March 2008

The Thyroid Patient Advocacy-UK (TPA-UK) Response to: "A Statement from the British Thyroid Association Executive Committee on Armour® Thyroid"

> "As often in the history of science, the biggest obstacle in finding the truth is not the difficulty in obtaining data, but the bias of the investigators on what data to chase and how to interpret them."
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> **—Peter H. Duesberg, PhD, *Inventing the AIDS Virus***
> **Washington, DC, Regnery Publishing, Inc., 1996**

Introduction

Thyroid Patient Advocacy-UK (TPA-UK) disagrees with many of the statements made by the Executive Committee of the British Thyroid Association (BTA) on natural desiccated porcine thyroid extract (Armour® Thyroid, USP). TPA-UK are very concerned that the BTA continue to advise that L-thyroxine (T4) replacement remains the treatment of choice despite the amount of evidence contrary to their opinion, showing it to be ineffective in relieving many patients' symptoms.[1]

Conventional medical practitioners have made no attempt to evaluate the evidence regarding the use of natural thyroid hormone, and their wholesale dismissal of the concept represents, at least in part, a biased attitude.

History of Thyroid Hormone Treatments

In 1875, Sir William W. Gull published his study of five women suffering from what he called myxoedema.[2] Sixteen years later, a successful attempt was made to implant a sheep thyroid gland under the skin of a woman suffering from myxoedema. This case was reported in the journal '*La Semaine Medicale* by Betancourt', Lisbon, Portugal on 18th August 1890.[3] One year later, myxoedema was successfully treated with enteral and parenteral administration of both thyroid glands and thyroid extract.[3, 4, 5]

Immediate improvement was seen after implantation of the sheep thyroid gland, and it became obvious that the beneficial clinical effect was due to a biological active compound released by the implanted sheep thyroid gland into the patient. In July 1891, based on a review of the literature, George R. Murray presented his observations at the Annual Meeting of the British Medical Association (BMA) of a female patient with myxoedema who had been treated successfully with hypodermic injections of extract from the thyroid glands of sheep.[3]

One year after Murray's publication, physicians Fox and MacKenzie reported that oral administration of fresh sheep thyroid gland and thyroid extract were effective in reversing the signs and symptoms of hypothyroidism in a female patient.[4, 5] The reports from MacKenzie and Fox were published back-to-back in the October 1892 issue of the *British Medical Journal* (*BMJ*).

Following this publication, oral preparations of thyroid extracts became available and were widely used to treat hypothyroidism successfully.

Based on his research, Bauman (1895) concluded that the active substance in the thyroid gland contains iodine. He attempted, unsuccessfully, to hydrolyze thyroidal proteins in order to isolate the active principle. Following Baumans' publication in 1895 reporting high concentrations of iodine tightly bound to proteins in extracts of the thyroid gland, thyroid extracts were standardized to contain 0.2% iodine in order to maintain equal potency of different preparations.[6]

In 1915, Kendall succeeded in hydrolyzing thyroid proteins into simpler constituents.[7] Further purification yielded a biologically active iodine-containing substance, which was crystallized

into a pure form. Kendall called this crystallized product thyroxine. He wrote: “In brief, the compound containing iodine, the presence of which, as a normal constituent of the thyroid, as foretold by Baumann 19 years ago, has been isolated in pure crystalline form, and further, it has been shown that this compound is the substance in the thyroid which is responsible for the physiologic activity of the gland.”[6] Unfortunately, Kendall incorrectly concluded that the structure was triiodohexahydroxyindole propionic acid.[7]

In 1926, Dr. C. R. Harrington of University College London showed that thyroxine is the tetraiodo derivative of thyronine, and he was able to synthesize the active compound.[8]

The Deliberate Hoax

Thyroid extracts continued their popularity and were not affected by the introduction of synthetic thyroxine in the 1930s until a hoax batch of thyroid extract, containing only iodine with no thyroid hormone, was shipped to Europe and the US in 1963, with the goal of discouraging the use of thyroid extracts. This hoax made thyroxine the only eligible thyroid preparation for hypothyroidism because the iodophobic domino effect of the 1948 Wolff-Chaikoff publication prevented physicians from supplementing their patients with iodine.[9]

Many doctors were reluctant to switch to thyroxine only, preferring to prescribe the desiccated gland. They were, however, eventually persuaded to change their allegiance.

