

THE EAR FOUNDATION OF SANTA BARBARA
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General Information

How do I contact the Ear Foundation?

You can reach the Ear Foundation by phone at (805) 569-1111, by e-mail at earfdn@aol.com, through the "Contact" form on our website <https://www.patulend.com/contact.html>, or send a written request to: The Ear Foundation, 2420 Castillo Street, Suite 100, Santa Barbara, CA 93101-4346

What is the history of PatulEND®?

From Dr Joseph Di Bartolomeo, MD FACS:

"Over 25 years ago, when I suffered from a Patulous Eustachian Tube, I was told there was no treatment for it. And so began my mission in 1992 when I filed a New Drug Application (NDA) for an Investigative New Drug (IND) study with the FDA. They immediately discouraged me, as an individual clinician, and throughout the process they continuously told me that an individual can't do it alone. The applications they review are traditionally sponsored or undertaken by a large pharmaceutical company, and prohibitively expensive. But for a rare disease the size of the population affected would be very small, and the potential sales market was not of any interest to commercial manufacturers.

Having no ENT Division, the FDA assigned my IND Application to the Pulmonary Division. As a small entity, my application fees were markedly reduced, which is something I believe they preferred to avoid. During the next 4-6 years I provided the results of my research for the national and international subject participants examined in Santa Barbara, and monitored by our local Institutional Review Board (IRB).

The FDA eventually approved the initial synthesis of Pre-clinical testing, research and development for *Phase I*. Several years later, I was approved to begin to conduct the *Phase II* study, clinical research and development, and animal testing. I was again cautioned that the staff of a pharmaceutical company was usually required. I received approval as principal investigator and successfully completed the *Phase II* requirements.

When they continued to discourage me from applying for approval to continue with *Phase III*, and would not grant me an interview, I insisted on an explanation. Finally, I was informed by telephone that my last reviewer within the Pulmonary Division, assigned to my IND Application, had lost my file.

I was simply advised to start over and resubmit the data that had been collected over the past decade a second time. I complied, reluctantly, and eventually was approved to begin the *Phase III* Clinical Trial of my IND study.

Being frustrated with the misunderstanding by the FDA reviewers assigned from the Pulmonary Division (they still had no ENT Division), and while at the same time trying to improve on the preliminary drug formulation, my curiosity and experience gained. Perusal of biochemistry literature led me to replace each of the pharmaceutical ingredients with non-pharmaceutical, tissue building nutrients and antioxidants. The new composition produced more predictable and prompt results, supported immuno-defenses, and promoted normal tissue healing for long term benefits, with little or no side effects.

After more than 12 years, without the financial help of a single Federal, National, or other governmental grant of any kind, I was able to develop the safest and most effective remedy for the disturbing autophony of PET disorders. Having been the original guinea pig and repeat subject throughout the pharmaceutical studies, I was personally relieved.

At this point, the FDA realized that the new formulation qualified as a supplement and was exempt from requiring a prescription. As such, it allowed PatulEND® to be dispensed OTC.”

What are the FDA patents?

PatulEND® has been awarded the US Patents 5,470,587 and 11/777,550. It is available without a prescription.

Is there an instruction manual?

There is an instruction manual included in your confirmation email, as well as a link to a Youtube video where Dr. Di Bartolomeo, creator of PatulEND® nose drops, demonstrates how to administer the nose drops.

Are there any other names for PET?

Patulous Eustachian Tube is also referred to as:

- Eustachian Tube Dysfunction
- Tuba Aberta/Aperta
- Klaffende tube
- Tuba beante
- Béance tubaire

Do you know of any chatrooms/support groups for people suffering from PET?

There is a Facebook group run from the UK that many Anglophones are using:

https://m.facebook.com/groups/16497323618/?ref=group_header&view=group.

Diagnosis

How do I know if I have Patulous Eustachian Tube?

Most patients report a sensation of hearing their own voice (autophony) or their own loud breath sounds (amphoria), but their otolaryngologist observes normal ear anatomy etc. Once the physician inspects the eardrum, it is observed to move to and fro with respiratory movements. There are diagnostic tests to also identify the movement of the tympanic membrane. As a rare disease, it is often undiagnosed by even the most astute physician.

Crackling and popping sounds in the ear, alongside a feeling of fullness that feels like fluid, are typical of the mild form of PET, a semi-patulous Eustachian tube.

I have tinnitus, does that mean I also have PET?

There are several hundred causes of tinnitus, separate from a Patulous Eustachian tube. A thorough ENT examination is the only way to possibly find out.

I think I have PET symptoms, and I take Adderall, do I have PET?

As an amphetamine, Adderall may affect the vascular system. When this occurs, the patient may hear a whooshing or swishing sound in the ears. This is not actually an ear phenomenon, but a vascular phenomenon. Essentially, one is hearing the blood circulation in the vessels near the ear. These symptoms do not subside when one lies down, as with PET symptoms. It is seen in patients, infrequently, where patients have other ear symptoms in addition to PET and sometimes they are

related to blood pressure or blood vessels, which are then usually evaluated and addressed by their internist or cardiologist.

Composition

What are the ingredients?

