



Trans-D Tropin®

NDC# 65448-2115-1



PROTOCOL
No. 99

www.amtrx.com

DESCRIPTION

Trans-D Tropin® is formulated to provide a high potency, convenient, growth hormone releasing hormone analog combinant administered by trans-dermal application. Each drop delivers approximately 485 ug (micrograms) of active ingredients.

FUNCTIONS

The active ingredients in Trans-D Tropin® are Amino acids including alanine, arginine, glutamine, glycine, histidine, isoleucine, leucine, lysine, phenylalanine, proline, serine, threonine, tryptophan, tyrosine, and valine, germaben, propylene glycol, sorbitol, almond oil and/or apricot oil, carnation/jasmine fragrance, sorbitol, distilled water, in a creme' base with EVITO™ (proprietary formula consisting of oleic acid, linoleic acid, gamma linolenic acid, stearic acid, hexadecenoic acid, palmitic acid, eicosenoic acid, docosenoic acid, tetracosenoic acid, eicosapentaenoic acid, docosahexaenoic acid, myristic acid, lauric acid, caprylic acid, capric acid, a, b, g & d tocopherols, tocotriols, and naturally occurring antioxidants and bioflavinoids).

ACTIONS AND PHARMACOLOGY (Function)

Trans-D Tropin® is a unique formulation of natural (L) amino acids which act as primary and secondary messengers in the human body for the production of growth hormone. It is composed of four unique condensates, which elicit a direct and indirect cascade of immediate physiological and programmed responses. Since Trans-D Tropin® is a growth hormone releasing hormone analog acting only as a messenger and is not direct administration of exogenous growth hormone, all responses are limited to normal physiological response within biological limits.

BIOLOGICAL PROGRAMMING RESPONSE

Upon administration of Trans-D Tropin®, endogenous growth hormone levels measured via radio-immunoassay have significantly increased. The response is not only immediate, but also re-establishes circadian growth hormone release rhythm (program) back to a youthful level. Responses measuring over 1500 % increase have been measured and are not unusual.

The greatest response observed with Trans-D Tropin® is in the middle aged population between the ages of 30 to 60 years, while the greatest efficacy is noted in the elderly. Normal responses include but are not limited to an increase in muscle strength, stamina, endurance, libido, cognitive skills, and cardiovascular strength. Trans-D Tropin® also moderates glucose and insulin levels, mineralcortocorticoids, lipids, IGF- I, IGF Binding Protein 3 levels and appears to increase Pregnenolone conversion to Progesterone.

When administering Trans-D Tropin®, one should increase vitamin and mineral intake and increase protein intake. This increase is necessary because of the systemic up-regulation of the entire physiological system. Interestingly, if the individual utilizing Trans-D Tropin® requires rest and recuperation but has neglected to fulfill this need, Trans-D Tropin® will down regulate unnecessary systems and force the individual into a down-regulation up to 48 hours, while up-regulating required reparative systems. This is usually manifested as a greater requirement for sleep in the first week of usage.

INDICATIONS AND USAGE

Trans-D Tropin® is indicated in any patient where an increase of endogenous GH is desired, without the associated risks and complications noted with injectible GH therapy.

DOSAGE AND ADMINISTRATION

Trans-D Tropin® is administered daily on an area of the body with minimal subcutaneous tissue in a capillary dense region with a high vascular supply. The most common area, for example, would be the volar aspect of the forearm. Apply several drops and smooth into skin for absorption. Normal dosage is usually applied in 3 separate doses during morning, early afternoon and prior to bedtime. Theoretically, for the best response, apply Trans-D Tropin® prior to eating on an empty stomach.

