

# The Use of HCG to Prevent / Reverse Testicular Shrinkage and Preserve Fertility

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# Human Chorionic Gonadotropin (From the book Testosterone: A Mans Guide )

Human chorionic gonadotropin (HCG) (not to be confused with human growth hormone, or HGH) is a glycoprotein hormone that mimics LH (luteinizing hormone), produced in pregnancy by the developing embryo soon after conception, and later by part of the placenta. Its role is to prevent the disintegration of the corpus luteum of the ovary and to maintain the progesterone production critical for pregnancy in women. It supports the normal development of an egg in a woman's ovary, and stimulates the release of the egg during ovulation. HCG is used to cause ovulation and to treat infertility in women.

You're probably asking yourself why you should care about this. But in men, HCG is also used in young boys when their testicles have not dropped down into the scrotum normally. Additionally, HCG is used to increase testicular size after long-term testosterone or anabolic steroid use.

Testosterone replacement therapy triggers the hypothalamus to shut down its production of GnRH (gonadotropin releasing hormone). Without GnRH, the pituitary gland stops releasing LH. Without LH the testes (testicles or gonads) shut down their production of testosterone. For males HCG closely resembles LH. If the testicles have shrunken after long-term testosterone use, they will likely begin to enlarge and start their testosterone production shortly after HCG therapy is instituted. HCG jump-starts your testes to produce testosterone and to increase their size.

HCG has also been shown to increase the amount of testosterone inside the testicles (Intratesticular testosterone or IT). The use of HCG alone to increase testosterone is not as popular as using testosterone replacement due to several factors: 1- cost since large doses of HCG would be required, 2- quality of life of HCG alone vs TRT may be worse (this has not been validated by comparison studies), 3- concerns about long term high dose HCG use and its potential effect on desensitization of Leydig cells to it.

When used in small doses 2-3 times per week along with testosterone replacement, HCG can reverse the decrease of intratesticular testosterone. HCG's effect as a LH mimicker plus its ability to increase IT seem to be the reasons why men were able to preserve fertility (normal sperm) when using testosterone replacement plus 500 IU HCG every other day in Dr Lipshultz' study (see study attached to this post). The main surprising result of that study is that normal sperm quality can be preserved by this combo even in the absence of FSH, a gonadotropin thought to be essential in sperm production.



#### How is HCG made?

HCG can be extracted from pregnant women's urine or through genetic modification. The product is available by prescription under the brand names Pregnyl, Follutein, Profasi, and Novarel. Novire is another brand but it is a product of recombinant DNA. Compounding pharmacies can also make HCG by prescription in different vial sizes. Brand names of HCG in regular pharmacies cost over \$100 per 10,000 IUs. The same amount of IUs cost around \$50 in compounding pharmacies. Many insurance policies do not pay for HCG since they consider its use for testicular atrophy while on TRT an off label use. So, most men using it pay for it themselves and get it from compounding pharmacies that sell it a lot cheaper.

#### How is HCG supplied?

HCG is dispensed as a powder contained in vials of 3,500 IUs, 5, 000 IUs or 10,000 IUs or more (most common is actually 11,000 IU). You can call compounding pharmacies and have them make vials for you with different IU amounts, though. These are usually accompanied by another vial of 1 mL (or cc) of bacteriostatic water to reconstitute the powder into a liquid solution.

What is an IU? When measuring testosterone we spoke in weights of grams and milligrams. HCG is measured not by weight but in IUs, or international units. IU is not about weight but refers to the amount of a substance that produces a particular biologic effect that has been agreed upon as in international standard. The IU from one substance to the next does not mean they have equivalent weights (for example, 1, 000 IU of vitamin C might have a different weight than 1,000 IU of vitamin A). Again, IU is not a weight measuring unit.

Bacteriostatic water (water with a preservative that is provided with the prescription) is mixed in with the powder to reconstitute, or dissolve, it before injection. This type of water can preserve the solution for up to 6 weeks when refrigerated. Some patients do not use the 1 mL water vials that come with the commercially (non compounded) available product and instead get their doctors to prescribe 30 cc bottles of bacteriostatic water so that they can dilute the HCG down to a more workable concentration that is more practical for men using lower doses of HCG weekly.

#### How is HCG administered?

HCG is given as an injection under the skin or intramuscularly (there is still debate on which method is best). The number of IUs per injection will depend on how much bacteriostatic water you add to the dry powder vial. If you add 1 mL to a 5,000 IU powder vial, then you will have 5,000 IUs per mL, so 0.1 mL would be 500 IU. If you add 2 mL to the 5,000 IU dry powder vial, then you will have 2,500 IU/mL; 0.1 ml (or cc) in an insulin syringe will equal 250 IU.

Ultra-fine needle insulin syringes are used to inject HCG under the skin, making this very easy to take even for the needle-phobic. Typical sizes are:

1 ml, 12.7 mm long, 30 gauge and 0.5 ml, 8 mm, 31 gauge syringes.

Syringes require a separate prescription. Some compounding pharmacies will automatically include them with the shipment, but do not forget to ask them. Never use the syringe that you used for injecting the bacteriostatic water into the powder for injecting yourself; the needle will be dull (I usually use a regular 23 gauge, 1 inch, 3 ml syringe to load up the water). Remember that you also need alcohol pads to clean the



injection area and the tip of the vial. Typical injection sites are the abdominal area close to the navel or in the pubic fat pad. Pinch a little of fat on your abdominals and inject into that pinched area, then massage with an alcohol pad. Discard syringes into the sharps container that can be provided by your pharmacy.

As I mentioned before, compounded HCG is a lot cheaper than the commercially available pharmaceutical products. Sometimes it is difficult to find commercially available HCG in regular pharmacies.

#### **Mixing Reconstitution Instructions:**

HCG comes in a small bottle with a white powder. You need bacteriostatic water (provided by the compounding pharmacy) to mix it with the powder. The most common HCG vials now come with 11,000 IUs. If you have one of these, follow these instructions.

Use a large syringe provided with the product to inject 11 ml of bacteriostatic water to the vial containing the HCG dry powder, aiming against the glass vial wall. Swirl the vial with a gentle rotary motion until contents are dissolved- DO NOT SHAKE.

