

Perrigo®

Prevalin allergy



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Section One: Brand Questions:

1.1 What is Prevalin?

PREVALIN™ ALLERGY is clinically proven to reduce allergic rhinitis symptoms, as it blocks allergens that cause the allergic reaction. PREVALIN™ ALLERGY nasal spray works directly where the allergic reaction starts, on the respiratory mucosa of the nose. PREVALIN™ ALLERGY'S patented Nasya™ technology uses a combination of oils and emulsifiers, which give unique transformation properties from gel to liquid for easy dispersion. Upon settling on the nasal mucosa, PREVALIN™ ALLERGY reverts to its original gel-like consistency to form an allergen-impermeable micro-gel barrier. As most airborne allergens come in through the nose, PREVALIN™ ALLERGY is an ideal solution for hay fever and allergic rhinitis.

1.2 Where can I buy Prevalin?

Most major pharmacies and supermarkets.

1.3 Is Prevalin safe to use?

Prevalin is considered safe for use when used in line with the instructions for use.

1.4 Where can I find out more information related to Prevalin?

For more information regarding Prevalin you can refer to the website at: <http://www.prevalin.com/uk/>. Alternatively you can contact us at 02035989601 or by email: UKLOcustomerservice@perrigo.com

1.5 Do I need a prescription?

Prevalin is available without a prescription.

1.6 Who do I contact if I have questions about Prevalin?

You can contact us at 02035989601 or by email: UKLOcustomerservice@perrigo.com

1.7 Can I use more than one of the products in Prevalin range at once?

No.

1.8 What is the difference between Prevalin Adults and Kids?

It contains the same Prevalin™ formula, only the dispensing tip is smaller so the amount sprayed into the nostril is especially adapted to the size of a child's nostril.

1.9 Has there been any recent update to the Prevalin Brand?

Prevalin Allergy and Prevalin Allergy Kids have had a formulation update. The product now contains preservatives. You may feel some form of irritation when the product is applied, which will subside quickly. If you experience any serious discomfort after application of the product, discontinue using and consult your physician.

1.10 What is the ‘triple action’ of Prevalin?

- It ‘defuses’ pollen so they cannot irritate the mast cells in the nasal mucosa. Its free fatty acids in the formula are known for decreasing their allergic potential and hence ‘defusing’ them from triggering the allergic reaction
- Prevalin™’s fine mist resettles as a barrier on the nasal mucosa, preventing pollen that will be inhaled from irritating the mast cells and triggering an allergic reaction
- The sesame oil in Prevalin™ stimulates the clearance of the pollen out of the nose, i.e. the mucociliary process.

1.11 Does it work immediately?

Prevalin™ does not need prior resorption into the cell, which is required to exert activity in the case of any drug / drug like substances (i.e. corticosteroids or decongestants). The gel-barrier will form immediately, and prevent further pollens inhaled from getting in contact with the nasal mucosa and subsequently attach to mast cells. This will ensure immediate action against further pollen exposure.

1.12 How does Prevalin ‘defuse’ pollen?

Its formula contains free fatty acids, which are known for decreasing the pollens’ allergic potential and hence ‘defusing’ them from triggering the allergic reaction.

1.13 Is Prevalin Just a barrier?

No. When sprayed into the nose, it does 3 things:

1. It encapsulates the pollen already inside the nose and decreases their allergenic potential
2. It forms a stable, impermeable, long-lasting gel-barrier on the nasal mucosa so future inhaled pollen will not be able to penetrate the mucosa and cause symptoms
3. It stimulates the clearance of allergens in the nose

1.14 Why do we claim 4 – 6 hours of protection?

The mucociliary clearance takes place approximately every 6 hours. This is a normal mechanism of the body to get rid of foreign particles in the nose. The Prevalin™ micro-gel on the nasal lining will thus be discarded over time. Therefore, re-application is recommended after 4-6 hours

1.15 Does Prevalin™ only treats and protects against pollen (hay fever) or also against other allergens such as dust mite, animal hair, etc?

