the water. This will lessen the chance of getting a fungal infection (thrush) in the mouth.
- If your child has used long-term corticosteroids and the dose is now being lowered or stopped, a warning card should be carried stating that your child may need corticosteroids during times of stress or during an asthma attack that does not get better with bronchodilator medicines.
- Your healthcare provider may check your child's blood, breathing and do eye exams while using budesonide inhalation suspension.
- Read the Patient Information and Instructions for Use at the end of this leaflet for detailed instructions about how to use budesonide inhalation suspension.

What are the possible side effects of budesonide inhalation suspension?

Budesonide inhalation suspension may cause serious side effects including:

- Thrush (candida), a fungal infection in your mouth and throat. Tell your healthcare provider if your child has any redness or white colored patches in the mouth or throat.
- Worsening of asthma or sudden asthma attacks.
- Allergic reactions. Tell your healthcare provider or get medical help right away if your child has:
 - o skin rash, redness or swelling
 - o severe itching
 - o swelling of the face, mouth and tongue
 - o trouble breathing or swallowing
 - o chest pain
 - o anxiety (feeling of doom)
- Immune system effects and a higher chance of infections. Your child is more likely to get infections when taking medicines that weaken the immune system. Symptoms of infection may include: fever, pain, aches, chills, feeling tired, nausea and vomiting. Tell your healthcare provider about any signs of infection while your child uses budesonide inhalation suspension.
- Adrenal insufficiency. Adrenal insufficiency is a condition in which the adrenal glands do not make enough steroid hormones. Symptoms of adrenal insufficiency include tiredness, weakness, nausea and vomiting, and low blood pressure.
- Decrease in bone mineral density (bone strength). Your healthcare provider may want to check your child for this during treatment with budesonide inhalation suspension.
- Slowed or delayed growth problems. Your child's healthcare provider may want to monitor your child's growth while using budesonide inhalation suspension.
- Eye problems, including glaucoma and cataracts. Your child's healthcare provider may suggest eye exams while using budesonide inhalation suspension.
- **Increased wheezing right after taking budesonide inhalation suspension. Always have a fast-acting inhaled bronchodilator medicine with you to treat sudden wheezing.**

Call your healthcare provider or get medical help right away if your child has any of the serious side effects listed above.

The most common side effects of budesonide inhalation suspension include:

- respiratory infections. Symptoms may include stuffy nose, sore nose and throat.
- runny nose
- cough
- viral infections
- viral irritation and inflammation of the stomach and intestine (gastroenteritis). Gastroenteritis symptoms may include: stomach area pain, diarrhea, nausea and vomiting, and loss of appetite.
- ear infections
- nosebleed
- pink eye (conjunctivitis)
- rash

Tell your healthcare provider if your child has any side effect that bothers him or her or that does not go away.

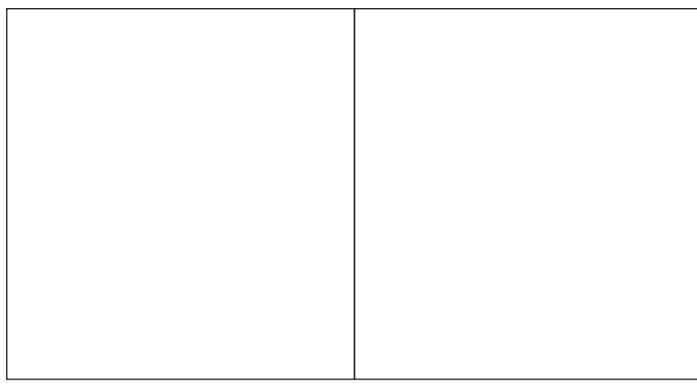
For more information, ask your healthcare provider or pharmacist.

Call your healthcare provider for medical advice about side effects. You may report side effects to Sun Pharmaceutical Industries, Inc. at 1-800-818-4555 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

How should I store budesonide inhalation suspension?