Patient Protocol for Trans-D Tropin®

The patient should implement the following necessary guidelines in order to get the optimum results:

- ❑ Apply Trans-D Tropin® to the inside of each forearm and rub forearms together. Try not to use your fingers to spread Trans-D Tropin®. Trans-D Tropin® is transdermal, i.e. enters through the skin. It should be applied to an area where there is minimal fat with the highest blood supply. The inside of the forearms are the best since the skin is very thin and doesn't slow down the absorption of Trans-D Tropin®. The inside aspects of the thighs as well as the neck area can also be used if necessary.
- ❑ **Shake the bottle well** before each use. **Standard Protocol:** Apply 15 drops (0.5 cc) of Trans-D Tropin®, to the inside of each forearm and rub arms together. Apply the above amount three times a day around 7:30 am, 4:30 pm and at bedtime. Once rubbed in completely, wait a few minutes before allowing your forearms to get wet. You may get in a shower or a pool 5 minutes after the application has been absorbed. **Athletic Protocol:** Apply 11 drops (just under 0.4 cc) of Trans-D Tropin® four times daily at around 7:30am, 11:00 am, 4:30 pm and at bedtime per the standard protocol above. **Above Age 65 Protocol:** Apply 20 drops (0.7 cc) of Trans-D Tropin® three times daily as per the standard protocol above.
- ❑ Trans-D Tropin® should be kept out of extreme temperatures, especially heat. Although Trans-D Tropin® is very stable in normal temperatures, extreme heat has the potential of denaturing the unique polypeptide complexes and rendering the bottle ineffective. Room temperature is optimum. If Trans-D Tropin® becomes frozen, do not thaw it rapidly. Do not use a microwave. Place bottle at room temperature and allow to slowly thaw.
- ❑ Use 5 days per week, taking two days off each week. Follow this cycle for six to eight weeks, then discontinue use for one to two weeks. For explanation of why this is recommended, please refer to the double blind study on Trans-D Tropin®. Some individuals may feel bad during the

2 week break. For those individuals, if they choose, they may continue on Trans-D Tropin®, during the scheduled two week off period. However, the 2 week off period is recommended to maximize the effects of Trans-D Tropin®.

- ❑ You must exercise to maximize the results of Trans-D Tropin®. Remember, Trans-D Tropin® is NOT GH. Trans-D Tropin® is naturally mimicking the action of GHRH, which is to potentiate endogenous (produced by your own body) GH. So it is necessary to exercise in order to get the maximum benefits.
- ❑ If you are an athlete, you will notice how quickly your performance will increase, usually within the first 72 hours. In addition, recovery time is also decreased significantly. However the tendency is to over train when on Trans-D Tropin®. Remember, the body grows during the resting phase. So leave adequate time for your body to rest and recover. Although you will find yourself not needing as much rest, your body still requires it. **Don't over train.**
- ❑ **Do not suppress your cravings for protein.** If you have an intense desire to eat something that you don't usually eat, especially protein, do not try and suppress it. Your body is telling you it is lacking something. It needs this essential substance to continue the rebuilding process. Trans-D Tropin®, acts as a "general contractor". It masterminds the changes. But just as a general contractor needs bricks, wood, nails, and other raw materials necessary to build a house, Trans-D Tropin®, needs to have the raw materials supplied that are necessary to rebuild your body.
- ❑ Don't be surprised if your consumption of water and frequency of urination increases. Water is the largest substrate in our body and as the physiological parameters shift to a younger state, the increase in metabolic reactions will increase the need for water. As you start to reduce body fat, your water requirements will also increase substantially and facilitate further loss of body fat. Drink at least 2/3rds your body weight in ounces of water daily. Thus, if 180 lbs, drink 120 oz.

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- ❑ Sleep is one of the first things affected. Trans-D Tropin® has significantly improved the quality of sleep for people with sleep disturbances. Furthermore, the amount of sleep needed is significantly reduced with patients experiencing deeper sleep with more vivid dreams, indicating REM (Rapid Eye Movement) sleep has increased. REM sleep is the most restful component of sleep. For people suffering from insomnia, Trans-D Tropin® improves the ability to fall asleep. However, people who normally fall asleep immediately seem to experience a delay in onset of sleep after initiating treatment. It takes about two weeks to normalize this cycle before sleep onset returns to normal.
- ❑ If you are obese, you will note a decrease in weight over time. However, if you are not obese, you will probably gain a few pounds. Lean body mass (muscle) increases and weighs more than the body fat that you are losing. Remember, muscle weighs more than fat. Clothes will fit better and you will look as if you have lost weight, although you will have gained (muscle) weight. Most people also note changes in facial and body contour. Lean body mass increases in obese patients as well but the obese patients lose far greater body fat and therefore, will see a drop in overall weight over time.
- ❑ Contraindications to Trans-D Tropin® use are listed on each bottle. Do not use Trans-D Tropin® if you're pregnant, have a pituitary tumor (IGF-I or prolactin test will rule out a pituitary tumor) or are under the age of 21.