Prevalin™’s formula resettles as an impermeable, non-porous barrier on the nasal mucosa. Theoretically, based on comparing the size of pollen versus other allergens, Prevalin™ should also be effective for other allergens as pollen are the smallest ones.

1.16 Does Prevalin™ only treats the nasal symptoms or also the itchy and runny eyes?

The majority of secondary eye symptoms can be traced back to the aggression of the nasal mucosa:

- Mast cells (containing histamine) are predominantly present in areas with good blood flow (i.e. nasal mucosa), once in contact with pollen the histamine is released and causes the allergic reaction. The histamine is distributed by the blood flow to neighbouring areas (i.e. eyes), and cause symptoms there as well. In the eye itself only the conjunctiva contains mast cells, but much fewer than in the nasal mucosa, and the surface area is also considerably smaller.

- The conjunctiva will not be exposed to allergens directly, so the symptoms that origin from the conjunctiva's mast cells will be less severe than the ones caused in the nasal mucosa. The mast cells are also present in the conjunctiva underneath the eyelids. Although the conjunctiva is not exposed directly to allergens in the air, allergens touching the exposed cornea may be trapped by tears and could be distributed to the conjunctiva.
- As there are fewer mast cells in the conjunctiva than in the nasal mucosa, there will be less symptoms, even if challenged with same quantum of pollen. Furthermore, the eyes are constantly moistened/ washed by the tears. As such, most of the allergens are being washed down before they can reach the conjunctiva.

1.17 What about pollen that enter through the mouth?

If inhaled, pollen will rarely reach the deeper bronchi, as they get trapped in the upper respiratory tract and transported out

1.18 Does Prevalin cover the complete sensitive area in the nose?

1. Prevalin has patented thixotropic properties, which when shaken turns the original gel-like consistency into a fine mist that can be sprayed easily up in the nose and reaches a broad inner surface of the nasal cavity, where it immediately resettles as a stable, impermeable barrier.
2. Research shows that even very crude application methods such as ointments or creams, which achieve less coverage of the nasal mucosa cause significant improvement of symptoms.
3. Mast cells have been shown to migrate to the nasal epithelium during the pollen season, which is predominantly exposed to pollen. This indicates that only the areas that are reached by Prevalin fine spray need to be covered, as the inhaled pollen will basically reach out to the same areas.
4. Recent study also show that pollen are affecting the frontal regions of the nose, where even nasal sprays with a particle size of 50µm reach a perfect coverage. As Prevalin™ has a spray particle size of <100µm, so its particles are distributed to cover the frontal area of the nose with some portion that may reach deeper to cover the upper half of the nasal cavity.

1.19 Can Prevalin™ be used together with nasal corticosteroids or antihistamines?

Prevalin™ is drug-free and contains mainly natural ingredients (food grade). It is inert and non-toxic. Prevalin™ is not known to interact with other medicines or with other forms of allergy treatment. The application of Prevalin™ should not affect the efficacy of anti-histamine tablets. If other nasal spray is needed, Prevalin™ should be applied **after** any other nasal spray in order not to disturb the formation of the impermeable barrier

1.20 What happens if Prevalin™ is not shaken before dispensed?

Prevalin™ is made with unique Nasya™ technology, its thixotropic properties allow transformation from gel to liquid state merely by shaking. Therefore, it is very important to shake well before spraying. There is a possibility to spray without shaking the bottle, but the spraying pattern would not be even and hence cannot form a proper layer of protection on the nasal mucosa. Without proper shaking, Prevalin fluid will not be dispensed as fine sprayed particles (spray droplet), but it will not clog at the tip of the bottle.

1.21 Where does Prevalin™ go a few hours after the application?

Prevalin™ gel is naturally dislodged and is then blown out as a natural reaction or is sneezed out. A small amount will drip down the back of the nose into the throat and is naturally spat out or swallowed. This is a normal mechanism by which our body gets rid of particulate matter in the nose. No unwanted side effect is expected as the product is made of food grade ingredients. Furthermore, the quantity involved is negligible.