PatulEND® is formulated from pure, pharmaceutical grade, essential nutrients and vitamins with antioxidant properties, and balanced electrolytes for absorption by the nasal membranes. This results in tissue healing and improved membrane function. It is a drug-free, topical supplement product manufactured without any alcohol, sugar, hormones, herbal derivatives, sugar, wheat, yeast, preservatives, artificial additives, or coloring. A prescription is not required.

The proprietary ingredients include: the essential vitamin C, nutrient complex derivatives with enhanced antioxidant properties, and minerals to increase bioavailability to the tissue hosts. The composition is included in the FDA publication GRAS (Generally Regarded As Safe) for the complete formula. Since it is drug-free, it is exempt from requiring a prescription.

Why don't you sell a prescription medication?

The original pharmaceutical composition was totally replaced after the information about the mechanisms responsible for PET symptoms were determined. The results derived from the study enabled us to develop the newly formulated, safer, drug-free essential nutrient product. PatulEND® has no known side effects and supports tissue healing when taken, which the prescription product could not do.

If PatulEND® is just a vitamin, how is it more effective than store-bought supplements?

PatulEND® is available without a prescription because it is drug free and contains only pure essential vitamin – nutrient supplements with antioxidant properties. These specific products are contained in any other therapeutic vitamin product. However, this formulation is different in that it is a liquid form that is modified to be absorbed by the nasal membranes to promote healing. As with any other vitamin/antioxidant compound tablets you have taken, there are no side effects or systemic reactions.

What do you mean by “essential nutrient vitamins”?

Essential, in this case, means nourishing or providing nutrition, a food or other substance that provides energy or building materials for the survival and growth of a living organism.

Essential nutrients are those nutrients (proteins, minerals, carbohydrates, fats, vitamins) necessary for growth, normal functioning, and maintaining life; they must be supplied by food, since they cannot be synthesized by the body.

PatulEND® is composed of essential nutrients and minerals that provide bioactive energy and metabolism for the healthy growth of living tissue. These include the most essential vitamins and minerals in an enhanced antioxidant state with increased transmembrane conductance for the greatest bioavailability and absorption by the impaired tissues and compromised immune defense system.

How is PatulEND® prepared?

As a licensed physician, Dr Di Bartolomeo is authorized to manufacture the drug-free, US-patented Orphan product in accordance with its FDA-Approved Novel Formula.

Every bottle is prepared, mixed, bottled, and batched in an assembly line team operating under FDA requirements, including hygienic gear such as laboratory coats and hair caps.

Ordering

How can I get the supplement?

You may order through our website www.patulend.com ("Order now" page), or by calling the office at (805) 569-1111.

The website also includes information regarding PatulEND® nose drops, as well as a video demonstrating how to administer the drops.

Our office is open 8AM-5PM Mon-Fri Pacific Standard Time.

What is the cost of the supplement?

PatulEND®20 (concentrated formula) is \$98.00 per bottle plus S&H (plus CA tax if applicable).

PatulEND® (original formula) is \$88.00 per bottle plus S&H (plus CA tax if applicable).

PatulEND®10 (milder formula) is \$78.00 per bottle plus S&H (plus CA tax if applicable).

What is the difference between the three concentrations of PatulEND® drops?

PatulEND® nose drops have been specifically formulated to provide maximum relief at a concentration level where over 95% of respondents found the stinging side effect tolerable.

For those who cannot tolerate the stinging (about 1%) we provided the PatulEND®10 formula, which is milder and therefore produces less stinging, but may require a longer treatment period, or more frequent applications, to provide relief.

For those who have particularly damaged Eustachian tubes, usually as the result of previous medical interventions, chemotherapy, or radiation, we provide our PatulEND®20 formula, which is more concentrated to provide greater relief to the affected tissues. This formula, however, does produce an increased stinging effect and is generally reserved for those for whom the original formula does not produce the desired result.

In general, we recommend adults begin with the original formula unless indicated otherwise by a physician. If the original formula produces results at a tolerable level of stinging, then most patients continue to use that concentration.

Is it possible to pay by wire transfer?

Unfortunately, we do not accept wire transfer or Paypal payments. Acceptable forms of payment are by debit/credit card. For domestic orders only, you may also pay by cash or check in U.S. Dollars.

How quickly will I receive my order?

Our offices are open 8AM-5PM PST, Monday through Friday. Orders received during business hours are generally processed and shipped the same day. Order placed during off-hours (weekend, holidays) are processed and shipped on the next business day.

The drops are mailed out via Priority Mail as soon as your order is processed.

If within the U.S., the standard delivery time is 2-4 business days.

For international orders, depending on customs clearance time, delivery can vary between 7-12 business days.

Can you explain your shipping fees?

We understand shipping rates are expensive, and seek to provide the most efficient, safest option for our clients. As such, we have set a flat (per order) shipping and handling rate.

We ship your drops via USPS priority mail, which includes tracking and insurance.

If you find the drops work for you, some of our clients prefer to order multiple bottles at once in order to offset shipping and handling.

Additionally, you may wish to contact your insurance provider and see if they will reimburse any future purchases of PatulEND®. We provide you a receipt of purchase with your order, which you can forward to your provider.

We can also provide you with a copy of PatulEND®'s FDA approval and a detailed invoice should they require it. They may also require a statement or prescription from your physician to establish your medical need for PatulEND®.