Suggested syringe size for injection under the skin: 30 Gauge needle of 5/16 inches in length containing 1 milliliter (30G 5/16x1ML). Note: ml = cc

How much HCG to draw depends on the dose to be used (follow physicians recommendations): For example, for 1,000iu per dose = draw 1ml= 100 on the syringe 500iu per dose = draw 0.5ml= 50 on the syringe 250iu per dose = draw 0.25ml= 25 on the syringe

You can divide all of the above numbers by half if you use 5.5 ml of bacteriostatic water to reconstitute instead of 11 ml. NOTE: Discard all used syringes in a sharps waste container. Most men use 5.5 mls instead of 11 ml to inject smaller volumes under the skin.

This is a good video to watch for mixing and injection technique: http://www.excelmale.com/content/64-How-to-Inject-HCG

#### What are HCG's effective doses?

A review of the literature reveals a wide range of doses of HCG used and that there is very little agreement among physicians. For male infertility, doses of HCG used alone range from 1250 IU three times weekly to 5000- 3000 IU twice weekly (these studies did not include men on testosterone replacement). A small study showed that men on testosterone replacement therapy who used 500 IU of HCG every other day were able to remain fertile (testosterone replacement can reduce sperm count).

How long does the boost in testosterone last after an injection of HCG? A study looked into that and also tried to determine if high doses would be more effective at sustaining that boost. The profiles of plasma testosterone and HCG in normal adult men were studied after the administration of 6000 IU HCG under two different protocols. In the first protocol, seven subjects received a single intramuscular injection. Plasma testosterone increased sharply (1.6 0.1-fold) within 4 hours. Then testosterone decreased slightly and remained at a plateau level for at least 24 hours. A delayed peak of testosterone (2.4 0.3-fold) was seen between 7296 hours. Thereafter, testosterone declined and reached the initial levels at 144 hours. In the second protocol, six subjects received two intravenous (IV) injections of HCG (5-8 times the dose given by injection to the first group) at 24-hour intervals. The initial increment of plasma testosterone after the first injection was similar to that seen in the first protocol despite the fact that plasma HCG levels were 58 times higher in this case. At 24 hours, testosterone levels were again lower than those observed at 24 hours and a



second IV injection of HCG did not induce a significant increase. The delayed peak of plasma testosterone (2.2 0.2-fold of control) was seen about 24 hour later than that in the first protocol. So, this study shows that more is not better when dosing HCG. In fact, high doses may desensitize Leydig cells in the testicles (this is also a highly debated issue). It also showed that testosterone blood levels peak not once but twice after HCG injections. I wish they had studied a lower dose than 6000 IU since very few physicians prescribe this high dose.

HCG may not only boost testosterone but also increase the number of Leydig cells in the testicles. It is well known that Leydig cell clusters in adult testes enlarge considerably under treatment with HCG. However, it has been uncertain in the past whether this expansion involves an increase in the number of Leydig cells or merely an enlargement of the individual cells. A study was performed in which adult male Sprague-Dawley rats were injected subcutaneously daily with 100 IU HCG for up to 5 weeks. The volume of Leydig cell clusters increased by a factor of 4.7 during the 5 weeks of HCG treatment. The number of Leydig cells (initially averaging 18.6 x 106/cm3 testis) increased to 3 times the control value by 5 weeks of treatment (P<0.001), while the average volume of individual Leydig cells (initially ~2200 m3) enlarged only 1.6 times. They concluded that chronic treatment with HCG increases the number of Leydig cells in the testes of adult rats. We do not know if these results can be extrapolated to men but this observation may explain why HCG restores testicular size in men who have used testosterone without it.

Currently there are no HCG guidelines for men who need to be on testosterone replacement therapy and want to maintain normal testicular size. A study that used 200 mg per week of testosterone enanthate injections with HCG at doses of 125, 250, or 500 IU every other day in healthy younger men showed that the 250 IU dose every other day preserved normal testicular function (no testicular size measurements were taken, however). Whether this dose is effective in older men is yet to be proven. Also, there are no long-term studies using HCG for more than 2 years.

Due to its effect on testosterone, HCG use can also increase estradiol and DHT, although I have not seen data that shows if this increase is proportional to the dose used.

So, the best dose of HCG to sustain normal testicular function while keeping estradiol and DHT conversion to a minimum has not been established since every man is different.

Some doctors are recommending using 200-500 IUs twice or three times a week for men who are concerned about testicular size or who want to preserve fertility while on testosterone replacement. Higher doses, such as 1,000 to 5,000 IUs twice a week, have been used but I believe that these higher doses could cause more estrogen and DHT-related side effects, and possibly desensitize the testicles for HCG in the long term. Some doctors check estradiol levels a month after this protocol is started to determine whether the use of the anastrozole (brand name: Arimidex), is needed to counteract any increases in estradiol levels. High estradiol can cause breast enlargement and water retention in men but it is important at the right blood levels to maintain bone, brain health and possibly sexual function.

Dr Lipshultz in Houston did an interesting study in men using gels or injections to see if every other day injections of HCG at 500 IU preserved their fertility while on TRT. He found that most men did indeed remain fertile with good sperm quality and count. This study is attached to this post.

For men using testosterone gels, the same dose every third day has anecdotally helps to preserve testicular size (the dose of the gel has to be adjusted after a month of HCG to compensate for the increased testosterone caused by HCG).

Some doctors believe that stopping TRT for a few weeks in which only 2000- 3000 IU HCG weekly is used provides a good way to stimulate testicular function without having to use HCG continuously. I have not seen any data to support this approach in the long term. Others believe that cycling HCG on and off while maintaining TRT may prevent any desensitization of testicular Leydig cells to HCG. Again, no data or reports have been published on this approach.



Some men have asked me why we cannot use HCG solely to make our own testicles produce testosterone without the use of TRT along with it. Using HCG as sole testosterone replacement option may not bring the same subjective benefit on sexual function as pure testosterone delivery systems do even when similar serum androgen levels are produced from comparable baseline values. However, supplementing the more traditional transdermal, or injected options, testosterone with the correct doses of HCG stabilizes blood levels, prevents testicular atrophy, helps rebalance expression of other hormones, and brings reports of greatly increased sense of well-being and libido. But in excess, HCG can cause acne, water retention, moodiness, and gynecomastia (breast enlargement in men).