1.22 What would happen if Prevalin™ reaches the sinuses?

Prevalin™ gel can get into the sinuses. It would be cleared through normal muco-ciliary clearance.

1.23 Does Prevalin™ affect the sense of smell?

No. The application of Prevalin™ should not affect the ability to smell.

1.24 Can Prevalin™ be used for long term?

The long term usage was not studied. However, Prevalin™ is made of natural, gras & food grade ingredients and the ingredients used are chemically inert & non-invasive. The long term usage would be based on own justification or recommendation from a physician.

1.25 What happens to the protective micro-gel barrier when the nose is blown?

Prevalin™ is expelled from the nose when blown. The Prevalin™ gel is naturally dislodged and is then blown out as a natural reaction or is sneezed out. A small amount will drip down the back of the nose into the throat and is naturally spat out or swallowed. This is a normal and natural mechanism by which our body gets rid of particulate matter in the nose.

There is no unwanted side effect because all ingredients used have acquired GRAS status and are chemically inert.

To maintain the protective barrier on nasal cavity, we suggest the application of Prevalin™ at 2-3 times a day (every 6 hours) and to blow the nose to clear off the disrupted Prevalin™ gel before every application. Since every application of Prevalin™ will be discarded over time, it will not remain in the nasal cavity.

1.26 Prevalin™ contains the ingredient Sesame. Is this dangerous for people who are allergic to sesame?

No. Sesamum indicum (sesame) seed oil is widely used for food, an edible oil or pharmaceutical products (intramuscular, subcutaneous or topical). It is generally regarded as non-toxic and non-irritant material. On top, the allergens in the seeds may be inactivated or destroyed by **heating** as heat extracted sesame oil or baked sesame seeds do not cause anaphylactic reactions in sesame seed allergic individuals.

1.27 Prevalin™ contains the ingredient Mint. Is this dangerous for people who are allergic to mint?

No. Menthol is widely used in pharmaceuticals, confectionery, and toiletry products as a flavouring agent or odour enhancer. It also exerts a cooling or refreshing sensation that is exploited in many topical preparations.

1.28 Can athletes and professional sportspeople use Prevalin™?

Yes. Prevalin™ is not a drug and it is non-systemic. It is non-sedating and does not contain ingredients forbidden by the international sports organizations.

1.29 Can people with peanut/nut allergies take Prevalin?

Sesame seeds do not fall into the same category as peanuts or tree nuts. We do not have any peanuts based ingredient in our formula. Sesame seeds are generally regarded as non-toxic and non-irritant material.

Based on biocompatibility studies of this product however. Prevalin is safe for use.

1.30 Do you know if Prevalin can be used safely by someone with nasal polyps?

Yes, prevalin can be used in patients with nasal polyps. However, if the patient is on treatment (nasal steroid spray) for the polyps, Prevalin should not be used concurrently as the mechanical barrier by Prevalin may reduce the efficacy of the nasal spray. Do inform the patient to consult his/her HCP's as well.

1.31 Can people with epilepsy take Prevalin?

We have to exercise caution with these patients as their trigger could be **anything**. The management of epilepsy is a joint management of HCPs. Therefore, usage of any medications/products MUST be discussed with the respective HCPs to avoid a relapse.

On the basis Prevalin is a medical device exerting its action via a physical barrier in the nose, Prevalin should be safe to be used in patients with epilepsy. Unless, the patient is allergic to components of Prevalin or his/her seizures are triggered by strong smells.

1.32 Can you recommend it with an antihistamine?

Prevalin™ is drug-free and contains mainly natural ingredients (food grade). It is inert and non-toxic. Prevalin™ is not known to interact with other medicines or with other forms of allergy treatment. The application of Prevalin™ should not affect the efficacy of anti-histamine tablets. If other nasal spray is needed, Prevalin™ should be applied **after** any other nasal spray in order not to disturb the formation of the impermeable barrier.