Why is my order marked "Pending"?

When you place your order on our website, it is marked "Pending" until we receive and process your order.

Most orders received during business hours are processed on the same day.

Orders received after business hours are processed on the next business day, Monday-Friday 8AM-5PM PST.

Week-ends and national holidays delay the processing time, which means that your order will remain "Pending" until the following business day.

Can I get a less expensive, trial-size bottle?

Unfortunately, we do not offer a "trial size" option for PatulEND®.

Depending on the severity of the Eustachian Tube distention, and the possible presence of scarred or irradiated tissue, result times can vary. For this reason, we recommend daily usage for at least one month before discontinuing. A standard bottle lasts the average user 2-3 months, which is generally enough time to produce results and begin rebuilding tissue, while a smaller bottle may have only begun to show results by the time it ran out.

Why has the price increased for PatulEND® Plus?

PatulEND®'s patented composition has been completely reformulated. PatulEND® now contains the purest form of pharmaceutical grade Vitamin C or its appropriate derivatives for synergistic effect of the supplement's natural anti-oxidant effect and host immune defenses. The ingredients are of pharmaceutical grade and prepared by a pharmaceutical team operating under the Food and Drug Administration regulations to assure the utmost quality control. The pH of the composition is modified to potentiate the co-enzyme factors of Ascorbic acid to support tissue healing. The osmotic properties of PatulEND® are balanced for optimal tissue absorption of the needed nutrients. The composition formula may include: specially formulated Vitamin E for solubility of the nutrients or bioflavonoid to facilitate capillary absorption across tissue membranes.

Can I bill my insurance provider for PatulEND®?

Because PatulEND® is a drug-free, natural product that does not contain botanicals, it does not require a prescription for dispensing. Your Otolaryngologist can request that it be approved for your special use because of its effectiveness and safety. If approved, you can submit your invoice for reimbursement. We have not received any responses from customers indicating that they were unable to obtain a refund. However, as we do not deal directly with insurance providers, we cannot confirm which companies or plans provide reimbursement.

I can't afford PatulEND®, can you help?

Unfortunately, as the dispensary we do not set prices and therefore cannot offer discounts on PatulEND® nose drops.

You may wish to contact your insurance provider and see if they will reimburse any future purchases of PatulEND®. We provide you a receipt of purchase with your order, which you can forward to your provider.

We can also provide you with a copy of PatulEND®'s FDA approval and a detailed invoice should they require it. They may also require a statement or prescription from your physician to establish your medical need for PatulEND®.

I am an international customer. Can I ship to a temporary address or a relative in the US to reduce shipping costs?

In general, we recommend for the drops to be sent to a permanent address or at a time when the recipient will be there for several weeks. We have noted instances where shipments were not delivered to addresses where the name did not match the information on the mailbox, or where delays of 1-2 days could result in a shipment arriving after the intended recipient had ended their stay. We advise you keep this information in mind if you attempt either of these methods.

I changed my mind. Can I get a refund for the drops I ordered?

You may contact us at any time before your drops are mailed to cancel your order. We can also credit you for the drops which were mailed out, but they must be returned to us in the original UNOPENED envelope. You may either refuse reception of the shipment and return to sender, or use a larger envelope to mail the drops back. Please inform us by phone or email if you wish to cancel your order. Your account will be credited upon receipt of the unopened order.

Application

How do I apply the PatulEND® drops?

Step-by-step instructions are included with your order. The written instructions include diagrams, but if you prefer there is also a video demonstration available on the front page of our website.

The important steps to remember are

1/ Tilt your head back about 45 degrees.

2/ Tilt your head about 45 degrees towards the side where you will be administering the drops (for right ear, place the drops in the right nostril, tilt head towards the right, and vice-versa).

3/ Place the dropper tip at the entrance of your nostril, and squeeze gently to release 1-2 drops. For wide ET openings, it may be necessary to use 3-4 drops.

4/ In brief bursts, sniff the drops back until you feel the stinging in your Eustachian Tube. The ET is located between the back of the nose and the inner ear. It is important to sniff the drops to help move them to the proper location before they are absorbed in the nostril (which causes temporary congestion and a stinging sensation). However, try to limit the sniffs to short bursts, as a long continuous sniff would likely move the drops past the ET and into the back of the throat (where you would taste the drops and feel the stinging sensation).

This procedure can be done sitting, standing, or laying down. Most people find it more convenient to administer the drops while sitting, but the important part is achieving the proper head positioning before administering the drops. If laying down, the head should be propped so that it is about 45 degrees above the horizontal line, in the same position as if you were tilting it back 45 degrees from standing.

Important: Only your examining physician knows your individual nasal anatomy (deviated septum, polyps, post surgical, etc). If you are applying the drops according to these instructions, but are not

reaching the Eustachian Tube, please consult with your ENT to determine whether your individual nasal anatomy requires adjusting the position.

How do I know when the drops have reached the Eustachian tube opening?

When the PET drops have reached the Eustachian tube opening, the sensation is different than that of a typical nasal spray. Because of the complex reflexes in the back of the nose, you may also experience brief tearing in the eye on the same side as the ear while both are in the lower position – below the nose. You should experience a stinging sensation when instilling the nose drops. This is purposeful and is necessary to stimulate the Eustachian tube mechanism to close. The stinging may last 30-60 seconds.