- Store budesonide inhalation suspension in an upright position at 20° to 25°C (68° to 77°F).
- Keep budesonide inhalation suspension in the aluminium foil pouch to protect from light until ready to use.
- After a budesonide inhalation suspension ampule is opened it should be used right away.
- Budesonide inhalation suspension ampules can be stored for 2 weeks after opening the protective aluminium foil pouch.
- Throw away budesonide inhalation suspension ampules if not used within 2 weeks of opening the protective aluminium foil pouch.
- Do not refrigerate or freeze.

Keep budesonide inhalation suspension and all medicines out of the reach of children.



General Information about budesonide inhalation suspension

Medicines are sometimes prescribed for conditions other than those listed in a Patient Information leaflet. Do not use budesonide inhalation suspension for a condition for which it was not prescribed. Do not give budesonide inhalation suspension to other people, even if they have the same symptoms that you have. It may harm them.

This Patient Information leaflet summarizes the most important information about budesonide inhalation suspension. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about budesonide inhalation suspension that is written for health professionals.

For more information, call 1-800-818-4555.

What are the ingredients in budesonide inhalation suspension?

Active ingredient: budesonide

Inactive ingredients: edetate disodium, sodium chloride, sodium citrate, citric acid monohydrate, polysorbate 80 and water for injection.

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Important:

Budesonide inhalation suspension is only for use with a jet nebulizer machine. Make sure you know how to use your jet nebulizer machine before your child uses budesonide inhalation suspension.

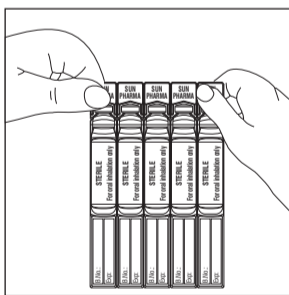
Budesonide inhalation suspension is a liquid that is turned into a mist by a nebulizer and inhaled into the lungs.

The face mask should be properly adjusted to optimize delivery and to avoid exposing the eyes to the nebulized medication. Corticosteroid effects on the skin can be avoided if the face is washed after the use of a face mask.

1. Budesonide inhalation suspension come in a sealed protective aluminium foil pouch.
 - Do not open the sealed pouch until you are ready to use a dose of budesonide inhalation suspension.
 - Open the sealed foil pouch along the dotted line and take out 1 single-dose ampule from the strip. See Figure 1.
 - Record the date that you opened the foil on the back of the pouch in the space provided.

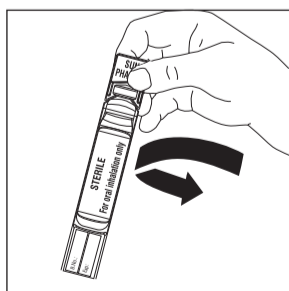
Return the unopened budesonide inhalation suspension ampules on the strip back into the foil pouch before storing.

Figure 1



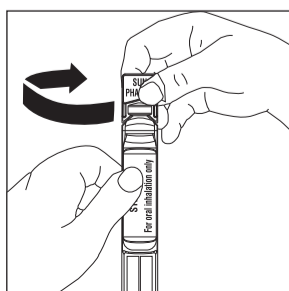
2. Gently shake the budesonide inhalation suspension ampule using a circular motion as shown in Figure 2.

Figure 2



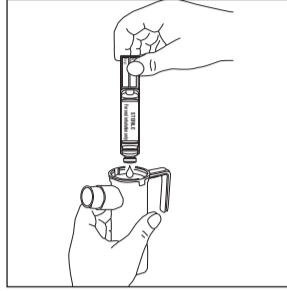
3. Hold the budesonide inhalation suspension ampule upright without squeezing the ampule and open by twisting off the top as shown in Figure 3.

Figure 3



4. Place the open end of the budesonide inhalation suspension ampule into the nebulizer cup (reservoir) and slowly squeeze all of the medicine from the ampule into the nebulizer medicine cup as shown in Figure 4. Throw away the empty ampule.

Figure 4



5. Use your jet nebulizer as directed.

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