1.33 Can asthmatics take Prevalin?

There is no clinical evidence on the usage of Prevalin by asthmatics, nor is there any evidence that Prevalin causes any side effects among asthmatics. However, Prevalin is drug-free and contains mainly natural ingredients (food grade). If other asthmatic medication is needed, Prevalin should not affect the efficacy of the medication because it is non-systemic and chemically inert. Furthermore, it has no known interaction with other medicines or with other form of allergy treatment.

If other nasal spray is needed, we would recommend to apply the nasal spray BEFORE Prevalin. This is simply due to the unique mode of action of Prevalin, which form an impermeable/non-porous barrier. This could affect the efficacy of another nasal spray.

We strongly recommend the asthmatic patient do seek advise from their healthcare professional before he/she starts on any medications, including Prevalin.

1.34 Can people on Warfarin take Prevalin?

Warfarin is an oral anticoagulant that is prescribed to people who are diagnosed with blood coagulation/ thrombosis or atrial fibrillation (AF). These people normally require warfarin to prevent recurrence of blood clotting or other complications. They are considered the high-risk group. Physicians or doctors normally treat this group of patients with extra caution. Even though Prevalin is a certified medical device that does not cause any pharmacological, immunological or metabolic effects, and is administered via nasal route, it is still strongly recommended that this group of patients seek further advise from their physician before taking Prevalin.

1.35 Does Prevalin contain any carbohydrates?

Carbohydrates are one of the main types of nutrients. The most common and abundant forms are sugars, dietary fibers and starches.

We can confirm that Prevalin Allergy Plus and Prevalin Allergy Adults do not contain carbohydrates.

Section Two: Product Questions:

2A – Prevalin Allergy – Core Questions:

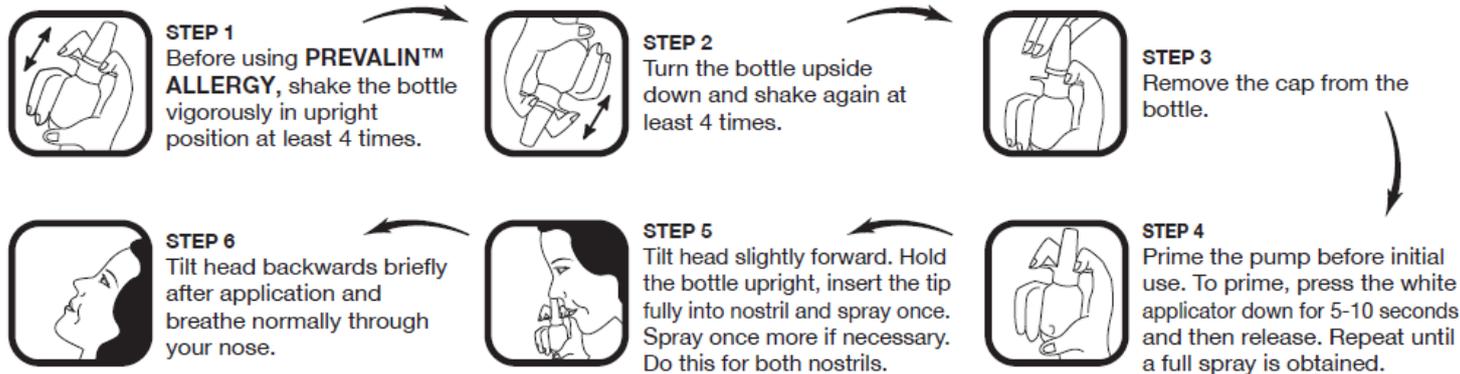
2.1 What is Prevalin Allergy?