How often should I use the drops?

Every individual has a different size and configuration of the Eustachian Tube opening. Some may require only 1-2 drops delivered to the Eustachian tube opening to produce adequate closure. The correct technique will initiate the sensation in the back of the nose. The appropriate amount of drops at the Eustachian tube will generate the congestion needed for closure of the Eustachian tube. Less than the required amount for the individual will not produce the desired effect.

The first time the supplement is taken, it may require more drops (3-4) until the technique is mastered and you become proficient at sniffing the supplement just back far enough to the Eustachian Tube and then stopping at that point so that it is absorbed at the opening. Within two to three weeks, one is usually more proficient at administering the drops and can relieve the disturbing symptoms with 1-2 drops to produce the same effect. If the drops have reached the Eustachian Tube, but your symptoms have not been improved within 10 minutes, the drops can be administered a second time or even a third time in rare cases.

The drops should be used when you anticipate the symptoms will begin: generally after getting up in the morning, or possibly when exercising. The drops can be repeated later in the day if symptoms recur. We recommend using the PatulEND® drops daily for at least the first month, even when you do not have active symptoms. The drops have healing components which will help the membranes rejuvenate and resume normal function. After that time, use them preventatively (before activities which might produce your symptoms) and when you are having problems with autophony.

Over time, the amount of drops may differ because of body weight, dietary choices, hormonal changes and salt intake.

Because PatulEND® supports tissue health as an essential nutrient, it is often necessary to take it for at least three months to establish adequate tissue strength. One can take it as long as necessary to relieve the symptoms. It has helped over 7,000 PET patients.

Due to HIPAA regulations, we cannot give individual medical advice. This information reflects general responses.

How long should a container of drops last?

The duration of a bottle depends on if you use the solution daily, and if you need it for both ears. Of course, at first you may use the bottle up faster as you gain experience with the placement of the drops. After that the average is 2-3 months per bottle.

Is it important to have my head positioned correctly?

The position of your head is critical to getting the drops to just the right spot. Only then can the healing begin and symptoms subside.

If you are having difficulty administering the drops, take the nose drops and instructions with you to the physician who diagnosed you. They can show you the best angle to administer the drops – your doctor knows your particular anatomy such as deviated septum, prior nasal surgery, trauma or allergic

condition. In some cases, the technique and position may need to be modified to receive the maximum benefit of the drops.

How can I judge the number of drops accurately?

Most people only need 1-2 drops in the right place to treat the membrane. Squeezing the bottle gently should only release 1-2 drops at a time, however, some people prefer to use an “eyedropper” so they can gauge the exact number and help to direct the drops more accurately to the Eustachian tube.

When after waking should I take the drops?

When we are lying down, fluid shifts from the ankles (in the standing position) to the rest of the body including the head and Eustachian Tubes (in the supine position). Those who have patulous Eustachian tubes notice that once they've been awake for a little while, fluid shifts away from the Eustachian tubes. As a result, the lumen of the Eustachian Tube gradually opens over 10-30 minutes. If we administer the drops as soon as we get up, the Eustachian Tube lumen is still closed and the drops do not penetrate very far. There's less stinging because it has not reached the deeper sensitive tissues in the tube. If we wait until we've been up for 20 minutes or more, the Eustachian Tube has had a chance to dehydrate and the supplement penetrates deeper into the tube and causes greater stinging to the more sensitive tissues. The response lasts longer and the healing properties of the supplement are potentiated over the next month or so. As a vitamin supplement, the drops can be repeated any time during the day. Rarely is it necessary to administer them more than three times.

How does the severity of symptoms affect how often I use the drops?

Intermittent symptoms upon arising: Since PET subsides when supine, most PET patients will begin to notice the “blocked ear” sensation shortly after getting up. Begin taking the PatulEND® nose drops each morning for at least one month. If it is not effective, you may not have reached the target opening of the Eustachian tube. If the drops have not reached the Eustachian Tube, you may repeat immediately. If symptoms reappear during the day, PatulEND® can be repeated, and can be taken a third time before bedtime since the drops will remain at the target longer while lying down.

Continuous autophony when upright, or even sitting: This generally means the lumen is widely Patulous and tissue healing may take several months to achieve adequate closure. Routinely take PatulEND® nose drops three times a day. They can be repeated at the onset of symptoms anytime.

Is it possible to get to a point where I can go for longer periods of time between treatments?

This is not unusual, and indicates a favorable response to the treatment.

If I'm not feeling symptoms when I take the drops, how can I tell if it's working?

The drops should provide obvious benefit when the autophony is present. If you want to take the drops when you do not have the autophony, there is no immediate difference to observe, but it is healthy for the tissues and there is no limit as to how long the drops may be taken.

Why go through the nose if the problem is affecting my ear?

The part of the Eustachian Tube that is malfunctioning is that part which opens into the back of the nose. Placing drops in the middle ear directly through the tympanic membrane (ear drum) will produce a lot of stinging, but no benefit. PatulEND® is a vitamin supplement which helps tissue heal. The problem is in the opening at the back of the nose, which is why the supplement is delivered to those tissues directly. There is much too broad a surface area in the middle ear to expect the two drops to be

concentrated into a particular recess. The nasal end of the Eustachian Tube is more pliable and it can congest to close the tube when PatulEND® is administered properly.