Many men have complained that their doctors do not know about HCG and how to use it (I do not blame doctors for being confused!). Some spend a lot of time trying to find doctors to feel comfortable prescribing it. One good way to find out what doctor in your area may be currently prescribing it is to call your local compounding pharmacies to ask them what doctors call them for their patients prescriptions. We can also help: http://www.excelmale.com/forms.php?d...fid=1&tabid=40

**Important Note**: Unlike testosterone, HCG is not a DEA controlled substance in most states. However, it is a controlled substance in the following states (state regulations may supersede DEA rules): California, Colorado, Connecticut, Illinois, Indiana, Louisiana, Maine, Nevada, New York, North Carolina, Pennsylvania, Rhode island.

#### Conclusion:

After reading this information, you probably agree with me that using HCG requires a lot of discipline since you have to remember to inject it weekly in addition to your weekly or bi-weekly testosterone injection. But I know of many men who have that type of commitment since they do not want testicular size reduction. And many of us may just be fine with our reduced testicular size as long as testosterone is actually doing its job in improving our sex drive. And some lucky men do not get testicular atrophy at all on testosterone (those with large testicles to start with usually do not seem to complain about shrinkage as much as men starting with smaller testicular size before TRT). So it is a personal decision at the end!

Click here to read published studies on the use of HCG in men.

For more information about how to prevent and reverse side effects of testosterone, please read: http://www.excelmale.com/threads/420...nagement-Table

This video provides very important information : http://www.youtube.com/watch?v=zF38G...re&index=6

Click Here to register on ExcelMale.com for updates, a free ebook, and to get answers to your questions.

#### HCG Stimulation Test to Determine How Your Testicles Are Working

Shippen's Chorionic Gonadotrophin Stimulation Test (for males under 60 years of age)

Even though there seems not be an accepted and clinically proven protocol to dose HCG, Dr. Eugene Shippen (author of the book "The Testosterone Syndrome"), has developed his own after his experiences.



Most doctors do not follow this protocol but I am showing it here since I get a lot of questions about it. I have never used this protocol myself since I have been on testosterone replacement for over 15 years.

Dr. Shippen has found that a typical treatment course for three weeks is best for determining those individuals who will respond well to HCG treatment. It is administered daily by injection 500 units subcutaneously, Monday through Friday for three weeks. The patient is taught to self administer with 50 Unit insulin syringes with 30 gauge needles in anterior thigh, seated with both hands free to perform the injection. Testosterone, total and free, plus E2 (estradiol) are measured before starting the protocol and on the third Saturday after 3 weeks of stimulation (he claims that salivary testing may be accurate for adjusting doses. This is source of great debate). Studies have shown that subcutaneous injections of HCG are equal in efficacy to intramuscular administration.

By measuring the effect on his HCG protocol on total testosterone, he identifies candidates that require testosterone replacement versus those who just require having their testicles "awaken" with HCG to produce normal testosterone. I am yet to see any data that substantiates his approach, however.

Here is how he determines Leydig (testicular) cell function:

1. If the HCG protocol causes less than a 20% rise in total testosterone he suggests poor testicular reserve of Leydig cell function (primary hypogonadism or eugonadotrophic hypogonadism indicating combined central and peripheral factors).

2. 20-50% increase in total testosterone indicates adequate reserve but slightly depressed response, mostly central inhibition but possibly decreased testicular response as well.

3. More than 50% increase in total testosterone suggests primarily centrally mediated depression of testicular function.

He then offers these options for treatment for patients depending on the response to HCG and patient determined choices.

1. If there is an inadequate response (< 20%), then replacement with testosterone will be indicated.

2. The area in between 20-50% will usually require HCG boosting for a period of time, plus natural boosting or "partial" replacement options.

I am yet to see what he means with natural boosting! Dr. Shippen believes that full replacement with testosterone is always the last option in borderline cases since improvement over time may frequently occur as the testicles' Leydig cell regeneration may actually happen. He claims that much of this is age dependent. He states that up to age 60, boosting is almost always successful. In the age range 60-75 is variable, but will usually be clear by the results of the stimulation test. Also, disease related depression of testosterone output might be reversible with adequate treatment of the underlying process (depression, obesity, alcohol, deficiency, etc.) He claims that this positive effect will not occur if suppressive therapy is instituted in the form of full testosterone replacement.

3. If there is an adequate response of more than 50% rise in testosterone, there is very good Leydig cell reserve. HCG therapy will probably be successful in restoring full testosterone output without replacement, a better option over the long term and a more natural restoration of biologic fluctuations for optimal response. But I am yet to see any data on long term use of HCG used in this approach! (I invite researchers to do such studies)

4. Chorionic HCG can be self-administered and adjusted according to response. In younger, high output responders (T > 1100ng/dl), HCG can be given every third or fourth day. This also minimizes estradiol blood levels which raise with HCG administration. In lower level responders (600-800ng/dl), or those with a higher



estradiol output associated with full dose HCG, 300-500 units can be given Mon-Wed-Fri. At times, sluggish responders may require a higher dose to achieve full testosterone response.

Dr. Shippen believes in checking salivary levels of free testosterone on the day of the next injection, but before the next injection to determine effectiveness and to adjust the dose accordingly. He claims that later as Leydig cell restoration occurs, a reduction in dose or frequency of administration may be later needed.

5. He recommends to monitor both testosterone and estradiol levels to assess response to treatment after 2 - 3 weeks after change in dose of HCG as well as periodic intervals during chronic administration. He claims that salivary testing will better reflect the true free levels of both estrogens and testosterone. (Pharmasan.com and others) Most insurance companies do not pay for salivary testing. Blood testing is the standard way to test for testosterone and estradiol.

6. Except for reports of antibodies developing against HCG (he mentions that he has never seen this problem), the claims that there are no adverse effects of chronic HCG administration.

Dr. Shippen's book was published in the late 90's. I know of no physician that uses his protocol. I have no opinion on its validity. The idea that testicular function can be improved with cycles of HCG in men with low testosterone caused by sluggish yet functioning Leydig cells is an interesting concept that needs to be studied. I guess that since this protocol requires very close monitoring, many doctors have avoided using it. The off label nature of the protocol's use of HCG can also make it expensive for patients who will have to pay cash for its use and monitoring.