There are two current protocols that work optimally. Sedentary patients have noticed changes within the first seven days generally. Your doctor will tell you which protocol is best suited for you. If you do not see significant changes within two weeks, especially if you are over the age of 65, let your doctor know so they can make the necessary changes. **But, DO NOT increase dosage yourself.**

As with any form of treatment, you must give the treatment a chance to work optimally. For example, if you are 40, remember that it took 40 years for you to get to this point in

your life. Despite the great majority of patients noticing some positive change relatively quickly, you should continue treatment with Trans-D Tropin®, for at least three months before determining the effectiveness of the treatments.

Trans-D Tropin®, results in a direct increase in endogenous growth hormone, which results in an upregulation of virtually all hormones. Please refer to the studies showing changes in testosterone, cortisol, glucose, etc. with the use of Trans-D Tropin®. Use of a melatonin, DHEA and other various hormones is not advised while taking Trans-D Tropin®. It may prevent you from getting optimal results due to disruption of the inhibitory feed back loops. The body knows what it needs and it definitely does NOT need to have the delicate hormonal balance disrupted. So it's better to just leave the individual hormone levels alone. With the exception of thyroid supplementation (if hypothyroid) or the use of progesterone, no other hormones are necessary when using Trans-D Tropin®.

People showing minimal response to Trans-D Tropin®, are the ones on anxiolytics (Xanax, Ativan, etc.) anti-depressants (Zoloft, Paxil, Prozac, Amitryptalene, etc.) and stimulants (amphetamines). Also, smokers don't get as good response. Chronically ill people seem to show a negative change initially, similar to a detoxification treatment course, but within two or three weeks, they also show significant positive changes. So be prepared for some negative changes initially, especially if you are a patient with a chronic health problem. If you have a liver or a gastro-intestinal imbalance or a heavy-metal toxicity, you may not see significant results. Ask your doctor about treating these imbalances first before you start your anti-aging therapy with Trans-D Tropin®.

If you are currently using injection treatments or secretagogue treatments and wish to change to Trans-D Tropin®, the recommendation is to stop the original treatments, wait at least two to four weeks, and then start on Trans-D Tropin®. This allows for a wash out period. Also, **don't use Trans-D Tropin®, with GH injections.** It can be

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dangerous. Some physicians recommend alternating between Trans-D Tropin®, and GH injections. However, do not use them both concurrently.

Please remember that it took years for your body to get where it is now. Although the majority of patients notice changes within the first few weeks, it may take a few MONTHS to get the results you expect. Even AFTER you stop noticing changes externally (outside), Trans-D Tropin®, continues to work internally. Consistency is paramount.

WARNINGS

Keep your bottle of Trans-D Tropin®, out of extreme temperatures especially heat. Keep it out of the reach of children. **Do not use** if you are pregnant, under the age of 18 or are actively being treated for a pituitary cancer. Although safe, it may be better not to use in lactating females.

CONTRAINDICATIONS

No known sensitivity to active or inactive ingredients.
Pituitary adenoma or high prolactin.

DRUG INTERACTIONS

No drug interactions have been assessed.

OVERDOSAGE

Discontinue use for two days and return to original schedule.

NOTE: There is not a direct dose dependent relationship. The dose relationship is a threshold dependent function or a step function: Below the threshold, no response is elicited; Upon attaining the threshold dose, the message is recognized and fully integrated; Upon additional increases in dosage, little additional increase in response is noted. However, when a great excess is administered, the system negates the response and returns to a minimal response as a result of the negative, inhibitory feed back loop being initiated via somatostatin.