PREVALIN™ ALLERGY is clinically proven to reduce allergic rhinitis symptoms, as it blocks allergens that cause the allergic reaction. PREVALIN™ ALLERGY nasal spray works directly where the allergic reaction starts, on the respiratory mucosa of the nose. PREVALIN™ ALLERGY'S patented Nasya™ technology uses a combination of oils and emulsifiers, which give unique transformation properties from gel to liquid for easy dispersion. Upon settling on the nasal mucosa, PREVALIN™ ALLERGY reverts to its original gel-like consistency to form an allergen-impermeable micro-gel barrier. As most airborne allergens come in through the nose, PREVALIN™ ALLERGY is an ideal solution for hay fever and allergic rhinitis.

2.2 How do I use Prevalin Allergy?

Apply 1 to 2 sprays into each nostril, 2 to 3 times a day (works up to 6 hours). Children of 12 years and below should use PREVALIN™ ALLERGY KIDS and only under adult supervision. Always blow nose thoroughly before each application.

During the first hour of use, you may experience a slight blocked nose sensation. This is a transient sensation that will subside quickly and will gradually disappear with subsequent use. If you experience any serious discomfort after the application, discontinue using the product or consult



your physician. If concurrent use of another nasal spray is required, PREVALIN™ ALLERGY should be re-applied afterwards in order not to disturb the formation of the impermeable barrier.

2.3 How does Prevalin Allergy work?

PREVALIN™ ALLERGY works directly where allergens trigger an allergic reaction, on the respiratory mucosa of the nose.

2.4 How long after opening Prevalin Allergy can it be used for?

The product should be used within 90 days after opening.

2.5 How long can I take Prevalin Allergy for?

The long term usage was not studied. However, Prevalin™ is made of natural, gras & food grade ingredients and the ingredients used are chemically inert & non-invasive. The long term usage would be based on own justification or recommendation from a physician.

2.6 What is the shelf life for Prevalin Allergy?

The shelf life for Prevalin Allergy is 30 months. The product should be used within 90 days after opening.

2.7 What is the age range for Prevalin Allergy?

12+

2.8 What is Prevalin Allergy classification?

Medical Device.

2.9 Can Prevalin Allergy be taken with other medication?

PREVALIN™ ALLERGY is not known to interact with other medicines or with other forms of allergy treatment.

2.10 Who should not use Prevalin Allergy?

Do not use this product in case you are hypersensitive to sesame seed oil or any other ingredients contained in PREVALIN™ ALLERGY.

2.11 Is Prevalin Allergy suitable for vegetarians / vegans?

Prevalin does not contain any ingredient of animal origin and is therefore it is suitable for vegetarians and vegans.

2.12 Is Prevalin Allergy safe while pregnant or breast-feeding?

Yes. Pregnant women can use Prevalin™. We have obtained an official expert opinion for this statement “The product can be used safely by pregnant and breastfeeding women” from Dr Lautenbacher.

2.13 Are there any side effects?

Very rare cases of allergic reactions have been reported, with symptoms such as blocked or running nose, localized soreness, dryness, itching, swelling, watery eyes or rashes. In such cases the use of product should be discontinued immediately and if symptoms persist medical treatment should be sought.

2B – Prevalin Allergy – Additional Questions:

2.14 Does it contain any ingredients derived from grain?

We confirm that none of the ingredients used in Prevalin is derived from any kind of grain, including corn or their derivatives. Also the Xanthan gum contained is derived by bio fermentation of a sugar source, which is not from grains, corn or their derivatives. However, an individual with known allergy might also be allergy to other plant base materials, hence you should consult your healthcare professional to assess need for an allergy test before start using Prevalin.

2.15 Why is there Sesame Seed oil in this product?

The packaging of this product states that one of the ingredients is sesame oil.

Sesamum indicum (sesame) seed oil is widely used for food, an edible oil or pharmaceutical products (intramuscular, subcutaneous or topical). It is generally regarded as non-toxic and non-irritant material. On top, the allergens in the seeds may be inactivated or destroyed by heating as heat extracted sesame oil or baked sesame seeds do not cause anaphylactic reactions in sesame seed allergic individuals. In the manufacturing process of Prevalin, heat is one of the main element. Heat is used throughout the process until the stage where the bulk is subjected to 121 degree Celsius.