Source: Testosterone: A Man's Guide

ExcelMale.com and DiscountedLabs.com

Concomitant Intramuscular Human Chorionic Gonadotropin Preserves Spermatogenesis in Men Undergoing Testosterone Replacement Therapy

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**Purpose:** Testosterone replacement therapy results in decreased serum gonadotropins and intratesticular testosterone, and impairs spermatogenesis, leading to azoospermia in 40% of patients. However, intratesticular testosterone can be maintained during testosterone replacement therapy with co-administration of low dose human chorionic gonadotropin, which may support continued spermatogenesis in patients on testosterone replacement therapy.

**Materials and Methods:** We retrospectively reviewed the records of hypogonadal men treated with testosterone replacement therapy and concomitant low dose human chorionic gonadotropin. Testosterone replacement consisted of daily topical gel or weekly intramuscular injection with intramuscular human chorionic gonadotropin (500 IU) every other day. Serum and free testosterone, estradiol, semen parameters and pregnancy rates were evaluated before and during therapy.

Results: A total of 26 men with a mean age of 35.9 years were included in the study. Mean followup was 6.2



months. Of the men 19 were treated with injectable testosterone and 7 were treated with transdermal gel. Mean serum hormone levels before vs during treatment were testosterone 207.2 vs 1,055.5 ng/dl (p <0.0001), free testosterone 8.1 vs 20.4 pg/ml (p = 0.02) and estradiol 2.2 vs 3.7 pg/ml (p = 0.11). Pretreatment semen parameters were volume 2.9 ml, density 35.2 million per ml, motility 49.0% and forward progression 2.3. No differences in semen parameters were observed during greater than 1 year of followup. No impact on semen parameters was observed as a function of testosterone formuation. No patient became azoospermic during concomitant testosterone replacement and human chorionic gonadotropin therapy. Nine of 26 men contributed to pregnancy with the partner during followup.

**Conclusions:** Low dose human chorionic gonadotropin appears to maintain se-men parameters in hypogonadal men on testosterone replacement therapy. Concurrent testosterone replacement and human chorionic gonadotropin use may preserve fertility in hypogonadal males who desire fertility preservation while on testosterone replacement therapy.

# RESULTS

A total of 31 consecutive hypogonadal men who desired fertility preservation were identified for study

# TRT:

- \* AndroGel® (5 gm daily) in 2 patients and Testim® (5 gm daily) in 5.
- † Testosterone enanthate (200 mg weekly) in 2 patients and testosterone cypi- onate (200 mg weekly) in 17.

In 26 of these men complete data were available on semen parameters and serum hormone quantitation before and after TRT. The average  $\pm$  SD age of our cohort was  $35.9 \pm 9.5$  years. Men were followed a mean of 6.2  $\pm$  4.9 months and up to 18 months (table 1). Of the men 19 men were treated with injectable T formulations, while 7 used transdermal gels. All men received intramuscular HCG (500 IU) every other day.

In the cohort mean serum hormone levels before vs during treatment were T 207.2  $\pm$  99.2 vs 1,055.5  $\pm$  420.9 ng/dl (p <0.0001), FT 8.1  $\pm$  3.9 vs 20.4  $\pm$  13.5 ng/dl (p = 0.02) and E 2.2  $\pm$  1.0 vs 3.7  $\pm$  2.6 ng/dl (p = 0.11), supporting the efficacy of TRT in these men. Mean pretreatment semen parameters were volume 2.9  $\pm$  1.4 ml, density 35.2  $\pm$  29.6 million per ml, motility 49.0%  $\pm$  10.4%, FP 2.3  $\pm$  0.3 and TMS count 84.6  $\pm$  82.4 million.

To ascertain the effects of exogenous TRT and HCG on semen parameters the men were followed at 2 to 4months intervals with semen parameters and hormonal assessment compared to pretreatment parameters. A statistically significant decrease in se- men volume was observed at 1 to 2 months of followup (p = 0.04). This small difference was not observed at any other followup point. Furthermore, no statistically significant differences were noted in other semen parameters at any followup time. No significant differences were observed in semen parameters between the injectable and transdermal TRT groups. Taken together, these data indicate that concomitant HCG therapy in the setting of TRT is effective for preserving semen parameters.



This study provide groundwork for Lipshultz's study of HCG+ TRT

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# Low-Dose Human Chorionic Gonadotropin Maintains Intratesticular Testosterone in Normal Men with

**Testosterone-Induced Gonadotropin Suppression** 

Andrea D. Coviello, et al

In previous studies of testicular biopsy tissue from healthy men, intratesticular testosterone (ITT) has been shown to be much higher than serum testosterone (T), suggesting that high ITT is needed relative to serum T for normal spermato-genesis in men. However, the quantitative relationship between ITT and spermatogenesis is not known. To begin to address this issue experimentally, we determined the dose-response relationship between human chorionic gonadotro-pin (hCG) and ITT to ascertain the minimum dose needed to maintain ITT in the normal range. Twenty-nine men with nor-mal reproductive physiology were randomized to receive 200 mg T enanthate weekly in combination with either saline placebo or 125, 250, or 500 IU hCG every other day for 3 wk. ITT was assessed in testicular fluid obtained by percutaneous fineneedle aspiration at baseline and at the end of treatment.

Baseline serum T (14.1 nmol/liter) was 1.2% of ITT (1174 nmol/ liter). LH and FSH were profoundly suppressed to 5% and 3% of baseline, respectively, and ITT was suppressed by 94% (1234 to 72 nmol/liter) in the T enanthate/placebo group. ITT increased linearly with increasing hCG dose (P < 0.001). Posttreatment ITT was 25% less than baseline in the 125 IU hCG group, 7% less than baseline in the 250 IU hCG group, and 26% greater than baseline in the 500 IU hCG group. These results demonstrate that relatively low dose hCG maintains ITT within the normal range in healthy men with gonadotropin suppression. Extensions of this study will allow determination of the ITT concentration threshold required to maintain spermatogenesis in man. (J Clin Endocrinol Metab 90: 2595-2602, 2005)

#### Excel Male

# HUMAN CHORIONIC GONADOTROPIN (HCG) INJECTION

#### http://www.empowerrxpharmacy.com/sit...CG%2011000.jpg Human Chorionic Gonadotropin is commonly prescribed for:

Increasing a woman's chance of pregnancy Helping the production of testosterone and sperm in males Treatment of cryptorchidism (specific birth problem of the testes) in male children

# Multiple strengths of Human Chorionic Gonadotropin are available:

3,000 IU - 50,000 IU per Lyophilized Vial

The dosage form available for Human Chorionic Gonadotropin is Injection Solution. Empower Pharmacy's injection solutions are compounded under the stringent USP 797 guidelines for sterile compounding, and sterility, endotoxin, potency and pH testing is performed on every batch. Our quality-assurance process



ensures the consistency and uniformity of every solution for injection we dispense.