Storage

How do I store PatulEND®?

PatulEND® nose drops have a six-month expiration date. Keep the drops in cool dry conditions, which is generally most easily accomplished by keeping the drops refrigerated. Do not expose to direct sunlight or any heat source. An expiration date is required by law but the potency extends beyond that date. If storing during regular use, keep the solution in the refrigerator. For long-term storage, you may keep PatulEND® in the freezer and defrost when needed. The expiration date is extended for the duration that it is frozen. When you wish to use it again, let it defrost in the refrigerator until it is liquid again. Shake it gently when you are ready to use it, and before each use. Some patients who are sensitive to cold drafts etc. may sneeze once, but that usually subsides after the third time.

Why did my drops color change from clear to light yellow?

PatulEND® is a natural, preservative free product. Unless refrigerated, the color may change to light yellow after several months due to oxidation. The color change does not indicate a decrease in the effectiveness of the solution for relieving the PET symptoms by producing hydration of the Eustachian Tube. The tissue healing potential is not affected.

A brown ring around the cap may appear due to the evaporation of any residual product.

What should I do if crystals form in the solution?

There is a crystal form of one of the components, and minute precipitation may occur if the temperature is cold. If you shake the bottle a little just before removing the cap, the extra crystals will remain in the solution. When the bottle is almost empty, any residual crystals will dissolve if you add one half teaspoon of distilled water.

Results

Do you have figures for how often it works for patients?

If you are indeed diagnosed with Patulous Eustachian Tube Disorder, the drops are effective. There are many variables for each person and it is difficult to predict individual results exactly. Remember that the necessary response when administering the drops is a stinging or sometimes a burning sensation to stimulate the natural inflammatory response for congestion and the beginning of the healing process. The original formula for PatulEND® has helped 95% of patients find relief from their symptoms. Because of past responses by 5% of patients, we also have a stronger and a gentler solution. For some patients who find the stinging too strong, the milder solution is available, but the duration of treatment may take a little longer. For those with a larger opening, a stronger formula can be requested with a more prompt response in the swelling that eventually closes the wide opening in the tube. The common reaction is the healing process which is achieved only through the bioactive nutrients in PatulEND®.

How long does it usually take to see the results?

In most cases, the drops should relieve your symptoms within a month of continuous use. Depending on the health and physical state of your Eustachian tube, it may respond right away OR take up to 3 months before experiencing results. Most subjects will become symptom free within a year and not require the

supplement except for potential intervals in which they have a brief recurrence of their symptoms. Unless we have examined you, we cannot know the state of your Eustachian tube.

Side Effects

Are there any side effects?

As a natural, drug-free product, the vitamin-nutrient ingredients of which are used by millions of people, there are no known side effects or any interactions with medications. There have been no reports of "tube fatigue" or scarring from prolonged use.

Is the stinging normal?

You should experience a stinging sensation when administering the nose drops. This is purposeful and is necessary to stimulate the Eustachian tube mechanism to close. The stinging may last 30-60 seconds. The mucous membrane inside the nose does not have the protection of the skin that lines the soft tissue outside the nose. When we wash the skin with soap, there is no sting or irritation. However, if there is a wound or cut on the skin, or if the soap gets in our eyes, there is a substantial sting produced. The same happens with the deeper mucous membranes inside the nose that may be sensitive to soap, vapors, or nasal sprays. If the drops are effective, but the stinging sensation is too uncomfortable, you may request the milder formulation. This milder formula should be applied following the same instructions. If the stinging is not tolerable when taken properly, discontinue taking the nose drops and consult an ENT Specialist.

Why is there blood when I blow my nose?

If you note regular bloody mucus, **please consult immediately with your examining ENT.** PatulEND® should not cause bloody discharge from your nasal passages. Blood in your mucus may indicate anything from irritated tissues (from increasing noseblowing, etc) to more severe preexisting conditions, which your examining ENT can correctly identify and respond to.

Why does my ear feel full/stuffed immediately after administering the drops?

It is perfectly normal to experience a sensation of fullness/stuffiness in the ear, as though a cotton ball is padded in. This occurs because the Eustachian tube closes, causing pressure to occur within the inner and middle ear. This sensation should pass as the Eustachian tube resumes normal function and pressure equalizes.

When I administer the drops, my ear feel like there is a bubble inside, which pops and causes a sensation of fluid flowing out. Is this normal?

The sensation of a "bursting bubble" and "flowing liquid" is a normal response to the solution interacting with the film covering the Eustachian tube. As a symptom of PET, the film coating the tube becomes thicker, and the release of surface tension as PatulEND® is absorbed can be felt more strongly. As the tissue rejuvenates, the film thins and this sensation should become less pronounced.

I have a pierced eardrum/surgical tubes. Will that affect the effectiveness of PatulEND®?