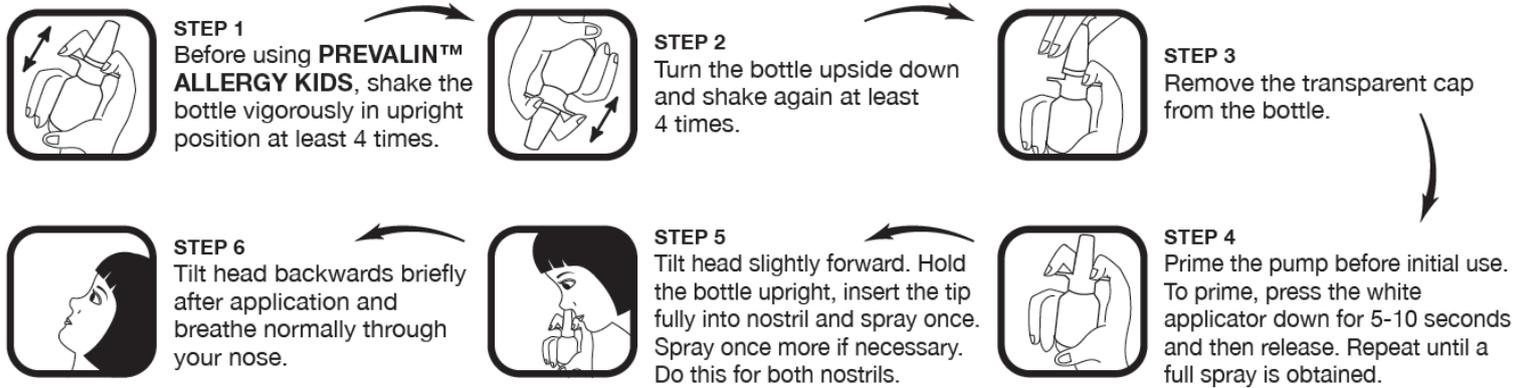
3A – Prevalin Allergy Kids – Core Questions:

3.1 What is Prevalin Allergy Kids?

PREVALIN™ ALLERGY KIDS is clinically proven to reduce allergic rhinitis symptoms, as it blocks allergens that cause the allergic reaction. PREVALIN™ ALLERGY KIDS nasal spray works directly where the allergic reaction starts, on the respiratory mucosa of the nose. PREVALIN™ ALLERGY KIDS's patented Nasya™ technology uses a combination of oils and emulsifiers, which give unique transformation properties from gel to liquid for easy dispersion. Upon settling on the nasal mucosa, PREVALIN™ ALLERGY KIDS reverts to its original gel-like consistency to form an allergen-impermeable micro-gel barrier. As most airborne allergens come in through the nose, PREVALIN™ ALLERGY KIDS is an ideal solution for hay fever and allergic rhinitis.

3.2 How do I use Prevalin Allergy Kids?

Apply 1 to 2 sprays into each nostril, 2 to 3 times a day (works up to 6 hours). PREVALIN™ ALLERGY KIDS is suitable for children between 6 and 12 years of age. PREVALIN™ ALLERGY KIDS should only be used under adult supervision. Always blow nose thoroughly before each application.



During the first hour of use, your child may experience a slight blocked nose sensation. This is a transient sensation that will subside quickly and will gradually disappear with subsequent use. If your child experience any serious discomfort after the application, discontinue using the product or consult your physician. If concurrent use of another nasal spray is required, PREVALIN™ ALLERGY KIDS should be re-applied afterwards in order not to disturb the formation of the impermeable barrier.

3.3 How does Prevalin Allergy Kids work?

PREVALIN™ ALLERGY KIDS works directly where allergens trigger an allergic reaction, on the respiratory mucosa of the nose.