# U.S. Brand Names: Pregnyl, Novarel

#### Pharmacologic Category: Hormone

#### What is this medicine used for?

Human chorionic gonadotropin (HCG) is used for different reasons in men and women. HCG is used in combination with other fertility drugs to increase a woman's chance of pregnancy. In men or adolescent boys, HCG helps the production of testosterone and sperm. HCG is also used in male children with cryptorchidism, a specific birth problem of the testes. It may also be used for weight loss in conjunction with a special diet.

**Key warnings before taking this medicine:** Your health care provider needs to know if you have any of these conditions: asthma; cyst on the ovary; heart disease; migraine; kidney disease; ovarian cancer or other female-related cancer; prostate cancer or other male-related cancer; seizures; an unusual or allergic reaction to HCG or other products; pregnant; breast-feeding. Your healthcare provider will monitor treatment, including urine samples, blood tests, or ultrasound exams. If you think you have become pregnant, contact your healthcare provider at once.

What are the precautions when taking this medicine? Possible interactions include: herbal or dietary supplements, like blue cohosh, black cohosh, or chasteberry. This list may not describe all possible interactions. Give your health care provider a list of all the medicines, herbs, non-prescription drugs, or dietary supplements you use.

**How is it best taken?** This medicine is either injected into a muscle (intramuscular) or under the skin (subcutaneous). Ask your doctor which way is right for you. Use exactly as directed. Take your medicine at regular intervals. It is important that you put your used needles and syringes in a special sharps container. Do not put them in a trash can. If you do not have a sharps container, call your pharmacist or healthcare provider to get one. Talk to your pediatrician regarding the use of this medicine in children. While this drug may be prescribed for male children as young as several months of age for selected conditions, precautions apply.

What do I do if I miss a dose? It is important not to miss your dose. Call your doctor or health care professional if you are unable to keep an appointment. If you are giving your own injections and miss a dose, take it as soon as you remember. If you forget until the next day, skip the missed dose and continue with your schedule. Do not use double or extra doses. Call your healthcare provider if you are unable to keep an appointment. For women receiving fertility treatment, it is important not to miss a dose as the success of your fertility treatment depends on proper use of this medication.

What are some possible side effects of this medicine? Changes in emotions or mood, headache; pain, irritation or inflammation at the injection site; fatigue. This list may not describe all possible side effects. Call your health care provider immediately if you are experiencing any signs of an allergic reaction: skin rash, itching or hives, swelling of the face, lips, or tongue. For boys: acne; breast enlargement; enlargement of penis and testes; development of facial or pubic hair; a sudden increase in height. For women on fertility treatments: indigestion; nausea, vomiting; passing small amounts of urine; shortness of breath; stomach area or pelvic pain or bloating; swelling; rapid weight gain.

**How should I store this medicine?** Keep this medicine in a refrigerator below 41°F (5°C). Keep all medicine out of the reach of children. Throw away any unused medicine after the expiration date. Do not flush unused medications or pour down a sink or drain.



**General statements:** Do not share or take any one else's medicine. Talk with your healthcare provider before starting any new medicine, including over-the-counter, natural products, or vitamins. This medication was compounded specifically for you. This patient information summarizes the most important information about your medication; if you would like more information, talk with your doctor.

#### Question:

Why is it good to take HCG with testosterone replacement?

I'm studying diligently to better understand the science behind male hormones. My question is as follows:

Testosterone injections, gels, etc tell the body to turn off the switch from internally producing T.

HCG tells the body to turn the switch back on.

How can taking both of these at the same time be beneficial? Would they not counter each other out or would the drug with the higher dose be dominant?

Am I making sense?

ExcelMale.com and DiscountedLabs.com

1 Attachment(s)

Answer from Nelson Vergel, Founder of ExcelMale.com and DiscountedLabs.com

This is a great question.

Yes, testosterone replacement shuts down LH and FSH, which shuts down the production of testosterone and sperm by the testicles. So the testicles' Leydig cells start losing volume due to inactivity. They do not die off, they just hibernate and lose size. The testosterone inside of the testicles also decreases which further decreases their size.

HCG mimics LH. It has been shown to make Leydig cells produce testosterone. It has also been shown to increase the amount of testosterone inside the testicles (Intratesticular testosterone or IT). The use of HCG alone to increase testosterone is not as popular as testosterone replacement due to several factors: 1- cost since large doses of HCG would be required, 2- quality of life of HCG alone vs TRT may be worse (this has not been validated by comparison studies), 3- concerns about long term high dose HCG use and its potential effect on desensitization of Leydig cells to it.



When used in small doses 2-3 times per week along with testosterone replacement, HCG can reverse the decrease of intratesticular testosterone. HCG's effect as a LH mimicker plus its ability to increase IT seem to be the reasons why men were able to preserve fertility (normal sperm) when using testosterone replacement plus 500 IU HCG every other day in Dr Lipshultz' study. The main surprising result of that study is that normal sperm quality can be preserved by this combo even in the absence of FSH, a gonadotropin thought to be essential in sperm production.

I would love to see a study that compares men using 2000-3000 IU of HCG per week to men using 500 IU 2-3 times per week +TRT monitoring their testicular size, sex drive and sperm quality over 6 months. That study would prove what we already know but will provide needed data for insurance reimbursement.

Print the attached study from Lipshultz et al that shows that HCG+TRT was able to preserve fertility in men. I am trying to get them to publish an extension of that data so that we also see the effect of quality of life and sex drive in these men.

This is an emerging field and unfortunately very few medical groups publish their results. I have been advocating for DR Lipshultz to also publish quality of life and sex drive data in men using TRT+ HCG since anecdotally know that HCG may boost sex drive in men on TRT alone. Testicular size is also increased back to baseline. However, these two anecdotal findings need to be validated by published data before insurance companies take this combination seriously.