The benefit of PatulEND® and the relief of symptoms is more noticeable when the tympanic membrane is intact, and the middle ear and Eustachian Tube have not been subject to any previous surgery, radiation, or trauma. We recommend that PatulEND® be tried before any surgical procedure has been undertaken. If tubes have been placed, PatulEND® is of significant tissue benefit, but the improvement in symptoms may not be noticeable until after the tube is removed, and/or the surgical

opening in the tympanic membrane is healed or closed. Attempting to administer the drops through the grommet tube is of no benefit and is NOT recommended. The middle ear membrane is very sensitive and the stinging would be most intense without actually reaching the Eustachian Tube.

Why do I feel like I have a sinus headache when taking PatulEND®?

The sinus opening is just above and in front of the Eustachian tube opening, which is at the level of the floor of the nose. A sensation of a sinus headache when taking the drops usually indicates that too many drops were taken, that the sniff was not effective (too weak or brief), or there may be nasal obstruction limiting the ease of flow so the drops are absorbed by the front nasal-sinus membranes and produce the sensation there. The drops are always diluted by nasal secretions, and passed to the back of the nose where they lubricate the membranes for swallowing, talking, etc.

Can administering the PatulEND® drops too far down the ear canal cause hearing loss?

When the PatulEND® nose drops are administered, it is intended for them to reach the Eustachian tube orifice. The hyperpatent Eustachian tube will draw the drops into the nasopharyngeal entrance of the Eustachian tube by surface tension. In the case of an extremely patent Eustachian tube with a large diameter lumen, the drops will migrate deeper into the Eustachian tube towards the isthmus. Here the subjected sensation is usually more intense because the thinner surface membrane of the deeper portion of the Eustachian tube is more sensitive to the physical properties (temperature, etc.) of any solution (antibiotic eardrops, steroids, antifungal agents, etc.).

Essential nutrients and supplements have been used throughout the body, on the skin, and membranes to support the health of these tissues. They have also been studied in the middle ear to evaluate the biochemical needs of traumatized middle ear tissues to promote successful healing. There are no reported or known adverse effects on hearing from taking essential nutrients or supplements in reasonable doses.

Is it harmful to the Eustachian tube if I use too many drops?

You cannot use “too many” drops. Once the Eustachian tube is saturated, the excess will overflow into the throat. This overflow is similar to taking a liquid vitamin by mouth. Any overflow means that there will be less in the bottle for future use and you may run out in a shorter period of time. However, if in doubt, it may be worth it to have a small overflow to confirm that a sufficient amount of solution reached the tube.

Is PatulEND® safe to use while pregnant?

PatulEND® contains only the purest form of a vitamin C derivative, which is an essential nutrient to support tissue healing. As stated in the insert, there are no other drugs or any preservatives. Please note that we do not give any medical advice. You should consult with your personal physician as to whether you can take vitamin C in its various forms: Ester C, ascorbic acid or ascorbate. The ingredients in this product will most certainly be contained in any prenatal vitamin tablet.

Is PatulEND® addictive?

It is not addictive. The primary vitamin in the composition is ingested every day in most fruits and some vegetables.

Why do my PET symptoms disappear when I have a cold?

A cold can cause PET symptoms to subside because of the congestion. PET treatment may be suspended until the nasal passages clear back up.

Issues

What factors affect the effectiveness of PatulEND®?

Known Factors that can influence the Eustachian Tube and/or the effectiveness of PatulEND® include:

- Tissue damage: previous radiation or limited post-surgical results from tumor surgery or anatomical changes (infection, scarring or trauma, temporomandibular or dental procedures, or hormonal disorders).
- TMJ: a TMJ evaluation can be extremely important because TMJ may be the primary factor underlying and occasionally awakening PET symptoms.
- Semicircular canal dehiscence: when the autophony is accompanied by one's voice sounding very loud, a semicircular canal dehiscence may be a factor.
- Other local procedures: if the tube is open due to extra-tubal reasons, ie; a deviated nasal septum, nasal septum injury, dental problems, weight or hormonal changes, a middle ear ventilation tube in place, other tube related surgical procedures - these factors may contribute to the original cause and limit the degree of success.
- Dental work: recent dental procedures that alter the interaction of the chewing muscles and Eustachian tube muscles (root canals, dental implants).
- Jaw development: developmental changes of the maxillo facial structures throughout life can be a factor. These include the jaw, teeth and bite, which change every ten years.
- Sleep hygiene: clenching one's teeth at night, or the use of a mouthguard to prevent clenching, can also affect the Eustachian Tube, as can sleep apnea or the use of a CPAP.
- Conflicting treatments: the more common medications that can cause a Patulous Eustachian tube include any cold medication or decongestant that produces vasoconstriction, steroid nasal sprays or eye drops, cortisone-type medications, antihistamines because of their drying effect, Hormone Replacement Therapy, certain forms of Alka-Seltzer or other GI preparations that may contain a decongestant or anti-inflammatory agent in them, Prednisone for arthritis, and some anti-inflammatory agents.
- Hormonal treatments: some Birth Control pills or hormones can accentuate PET.
- Hormonal variances: if your symptoms tend to appear during a particular week of your monthly cycle and this repeats itself, or during the different stage of pregnancy, this may be a hormonal factor.
- Nasal congestion: if one has a cold or enjoys some products like red wine or milk, which can cause congestion or an increase in mucous, the interaction between the anatomy and the environment of the nose at the time the PatulEND® is taken will certainly be a factor.
- Infections: the components of public swimming pools and some ocean water also contain various contaminants and algae which introduce the possibility of infection. This affects the healing power of PatulEND®.
- Altitude: do not take the PatulEND® and certainly do not take a decongestant before flying.
- Humidity: dry climate, indoor heating or dry air due to air conditioning may impair the transport of PatulEND® to the back of the nose where it can reach the Eustachian tube opening.
- Surface tension: the stickiness of the lining of the Eustachian tube is can impact the ability of the drops to be absorbed through surface tension.
- Weight loss: weight reduction by dieting, appetite suppressants, or diuretics, will decrease the passive resistance of the Eustachian tube and may reproduce the symptom of autophony.
- Exercise: moderate or vigorous exercise will also open the tube. Excitation, which produces adrenalin, has a vasoconstrictor effect on the Eustachian tube and results in a decrease in passive pressure and a tendency towards PET.