3.4 How long after opening Prevalin Allergy Kids can it be used for?

The product should be used within 90 days after opening.

3.5 How long can I take Prevalin Allergy Kids for?

The long term usage was not studied. However, Prevalin™ is made of natural, gras & food grade ingredients and the ingredients used are chemically inert & non-invasive. The long term usage would be based on own justification or recommendation from a physician.

3.6 What is the shelf life for Prevalin Allergy Kids?

The shelf life for Prevalin Allergy Kids is 30 months. The product should be used within 90 days after opening.

3.7 What is the age range for Prevalin Allergy Kids?

6 – 12 years old, supervised by an adult.

3.8 What is Prevalin Allergy Kids classification?

Medical Device.

3.9 Can Prevalin Allergy Kids be taken with other medication?

PREVALIN™ ALLERGY KIDS is not known to interact with other medicines or with other forms of allergy treatment.

3.10 Who should not use Prevalin Allergy Kids?

Do not use this product in case you are hypersensitive to sesame seed oil or any other ingredients contained in PREVALIN™ ALLERGY KIDS.

3.11 Is Prevalin Allergy Kids suitable for vegetarians / vegans?

Prevalin does not contain any ingredient of animal origin and is therefore it is suitable for vegetarians and vegans.

3.12 Is Prevalin Allergy Kids safe while pregnant or breast-feeding?

N/A – it's designed for ages 6 – 12.

3.13 Are there any side effects?

Very rare cases of allergic reactions have been reported, with symptoms such as blocked or running nose, localized soreness, dryness, itching, swelling, watery eyes or rashes. In such cases the use of product should be discontinued immediately and if symptoms persist medical treatment should be sought.

3B – Prevalin Allergy Kids – Additional Questions:

3.14 Why is the dosage smaller for Prevalin Allergy Kids?

Drug companies and physicians for many years assumed that medical providers could safely extrapolate study results in adults and scale down the dosage levels for children. The anatomy of the nose, sinuses and nose cavity of a child (6-12 years) and an adult are quite similar, only differ in size. The Kids' dosage was proportional reduced from 0.14ml to 0.07ml. It can be expected that the reduced dosage is sufficient to provide efficacious allergy protection for children, age 6-12.

In terms of safety, the biocompatibility tests & toxicity data obtained from Prevalin™ can be used by Prevalin™ for Kids, as the formulation & ingredients used are the same.

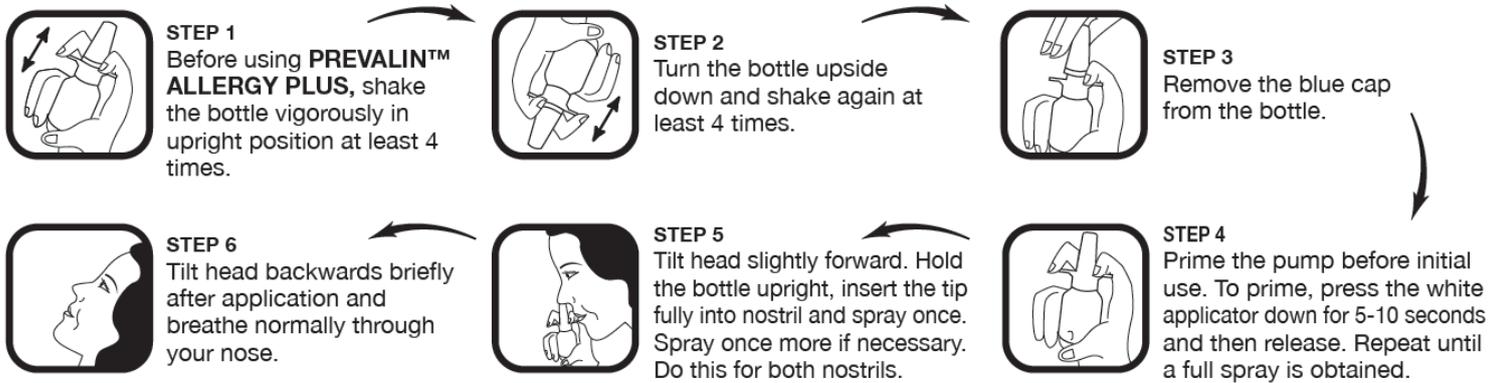
4A – Prevalin Allergy Plus – Core Questions:

4.1 What is Prevalin Allergy Plus?

PREVALIN™ ALLERGY PLUS is a drug-free nasal spray with a double protection action to provide fast relief and extra protection against hay fever, dust mite and pet allergies. This product contains a patented combination of oil and emulsifiers, Nasya™ Technology with clinically proven efficacy, which gives unique transformation properties from gel to liquid for easy dispersion. Upon settling on the nasal mucosa, PREVALIN™ ALLERGY PLUS reverts to its original gel-like consistency to form an impermeable micro-gel barrier, hence blocking the body's allergic responses. If the allergic reaction has been triggered, the therapeutic oil in Nasya™ will act as a mast cell stabiliser, thus reducing sensitivity to allergens. Symptoms such as sneezing, blocked/runny nose or itchy/watery eyes will be relieved.

4.2 How do I use Prevalin Allergy Plus?

Apply 1 to 2 sprays into each nostril, 2 to 3 times a day (works up to 6 hours). Children of 12 years and below should use PREVALIN™ ALLERGY KIDS and only under adult supervision. Always blow nose thoroughly before each application.



During the first hour of use, you may experience a slightly blocked nose. This sensation is transient. It will subside quickly and disappear with subsequent use. You may also feel some form of irritation when PREVALIN™ ALLERGY PLUS is applied, which will subside quickly. If you experience any serious discomfort after application of PREVALIN™ ALLERGY PLUS, discontinue using and consult your physician. If concurrent use of another nasal spray is required, PREVALIN™ ALLERGY PLUS should be re-applied afterwards in order to continue the impermeable barrier protection. Avoid contact with open wounds.

4.3 How does Prevalin Allergy Plus work?

PREVALIN™ ALLERGY PLUS works directly where allergens trigger an allergic reaction, on the respiratory mucosa of the nose.

4.4 How long after opening Prevalin Allergy Plus can it be used for?

The product should be used within 90 days after opening.

4.5 How long can I take Prevalin Allergy Plus for?

The long term usage was not studied. However, Prevalin™ is made of natural, grass & food grade ingredients and the ingredients used are chemically inert & non-invasive. The long term usage would be based on own justification or recommendation from a physician.

4.6 What is the shelf life for Prevalin Allergy Plus?

The shelf life for Prevalin Allergy Plus is 30 months. The product should be used within 90 days after opening.

4.7 What is the age range for Prevalin Allergy Plus?

12+

4.8 What is Prevalin Allergy Plus classification?

Medical Device.

4.9 Can Prevalin Allergy Plus be taken with other medication?

PREVALIN™ ALLERGY PLUS is not known to interact with other medicines or with other forms of allergy treatment

4.10 Who should not use Prevalin Allergy Plus?

Do not use this product if you are sensitive to sesame/perilla seed oil or any of the other ingredients in PREVALIN™ ALLERGY PLUS.

4.11 Is Prevalin Allergy Plus suitable for vegetarians / vegans?

Prevalin does not contain any ingredient of animal origin and is therefore it is suitable for vegetarians and vegans.

4.12 Is Prevalin Allergy Plus safe while pregnant or breast-feeding?

PREVALIN™ ALLERGY PLUS is a drug-free solution. Suitable for use by athletes, pregnant & breast feeding women.

4.13 Are there any side effects?

Very rare cases of allergic reaction have been reported. They include symptoms such as blocked and runny nose, localised pain, dryness, itching and swelling in the nose, watery eyes and rashes. In such cases, the use of the product should be discontinued immediately and if symptoms persist, consult your physician.