#### ExcelMale.com and DiscountedLabs.com

This is the package insert (product label) of Profasi, Serono's HCG brand (expensive brand found in regular pharmacies, NOT compounded HCG)

#### **DESCRIPTION:**

Human chorionic gonadotropin (HCG), a polypeptide hormone produced by the human placenta, is composed of an alpha and a beta sub-unit. The alpha sub-unit is essentially identical to the alpha sub-units of the human pituitary gonadotropins, luteinizing hormone (LH) and follicle-stimulating hormone (FSH), as well as to the alpha sub-unit of human thyroid-stimulating hormone (TSH). The beta sub-units of these hormones differ in amino acid sequence.

Chorionic Gonadotropin is a water soluble glycoprotein derived from human pregnancy urine. The sterile lyophilized powder is stable. When reconstituted, the solution should be refrigerated and used within 30 days.

Each vial, when reconstituted with provided diluent, will contain: Chorionic Gonadotropin **2,000**, **5,000**, or **10,000** USP Units, Mannitol 100mg, Dibasic Sodium Phosphate 16 mg, Monobasic Sodium Phosphate 4 mg, with Benzyl Alcohol 0.9% as preservative, in Water for Injection.

#### CLINICAL PHARMACOLOGY:

The action of HCG is virtually identical to that of pituitary LH, although HCG appears to have a small degree of FSH activity as well. It stimulates production of gonadal steroid hormones by stimulating the interstitial cells (Leydig cells) of the testis to produce androgens and the corpus luteum of the ovary to produce progesterone. Androgen stimulation in the male leads to the development of secondary sex characteristics and may stimulate testicular descent when no anatomical impediment to descent is present. This descent is



usually reversible when HCG is discontinued. During the normal menstrual cycle, LH participates with FSH in the development and maturation of the normal ovarian follicle, and the mid-cycle LH surge triggers ovulation. HCG can substitute for LH in this function.

During a normal pregnancy, HCG secreted by the placenta maintains the corpus luteum after LH secretion decreases, supporting continued secretion of estrogen and progesterone, and preventing menstruation. HCG HAS NO KNOWN EFFECT ON FAT MOBILIZATION, APPETITE OR SENSE OF HUNGER, OR BODY FAT DISTRIBUTION.

# INDICATIONS AND USAGE:

HCG HAS NOT BEEN DEMONSTRATED TO BE EFFECTIVE ADJUNCTIVE THERAPY IN THE TREATMENT OF OBESITY. THERE IS NO SUBSTAN- TIAL EVIDENCE THAT IT INCREASES WEIGHT LOSS BEYOND THAT RESULTING FROM CALORIC RESTRICTION, THAT IT CAUSES A MORE ATTRACTIVE OR "NORMAL" DISTRIBUTION OF FAT, OR THAT IT DECREASES THE HUNGER AND DISCOMFORT ASSOCIATED WITH CALORIE-RESTRICTED DIETS.

1. Prepubertal cryptorchidism not due to anatomic obstruction. In general, HCG is thought to induce testicular descent in situations when descent would have occurred at puberty. HCG thus may help to predict whether or not orchiopexy will be needed in the future. Although, in some cases, descent following HCG administration is permanent, in most cases the response is temporary. Therapy is usually instituted between the ages of 4 and 9.

2. Selected cases of hypogonadotropic hypogonadism (hypogonadism secondary to a pituitary deficiency) in males.

3. Induction of ovulation and pregnancy in the anovulatory, infertile woman in whom the cause of anovulation is secondary and not due to primary ovarian failure, and who has been appropriately pretreated with human menotropins.

#### **CONTRAINDICATIONS:**

Precocious puberty, prostatic carcinoma or other androgen-dependent neo- plasm, prior allergic reaction to HCG. HCG may cause fetal harm when administered to a pregnant woman. Combined HCG/PMS (pregnant mare's serum) therapy has been noted to induce high incidences of external con- genital anomalies in the offspring of mice, in a dose-dependent manner.

The potential extrapolation to humans has not been determined.

#### WARNINGS:

HCG should be used in conjunction with human menopausal gonadotropins only by physicians experienced with infertility problems who are familiar with the criteria for patient selection, contraindications, warnings, precautions, and adverse reactions described in the package insert for menotropins. The principal serious adverse reactions during this use are: (1) Ovarian hyperstimulation, a syndrome of sudden ovarian enlargement, ascites with or without pain, and/or pleural effusion; (2) Enlargement of preexisting ovarian cysts or rupture of ovarian cysts with resultant hemoperitoneum; (3) Multiple births, and (4) Arterial thromboembolism.

The diluent used for reconstitution contains benzyl alcohol. Benzyl alcohol has been reported to be associated with a fatal "Gasping Syndrome" in premature infants.

#### PRECAUTIONS:



General:

1. Induction of androgen secretion by HCG may induce precocious puberty in patients treated for cryptorchidism. Therapy should be discontinued if signs of precocious puberty occur.

2. Since androgens may cause fluid retention, HCG should be used with caution in patients with cardiac or renal disease, epilepsy, migraine, or asthma.

**Drug/Laboratory test:** HCG can cross react in the radioimmunoassay of gonadotropins, especially luteinizing hormone. Each individual laboratory should establish the degree of cross reactivity with their gonadotropin assay. Physicians should make the laboratory aware of patients on HCG if gonadotropin levels are requested.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** There have been sporadic reports of testicular tumors in otherwise healthy young men receiving HCG for secondary infertility. A causative relationship between HCG and tumor development in these men has not been established. Defects of fore- limbs and of the central nervous system, as well as alterations in sex ratio, have been reported in mice on combined gonadotropin and HCG regimens. The dose of gonadotropin used was intended to induce superovulation. No mutagenic effect has been clearly established in humans. Fertility—see "Indications and Usage."

**Pregnancy: Teratogenic effects**—Category X: See "Contraindications" section. Combined HCG/PMS (pregnant mare's serum) therapy has been noted to induce high incidences of external congenital anomalies in the offspring of mice, in a dose-dependent manner. The potential extrapolation to humans has not been determined.

**Nursing Mothers:** It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when HCG is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children below the age of 4 have not been established.