Packaging: 1 oz bottle
Storage: 15-30 deg C (59-86 deg F)
Manufacturer: V-SAB Medical Labs, Inc.
Made in U.S.A.

Further Editorial Information of Interest

The physiological approach utilized to formulate Trans-D Tropin®, is vital to understand the goal of therapy. Rather than emulate the desired end product with a synthetic substance, the goal was to identify the messenger that would allow the body to increase the desired end product by increasing the body's own production. Once identified, the messenger was mimicked to increase the desired end product endogenously.

In the case of Trans-D Tropin®, this approach allowed for the identification of the various hypothalamic specific polypeptides which form GHRH. GHRH is responsible for the release of growth hormone from the pituitary. Thus, Trans-D Tropin®, (various hypothalamic specific polypeptide analog combinants) is a GHRH analog or mimicker, emulating the function of GHRH and resulting in an increase in the natural pulsatile release of endogenous GH.

The sequencing technology utilized to manufacture Trans-D Tropin®, is far more advanced than any currently available and estimated by some scientists to be 15 to 20 years ahead of it's time. Very simply, this technology allows for the creation of any amino acid combinant peptide analogs. In this specific case, it allows for the creation of hormonal messenger analogs, mimicking the action of the body's own endogenous hormonal messengers. It is important to realize that simply blending amino acids or combining amino acid stacks will not accomplish the task achieved by Trans-D Tropin®, (or any of the other unique transdermal polypeptide combinant analogs by Balance Dermaceuticals,).

To best understand this concept, think of your own body's composition. If you take the exact chemical constituents that make up your own body down to every single component, add the necessary amount of water and bring the resulting concoction up to 98.7 degrees Fahrenheit, would you have a clone of yourself? How about another human? How about anything that even resembles life? The answer is, obviously not.

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However, the real question that must be asked is, what makes you physically different from the concoction that you just created? The answer: It's "HOW" you were put together which makes you different. NOT the ingredients! This is the reason why Trans-D Tropin®, and the other transdermally delivered polypeptide combinant analog complexes by Balance Dermaceuticals, are so efficacious. It is "HOW" they are put together that makes them so effective.

The last key component is the delivery mechanism. A relatively uncharted area of science incorporates the utilization of EFAs (essential fatty acids) as a mechanical means of therapy, such as employment in a drug delivery system. Already, the delivery method for a number of unique experimental treatment modalities such as B Lymphocyte stimulators as well as established treatment modalities such as growth hormone releasing hormone analogs utilizing polypeptide synthesis technologies (Trans-D Tropin®) have been achieved utilizing EFAs as the mode of transport.

The delicate nature of these polypeptide combinant analogs renders them susceptible to denaturing by gastrointestinal acids and digestive enzymes as well as the fact that our modern day society has created a tremendous vacillation in gut function and poor gut absorption. This results in preventing oral delivery mechanism from being a viable or effective option. Conventional paraenteral routes (IV, IM or SQ injections) raise the issue of compliance due to the necessity for daily injections as well as the concern for convenience. The very sensitive nature of these polypeptide combinant structures, which result in actions analogous to hormones, prevents traditional drug delivery mechanisms from being utilized.

Utilizing specific combinations of EFAs with other carrier substances, these new polypeptide treatment modalities now have a way of being delivered into the system in a transdermal manner without the concerns of denaturing or issues regarding compliance. Evito' is one such transdermal delivery modality utilized to deliver the active

constituents of Trans-D Tropin®. Furthermore, not only do these EFA transdermal transport delivery mechanisms allow for convenient dosing, they have also been actually found to contribute to stabilizing the amino acid combinant peptide analog structures. Not surprisingly, assimilation into the system is achieved beyond that of other delivery mechanisms including other non-EFA transdermal delivery mechanisms.


For further information regarding Trans-D Tropin®, please refer to the Trans-D Tropin®, support packet and search for "The Inter-Relationship Between GH and IGF-I: Correlation with Cancer" as published in Anti-Aging Medical Therapeutics, Volume 5.