- **It could take three months for the tube to fully heal. In cases where the Eustachian tube is very wide open, it could take more than a month to respond.**
- **We are not aware of a significant incidence of Prilosec causing an open tube.**

I don't think the drops are working, can I return the bottle?

Unfortunately, we cannot accept returns on opened bottles.

However, given that not all users experience immediate relief, and the fact that PatulEND® contains no harmful ingredients, our recommendation is that you continue to use the drops as the results may simply be delayed.

Unless we have examined you, we cannot make a judgment as to the state of your Eustachian tube(s), but symptoms can take over a month to begin abating (which is still well within the amount of time one bottle should last you).

The only reason to stop using PatulEND® would be if you begin to experience intense discomfort resulting from the drops, in which case you should consult a physician.

Please feel free to contact us if you have any further hesitations.

What if the drops don't work consistently for me?

We hope you will continue to use the drops you have. Positive results, even inconsistently, indicate the drops can be of greater benefit. Please review the instructions to ensure you are administering the drops properly. You may also wish to consult with an ENT to ensure there are no individual considerations for your nasal anatomy.

To help us better understand where the issue may lie, please send us your response to the following questions:

1. On a scale of 1-10, with 1 being no stinging sensation at all and 10 being a burning sensation, how would you rate the effect of the sensation of the drops taken?
2. When they reach the Eustachian Tube target, was there associated tearing of the eye on the same side to confirm the accurate delivery of the supplement?
3. Was there any response or change in your symptoms after taking PatulEND?
4. How long did it take for the response to become apparent?
 - a) 20 minutes
 - b) After 1, 2, 3 days
 - c) Delayed and occurred after 1, 2, 3 weeks
5. Did you have to repeat the drops during the day?
6. If yes, how often did you repeat them throughout the day?
7. Were you able to discontinue the drops after a period of time?
 - a) 1 day
 - b) 1, 2 or 3 weeks
 - c) 1 month
 - d) I still continue them

Your answers would be greatly appreciated.

Why is PatulEND® not working for me?

Is rare for us to receive a response that the product did not work, but in almost every situation the failure was due to one of the following reasons:

- 1/ The instructions were not followed properly. This is usually resolved with some practice.
- 2/ There were individual differences in one's own nasal anatomy, such as a deviated nasal septum, prior nasal surgery, or a middle ear tube still in place. In such cases, it is most helpful to have the ENT

specialist who examined the nose assist the patient in their office, modifying the technique according to their own unique internal nasal anatomy.

3/ There are multiple ear factors (middle and inner) which are active. The drops cannot make a difference while there is another opening in the eardrum. PatulEND® was developed to resolve autophony (hearing one's own breath sounds) due to an open Eustachian tube. The solution works by closing the tube upon direct physical contact, when applied through the nasal passage on the same side as the affected ear. Other ear symptoms not related to a patulous Eustachian tube are not affected.

I don't feel the effect from the drops, have I developed an immunity?

One does not build up immunity to the essential vitamins that our body needs. If the supplement does not sting, it may be past the expiration date for full potency.

Why have the drops stopped working?

There is some evidence that the effectiveness of the drops will be diminished following temporary weight loss, use of cold medications containing decongestants, nasal sprays, antihistamines or steroids as well as amphetamines, diet control medications, anti-anxiety medications, or antiepileptics. The hormonal fluctuation of Estradiol during one's monthly cycle also has a decongestant effect on the Eustachian Tube and this may alter the typical benefit during that phase of the cycle. Please see above for a more complete list of factors that can interfere with the effectiveness of PatulEND®.

I'm using the original drops correctly, but not achieving results, is there anything else I can try?

The wider the tube is at the time the drops are being administered, the longer it takes for the tissue to fill in the gap and close. If the drops are not strong enough to hydrate the exceptionally wide diameter and close it, we have a stronger composition. Our concentrated formula produces stronger results, but it the stinging sensation is also more pronounced. Please also note that there is a limit to the amount of tissue volume that can be rebuilt or restored to the lumen. When the gap of the tube is too wide or large in diameter, it may need to have a plug inserted into the tube to close the gap. The widest tubes may require surgical closure. Only your examining ENT can determine whether this is the case.

I've tried all your suggestions, but PatulEND® is not helping me, what can I do?

Thank you for keeping us informed of your progress in treating your symptoms. It is unfortunate that you haven't had relief. Without knowing more of your medical history, we are at a disadvantage to make helpful suggestions. If you are able to travel to California, we would be pleased to examine you here in our office. Call our office for details if that is a possibility.