ADVERSE REACTIONS: (See WARNINGS)

Headache, irritability, restlessness, depression, fatigue, edema, precocious puberty, gynecomastia, pain at the site of injection. Hypersensitivity reactions both localized and systemic in nature, including erythema, urticaria, rash, angioedema, dyspnea and shortness of breath, have been reported. The relationship of these allergic-like events to the polypeptide hormone or the diluent containing benzyl alcohol is not clear.

DOSAGE AND ADMINISTRATION: (Intramuscular Use Only):

The dosage regimen employed in any particular case will depend upon the indication for use, the age and weight of the patient, and the physician's preference. The following regimens have been advocated by various authorities.

Prepubertal cryptorchidism not due to anatomical obstruction:

(1) 4,000 USP Units three times weekly for three weeks.

(2) 5,000 USP Units every second day for four injections.

(3) 15 injections of 500 to 1,000 USP Units over a period of six weeks.

(4) 500 USP Units three times weekly for four to six weeks. If this course of treatment is not successful, another is begun one month later, giving 1,000 USP Units per injection.



Selected cases of hypogonadotropic hypogonadism in males:

(1) 500 to 1,000 USP Units three times a week for three weeks, followed by the same dose twice a week for three weeks.

(2) 4,000 USP Units three times weekly for six to nine months, following which the dosage may be reduced to 2,000 USP Units three times weekly for an additional three months.

Induction of ovulation and pregnancy in the anovulatory, infertile woman in whom the cause of anovulation is secondary and not due to primary ovarian failure and who has been appropriately pre-treated with human menotropins (See prescribing information for menotropins for dosage and administration for that drug product).

5,000 to 10,000 USP Units one day following the last dose of menotropins. (A dosage of 10,000 USP Units is recommended in the labeling for menotropins).

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

#### **HOW SUPPLIED**

Chorionic gonadotropin for injection, USP, is available in 10 mL lyophilized multiple dose vial sets containing either:

5,000 USP Units per Vial—NDC 44087-8005-3 10,000 USP Units per Vial—NDC 44087-8010-3

with 10 mL vial bacteriostatic water for injection, USP (containing benzyl alcohol 0.9% v/v).

Storage: Store dry product at controlled room temperature 15°-30° C (59°-86° F). AFTER RECONSTITUTION, REFRIGERATE THE PRODUCT AT 2°-8° C (36°-46° F) AND USE WITHIN 30 DAYS.

#### • 05-20-2014, 11:17 PM

#### Excel Male

How to find a doctor that prescribes HCG: http://www.excelmale.com/showthread....nd-Anastrozole

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### • 06-05-2014, 12:02 PM

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#### Best HCG Posts on ExcelMale.com

These are the top HCG related posts on ExcelMale.com as of June 2014

What is HCG and how can it help men?

How to Inject HCG

HCG-Is It Worth It ?

Testicle Size: Testosterone Injections vs hCG vs T gel

Dosing and freq of T and HCG

how to use hcg with T Gels

First blood work after adding testosterone to HCG solo treatment

How to mix my HCG?

Hcg?

HCG monotherapy: Good first option for a Secondary case?

Now on TRT plus HCG to preserve fertility

Human Chorionic Gonadotropin, Pregnenelone and DHEA – By Gene Devine

Why is it good to take HCG with testosterone replacement?

Dr. has no problems with me buying hcg from him but wont give me a handwritten prescription for it

HCG use in testosterone stimulation and restoration

**Reputable Online supplier of HCG** 

**Getting OFF testosterone questions** 

**Prions in hcg** 

HCG How long until it starts to work

**Testosterone and HGC** 

Converting HCG units - mcg to IU



How to travel with T and HCG? HCG Injections: Morning or night. Does it matter? struggling with hcg solo treatment, feel very sick, please help hCG Expiration **Clomid vs hcg** Testosterone and hCG Mix Sublingual HCG Two Studies That Used HCG with Testosterone Cost and availability of HCG Good Online Source For HCG Inj **HCG Starting Dose** How to mix 11,000iu HCG vial? **HCG and Hematocriti Testapel and HCG to Keep Testicle Size** HCG--Does it expire/lose potency if too old or not refriger'd? Article: Why many doctors do not prescribe HCG or anastrozole Can you inject HCG and hgh together? Best days to use HCG, when inj. testosterone bi-weekly? Cycling HCG 2 questions about hcg mono Effects of Three Different Medications on Metabolic Parameters and Testicular Volume HCG is not working anymore. Do I have antibodies to it? Can HCG make your penis grow? Types Of HCG

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Another interesting study that showed that HCG use along with testosterone improves testicular function and testosterone despite increases in estradiol. They did not see regression of testicular size or functions after using a high dose of HCG for 5 months.

# Human Chorionic Gonadotropin and Testicular Function: Stimulation of Testosterone, Testosterone Precursors, and Sperm Production Despite High Estradiol Levels

Matsumoto et al. The Journal of Clinical Endocrinology & Metabolism. Volume 56, Issue 4

#### Abstract

Excessive gonadotropin stimulation of the testis induced by the administration of high doses of hCG or LH markedly decreases testicular function in experimental animals. The adverse effects of supraphysiological gonadotropin stimulation are thought to be mediated, in part, by the very high levels of estradiol produced. We administered a supraphysiological dosage of hCG together with exogenous testosterone (T) to normal men for several months. The combination of these agents produced very high serum estradiol (E<sub>2</sub>) levels and (we assume) high intratesticular E<sub>2</sub> levels. In this setting of supraphysiological gonadotropin stimulation and high E<sub>2</sub> levels, we examined serum levels of T, the  $\delta^4$  and  $\delta^5$  steroid precursors of T, and sperm production. After a 3-month control period, five normal men received T enthanate (T; 200 mg, im, weekly) for 3–5 months. Then, while T was continued in the same dosage, all subjects were given hCG (5000 IU, im, three times weekly) for an additional 4–6 months. Serum E<sub>2</sub> levels during hCG plus T treatment increased to a mean (±SEM) of 158 ± 16 pg/ml.