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FORMULA

www.balancederm.com NDC 65448-2115-1



Balance
DERMACEUTICALS
PHYSICIAN'S FORMULA

Trans-D Tropin®

Disp: 30 cc (900 gtts) - Use as directed
Use ONLY Under Medical Supervision

Ingredients:
Amino acids including alanine, arginine, glutamine, glycine, histidine, isoleucine, leucine, lysine, phenylalanine, proline, serine, threonine, tryptophan, tyrosine, and valine, gematen, propylene glycol, sorbitol, almond oil and/or apricot oil, carnation/jasmine fragrance, sorbitol, distilled water, in a creme base with EMTOP® (proprietary formula consisting of oleic acid, linoleic acid, gamma linolenic acid, stearic acid, hexadecenoic acid, palmitic acid, eicosenoic acid, docosenoic acid, tetracosenoic acid, eicosapentaenoic acid, docosahexaenoic acid, myristic acid, lauric acid, caprylic acid, capric acid, a, b, g & d tocopherols, tocotrienols, and naturally occurring antioxidants and bioflavonoids).

Manufactured Exclusively for
Balance Dermaceuticals™, Inc.
www.balancederm.com

Warnings:
Do not use if pregnant, under the age of 18 (unless GH deficiency has been established) or if you have a pituitary tumor. **Keep out of reach of children. Do not use with GH Injection Therapy.**

FOR MEDICAL USE ONLY.

Directions:
Shake well before use. Keep out of extreme temperatures. Use as directed by your physician or apply 15 drops 3 times per day, five days on, two days off. Repeat each week. Apply at 7:30 am, 4:30 pm, and at bedtime. Apply 1/2 dose to inside of each forearm and rub together. Try NOT to use fingers for application.

For external use only.

MANUFACTURED BY
SAB
V-SAB MEDICAL LABS INC.
CORNELIUS, NC 28031

% DV (Daily Value) Percentage of U.S. Recommended Daily Allowance (RDA) for adults and children four or more years of age.

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All ingredients in the Balance Dermaceuticals® therapeutic product line are of the highest possible quality available. All ingredients are pharmaceutical grade or higher, when applicable. Certain ingredients, herbs as an example, do not have a designation of pharmaceutical grade. However, of these ingredients that are included in the Balance Dermaceuticals® therapeutic product line, all are tested extensively and analyzed to ensure the highest possible quality, potency and purity. This ensures that you are provided with the most efficacious therapeutics and protocols available in the medical marketplace today.

All Balance Dermaceuticals® therapeutics are manufactured in FDA registered and inspected laboratories and adhere to GMP (Good Manufacturing Processes) standards. All protocols, products and therapeutics not only meet but consistently exceed USP standards. The manufacturing facilities take great measures to ensure unparalleled integrity of every product manufactured and Balance Dermaceuticals® prides itself on demanding superior quality throughout every step of the manufacturing process. Written standard operating procedures (SOP) prepared in accordance with GMP for nutritional supplement USP XXIV production are meticulously followed in order to adhere to strict in-process quality control standards.

Every raw material ingredient is inspected and undergoes stringent quality control measures prior to production. All raw products used are obtained from the most reliable and well-reputed sources. Processing and storage of raw materials as well as harvesting time and transportation methods have all been addressed. Extraction methodologies used are unique to each separate component and are based on maintaining stability of active constituents. As a result, cold process extraction methods are predominantly utilized when possible with chemical and heat extraction methods used only when absolutely necessary.

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The manufacturing facilities are maintained at constant temperature and humidity levels to ensure optimal freshness of all products produced. The Balance Dermaceuticals® products contain no yeast, wheat, gluten, soy protein, milk, corn, sodium, sugar, starch, artificial coloring, preservatives, or flavoring unless otherwise specifically noted.

Use ONLY Under Medical Supervision.

All ingredients are pharmaceutical grade or higher.** The quality and purity of each protocol is assured. Certificate of analysis is available upon request.

Manufactured in FDA inspected laboratories, using strict GMP Standards.
These statements have not been evaluated by the Food and Drug Administration.

This protocol is not intended to diagnose, treat, cure or prevent any disease.

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