PatulEND® worked and I was symptom-free for several months/years. Why have my symptoms returned?

We cannot dispense medical advice without examining you. However, we encourage you to review any change in your medical history or medications, recent ENT, dental, or cosmetic procedures, and dietary or weight changes. All of these can cause the Eustachian tube to become patulous.

Is it normal for the crackling in my ears to worsen after taking PatulEND®?

PatulEND® should not cause a worsening of your symptoms. If this occurs, you may consider seeing a chiropractor or a specialist regarding a TMJ diagnosis before resuming your treatment with PatulEND®.

The drops work, but why is there a very painful feeling in my ear after application?

If the lumen of the Eustachian tube is exceptionally wide, the drops can migrate into the virginal area of the Eustachian Tube. This produces a greater degree of stinging because this mid portion of the tube never comes into contact with any liquid. Even cold saline drops would produce the same burning effect. Lie down for a moment and let the Eustachian tube congest by simple redistribution in the body water content. This usually closes the tube and demonstrates why we do not have the symptoms while we are lying down. Using this delayed time to administer the drops will usually assure their absorption only at the entrance of the tube because it has essentially closed after a few minutes in the supine position. This technique may be adequate to close the tube without having the drops reach deep in the lumen. You may also want to decrease the number of drops and/or the frequency of application. If this is not helpful and the stinging or burning still occurs, stop using the drops and consult your Ear, Nose and Throat specialist. The luminal orifice on the Eustachian tube may too wide for even PatulEND® to produce edema and swelling with closure. You may have to consider other alternatives to closing the tube or putting a plug in it. Such is the case in approximately one out of four hundred PET patients.

Alternative Products/Methods

The stinging is too much, is there a milder alternative?

Please know that you can dilute PatulEND® with 1/2 the amount of distilled water (1 part distilled water to 2 parts PatulEND®). This will not sting as much, if at all. However, it will not be as effective. It will still continue to heal the membrane and result in relief of symptoms with regular use. If this works for your situation, the drops can be ordered in the milder solution.

Can I use a spray rather than nose drops?

Unfortunately, this is not currently possible. The Eustachian tube opening sits in the back of the nose on the wall closest to the ear involved. The membranes between the nostril and the Eustachian tube opening are semi-permeable, which means that they will absorb some of the solution during its transport to the back of the nose. Since the primary effect of the solution is to cause congestion, it important to deliver the product preferentially to the back of the nose where the Eustachian tube opening is located. This is best accomplished by drops, which can be transported intact by inhaling or by sniffing briefly. A spray would cause the whole nose to swell, whereas the drops can be delivered to the exact target. At the present time, the drops are most effective.

Can a saline solution help with my PET?

We do not advise using a saline spray, as the saline could be shot into the middle ear if the Eustachian tube is open and you apply too much pressure when squeezing the bottle. Additionally, saltwater is not beneficial for PET. In fact, it may increase it. For this reason, a hydrochloric acid formula for PatulEND® was rejected and replaced by the improved drug free formulation.

Can I use a catheter or syringe to squirt PatulEND® rather than a dropper?

We do not recommend this as squirting with a catheter or syringe most often shoots the solution past the ET on the side of the nose, and into the throat.

Why do nasal sprays and decongestants affect my PET?

While nasal sprays do open the nasal passages, they may also open the tube more, if the overspray reaches it.

Did cutting out alcohol help relieve my PET?

Alcohol is a diuretic – causing dehydration by affecting the diuretic hormone. You may wish to consider the following questions, and discuss them with your physician. Have you had any hormone studies or kidney testing? Have your weight patterns been stable? (Weight before/after drinking?) Did the salt factor change in your diet with the reduction of alcohol? Do you have high blood pressure?

Can Vicodin help with PET?

Vicodin may relax the tissue but it doesn't treat the cause. Please note that Vicodin can potentially have an adverse effect on hearing with prolonged use.

Should I use PatuEND® before a flight?

We do not generally recommend taking PatuEND® before a flight, as the drops will cause temporary swelling in the Eustachian tube that may cause discomfort due to the pressure changes during takeoff and landing.

PatuEND® should be reserved for days when you are not scheduled to fly. On those days when you will be flying, we recommend disposable pressure filtering ear plugs such as EarPlanes. These can alleviate discomfort due to pressure changes, and can help prevent occurrences of ET dysfunction caused by pressure changes.

Consultations

What insurance providers do you accept for consultations?

We are not contracted with any private insurance plans for our services. You have the option of going to your health care provider or to be seen here as a private patient. You may or may not be reimbursed by your provider depending upon the terms of your policy. If you choose to be examined here payment is expected at the time of service. At the end of your visit, you will be given an itemized claim statement to submit to your own insurance carrier.

What paperwork do you need before an appointment?

Please be sure to send us all your medical records including labs, hearing tests, nasal examinations and/or surgeries, any head or neck X-rays, MRI's, or CT scan reports in advance, as Dr. Di Bartolomeo likes to look over all the records prior to the scheduled appointment.

Does your office offer teleappointments?

Unfortunately, we cannot offer remote appointments, only in-person appointments in our Santa Barbara office.