Despite the very high  $E_2$  levels generated by this prolonged administration of hCG and T, hCG stimulated a mean increase of 5.1 ng/ml in the total T level and 0.18 ng/ml in the free T level over those found during T administration alone. These increments in T levels approximate normal blood T levels in man. Significant changes in serum levels of  $\delta^4$  steroid precursors of T biosynthesis occurred during the study. Serum progesterone and 17-hydroxyprogesterone levels fell significantly with gonadotropic suppression induced by T administration alone and then increased significantly with hCG stimulation. In contrast to the changes seen in serum levels of  $\delta^4$  precursors, there were no significant changes in levels of  $\delta^5$  steroid precursors of T biosynthesis. An increased ratio of 17-hydroxyprogesterone to T during hCG administration was the only suggestion of an  $E_2$ -induced block in steroid synthesis. hCG also significantly stimulated sperm production, as assessed by sperm concentration, motilities, and morphologies, in spite of the very high serum  $E_2$  levels; the mean sperm concentration increased from 1.0 ± 1.0 million/cc during T administration alone to 46 ± 16 million/cc during hCG plus T treatment.

We conclude that chronic administration of supraphysiological dosages of hCG can stimulate testicular function in man, despite very high E<sub>2</sub> levels, and that hCG in these dosages does not lead to severe testicular regression in man. Perhaps a higher dosage of hCG administered to men would replicate the severe testicular suppression reported in experimental animals. (*J Clin Endocrinol Metab* 56: 720, 1983)

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#### Does your doctor prescribe testosterone plus HCG?

Please help your doctor get more business and other men who are looking for good doctors. Let us know if your doctor prescribes testosterone plus HCG by filling out this survey. Thanks!!

https://www.surveymonkey.com/s/TRTHCGdoctors

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New video that shows how to combine HCG in the same injection with testosterone twice per week:

http://youtu.be/0uXoBb6mkys?list=UUbB4QnYFDWHzoKVcRVFyJMw

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Using Testosterone But Having Problems Getting a Prescription for HCG? CLick here

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#### Effects of Three Different Medications on Metabolic Parameters and Testicular Volume

# Preserving fertility in the hypogonadal patient: an update

Ranjith Ramasamy, Joseph M Armstrong, Larry I Lipshultz

#### Recovery of spermatogenesis in anabolic steroid suppressed patients

For healthy patients who use exogenous testosterone and are unable to establish a pregnancy because of the deficient spermatogenesis, there are now solutions to reverse the negative impact of testosterone supplementation. In our experience treatment involves discontinuation of exogenous testosterone and administration of 3000 units of hCG (either with the aromatase inhibitor anastrozole or the selective estrogen receptor modulator tamoxifen or clomiphene citrate) intramuscularly every other day for 3 or more months. As higher doses of hCG are known to suppress FSH levels, simultaneous administration of clomiphene citrate not only preserves, but enhances the secretion of FSH and LH from the anterior pituitary. With such treatments, testosterone-induced azoospermia was successfully reversed with hCG therapy in nearly all men receiving treatment. While further studies need to be carried out, every-other-day intramuscular hCG therapy is a viable option in the treatment of men who suffer suppressed spermatogenesis due to testosterone replacement. However, recovery is not immediate; patient spermatogenesis returned in 4-6 months.

Algorithm for simultaneous treatment of hypogonadism and preservation of fertility



An algorithm based on historical evidence may be followed in determining the appropriate course of therapy for men who desire to maintain fertility yet wish to correct their significant symptoms of hypogonadism with TST ([Figure 1]). In men seeking for hypogonadal symptoms and low testosterone, the first question addressed must be whether fertility is desired. If it is not, the patient may maintain testicular size by adding 1500 IU hCG weekly. If the patient desires to maintain some degree of testicular size, he may cycle off of TST every 6 months, with a 4 week treatment cycle of 3000 IU hCG every other day. If a man does wish to maintain fertility, a baseline semen analysis should be performed and the timeframe for which the patient desires to establish a pregnancy discussed. For those patients desiring to establish a pregnancy within 6 months, testosterone therapy should be discontinued, and treatment begun with 3000 IU hCG  $\pm$  clomiphene citrate (25 mg daily) and a semen analysis performed every 2 months. If the semen analysis remains suboptimal and FSH continues to be suppressed, adding Gonal f (FSH) 75 IU to an hCG regimen can be considered. In those patients desiring to establish a pregnancy within 6-12 months, testosterone therapy can be continued with 500 IU hCG every other day  $\pm$  clomiphene citrate. Those patients desiring to establish a pregnancy after more than 12 months should cycle off testosterone every 6 months with a 4 week cycle of 3000 IU hCG every other day.

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Gonadotropin Therapy in Men With Isolated Hypogonadotropic Hypogonadism: The Response to Human Chorionic Gonadotropin Is Predicted by Initial Testicular Size Allan Burris et al.

The Journal of Clinical Endocrinology & Metabolism. Volume 66, Issue 6>

#### Abstract

This study was designed to determine whether exogenous hCG alone can complete spermiogenesis in men with isolated hypogonadotropic hypogonadism (IHH). hCG was administered to 22 men with IHH until maximal testicular growth was achieved. Their mean testicular volume increased from  $5.5 \pm 1.1$  (±se) mL (pretreatment) to  $10.8 \pm 1.6$  mL (maximum) during treatment ( $P < 10^{-6}$ ). The maximum mean testicular volume was highly positively correlated with initial volume (r = 0.84;  $P < 10^{-6}$ ). All men attained normal serum testosterone levels, and 7 of 22 men achieved supraphysiological serum estradiol levels. During hCG treatment, 14 of the 22 men had sperm appear in their semen. Six of 11 men with complete gonadotropin deficiency, defined as an initial mean testicular volume less than 4 mL, became sperm positive during hCG treatment. In contrast, 9 of 11 men with partial gonadotropin deficiency (initial mean testicular volume of 4 mL or more) produced sperm during treatment (P < 0.001). Sperm concentration was highly positively correlated with both pretreatment (r = 0.65; P < 0.01) and final testicular volume (r = 0.73; P < 0.0001). Of 13 men attempting to impregnate their partners, 7 were successful in initiating conception; a total



of 8 pregnancies ensued. The sperm concentration at the time of conception was less than 10 million/mL in all but 1 man.

Our study demonstrates that hCG, in the absence of exogenous FSH, can complete spermiogenesis in men with partial gonadotropin deficiency. The response to hCG in men with IHH is predicted by the initial testicular volume.

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**Testosterone Side Effect Management Table** 

How to care for and store your HCG (or any peptide)