WHAT IS NASCOBAL®?

NASCOBAL® is a prescription medicine used:

- For maintenance therapy to treat vitamin B₁₂ deficiency (low levels of vitamin B₁₂) in adults with pernicious anemia who achieved healthy vitamin B₁₂ levels after receiving vitamin B₁₂ shots and do not have nervous system problems.
- To treat vitamin B₁₂ deficiency caused by:
  - other medicines that cause vitamin B₁₂ deficiency, or
  - lack of absorption (malabsorption) that are not related to pernicious anemia.
- To prevent vitamin B₁₂ deficiency in adults that need to increase their levels of vitamin B₁₂ higher than normal levels.

NASCOBAL® should not be used for a vitamin B₁₂ absorption test known as the Schilling test.

In people who have corrected or have fixed their short-term causes of vitamin B₁₂ deficiency, the benefit of continued long-term use of NASCOBAL® is not known after vitamin B₁₂ deficiency has been corrected.

It is not known if NASCOBAL® is effective in people who currently have a stuffy nose, allergies or an upper respiratory infection. You should wait until these symptoms have gone away before using NASCOBAL®.

It is not known if NASCOBAL® is safe and effective in children.

Please see Important Safety Information continued inside. Please click here for full Prescribing Information.
Vitamin B12 is an essential vitamin. Everyone needs it to stay healthy. Vitamin B12 helps your body work properly. It protects your nerve cells so they can grow the right way. Vitamin B12 also helps make red blood cells, which give oxygen to the tissues in your body.

VITAMIN B12 DEFICIENCY

There are many causes for vitamin B12 deficiency:

- Celiac disease
- Immune system disorders
- Heavy drinking
- HIV infection
- Strict vegetarian or vegan diet
- Crohn’s disease
- Long-term use of certain medications such as metformin and proton pump inhibitors
- Atrophic gastritis
- Gastric surgery
- Hypothyroidism

TALK TO YOUR DOCTOR ABOUT BEING SCREENED FOR VITAMIN B12 DEFICIENCY.

Symptoms of vitamin B12 are non-specific.

Symptoms may include:

- Diarrhea or constipation
- Shortness of breath, mostly during exercise
- Fatigue, lack of energy, or lightheadedness when standing up or with exertion
- Swollen, red tongue or bleeding gums
- Loss of appetite
- Numbness and tingling of hands and feet
- Problems concentrating
- Confusion or change in mental status
- Loss of balance

IMPORTANT SAFETY INFORMATION FOR NASCOBAL®

Do not use NASCOBAL® if you are allergic to cobalt, vitamin B12, or any of the ingredients in NASCOBAL®.

NASCOBAL® can cause serious side effects, including:

- Weakening of your eye nerve in patients with early Leber’s disease. Tell your healthcare provider if you or your family has a history of early Leber’s disease.
- Serious allergic reactions. Serious, life-threatening allergic reactions, including death, have happened in people who have received vitamin B12 by injection or by intravenous (IV) infusion (parenteral). Tell your healthcare provider if you have ever had a reaction after you received vitamin B12 by injection or IV infusion.

Please see Important Safety Information continued on following pages.

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WHAT IS NASCOBAL®?

NASCOBAL® Nasal Spray is the only FDA-approved prescription vitamin B₁₂ nasal spray used as a supplement to treat vitamin B₁₂ deficiency. It is designed to bypass the GI tract and be absorbed directly into the bloodstream. It is clinically proven to have increased and maintained healthy vitamin B₁₂ levels. NASCOBAL® is a tasteless and odorless fine mist with a convenient, once-weekly dosing regimen:

1 spray, 1 nostril, 1x a week*

Do not drink hot liquids or eat hot foods at least 1 hour before and 1 hour after taking NASCOBAL® Nasal Spray.

*Dose adjustments may be required.

IMPORTANT SAFETY INFORMATION FOR NASCOBAL® (continued)

• **Hiding (masking) a folate deficiency.** Your healthcare provider may do certain blood tests to check your vitamin B₁₂ and folate levels.

• **Low potassium levels (hypokalemia) and low blood platelets (thrombocytopenia)** can happen in people with serious megaloblastic anemia. Your healthcare provider may monitor your potassium levels and platelet counts during your treatment with NASCOBAL®.

Please see Important Safety Information continued on following pages.

Please click here for full Prescribing Information.
HOW TO USE NASCOBAL®

BEFORE YOU TAKE NASCOBAL®

▶ The unit contains only 1 spray: DO NOT prime before use
▶ Blow nose gently to clear both nostrils
▶ Hold the unit with your thumb, supporting it at the bottom, and your index and middle fingers on either side of the nozzle

TAKING NASCOBAL®

▶ Gently close 1 nostril with your other index finger. Insert the nozzle into open nostril approximately ½ inch, or as far as feels comfortable, and tilt your head slightly forward. Do not press the plunger yet
▶ Breathe in gently through your nose, close your mouth, and at the same time, press the plunger firmly with your thumb

AFTER YOU TAKE NASCOBAL®

▶ Remove the nozzle from your nostril. At the same time, keep your head level for 10 to 20 seconds while gently breathing in through your nose and breathing out through your mouth

Do not drink hot liquids or eat hot foods at least 1 hour before and 1 hour after taking NASCOBAL® Nasal Spray.

VITAMIN B₁₂ OPTIONS

NASCOBAL® NASAL SPRAY

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<tr>
<th>Feature</th>
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SUBLINGUAL (under-the-tongue)

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INJECTIONS

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IMPORTANT SAFETY INFORMATION FOR NASCOBAL® (continued)

Vitamin B₁₂ deficiency may hide signs of a blood condition called polycythemia vera. Treatment with NASCOBAL® may uncover this condition.

Tell your doctor if you are pregnant or planning to become pregnant (it is not known if NASCOBAL® will harm your unborn baby).

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Please see Important Safety Information continued on following pages.

Please click here for full Prescribing Information.
IMPORTANT SAFETY INFORMATION FOR NASCOBAL® (continued)

The most common side effects include infection, headache, feeling weak, nausea, swelling of your tongue, runny nose, tingling of the hands and feet.

These are not all the possible side effects of NASCOBAL®. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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Please [click here](#) for full Prescribing Information.