In 1969, Dr. Wolff from the National Institute of Health published his paper titled, “Iodide goiter and the pharmacologic effects of excess iodide”.[9, 10] In 1970, Goodman and Gilman stated, ‘This episode gave thyroid a bad name because several publications about the unreliability of thyroid appeared before the hoax was uncovered’.[11] There was widespread concern that the effects of this “drug” were not consistent with previous clinical experience and so all thyroid extract was labelled “unreliable”. Although the hoax was uncovered seven years later and ‘The Medical Letter’ in 1973 maintained that desiccated thyroid extract had never been unreliable, mud sticks, and doctors started using synthetic l-thyroxine.[10]

To quote Derry “. . . by 1976 about half (52%) of the prescriptions written for thyroid hormone in the United States were for desiccated thyroid or other natural products.[12] The best pharmacological authorities confirmed desiccated thyroid remains a remarkably clinically, predictable safe and effective preparation which is well absorbed”. So why the continued misinformation perpetrated by the BTA?

BTA Statement

A. Armour Thyroid contains both thyroxine (T4) and tri-iodothyronine (T3) extracted from the thyroid gland of pigs. One grain, about 60 mg, of desiccated pig thyroid extract contains about 38mcg of T4 and 9mcg of T3, a ratio of around 4 to 1. The normal concentration of these hormones in the human thyroid is, however, at a ratio of 14 to 1. In other words, Armour thyroid extract contains excessive amounts of T3 relative to T4 when used to replace thyroid hormone in man. Moreover, as pig thyroid contains other substances apart from T4 and T3, Armour Thyroid is not a pure preparation of thyroid hormones. Historically, extracts of animal thyroid glands were the only way to treat thyroid underactivity, but since the 1950s pure synthetic thyroid hormones have been available in tablet form (thyroxine sodium [T4] and liothyronine [T3]).

“All thyroid hormone products, both animal-derived and synthetic, are unstable compared to many other drugs. Thyroid hormones consist of iodine atoms bound to the amino acid tyrosine. The iodine atoms easily separate from the tyrosine”.[13] Therefore, it is prudent for both doctors and patients to be vigilant for sub-potent tablets or capsules.

There is no evidence showing that thyroxine sodium and liothyronine are more stable than Armour® thyroid. The BTA statement causes confusion for doctors, often to the detriment of patients. It is the belief of TPA-UK that such statements by the BTA should be evidence-based and TPA therefore supply herewith the references to support their claims.

It appears that some NHS doctors do not recommend Armour® thyroid because they believe the amount of thyroid hormone varies between batches and/or they believe the higher ratio of T3 to T4 in Armour® could be harmful or cause adverse reactions. The evidence does not support such reasoning, and in fact the variation of thyroid hormone in Armour® is minimal and well controlled (maximum 5-10 %) as specified by the US FDA.[14, 15]

There are many thyroid extract preparations and the trademark Armour® Thyroid should not be used as a generic name for these. There is much evidence that Armour® Thyroid is the most reliable of the desiccated thyroid preparations in the US.[15, 16, 17, 18, 19]

Evidence is presented in the *Empirical use of Armour thyroid* by Gaby that many people have hypothyroidism undetected by laboratory thyroid-function tests, and cases are reported to support the empirical use of Armour® Thyroid. Clinical evaluation can identify individuals with sub-clinical hypothyroidism that is likely to benefit from thyroid-replacement therapy. In a significant proportion of cases, treatment with thyroid hormone has resulted in marked improvement in chronic symptoms that had failed to respond to a wide array of conventional and alternative treatments. In some cases, treatment with desiccated thyroid has produced better clinical results than levothyroxine. Research supporting the existence of sub-clinical hypothyroidism is reviewed, and the author's clinical approach to the diagnosis and treatment of this condition is described.[19]

Armour® Thyroid does have a higher amount of T3 compared to T4 than the relative amounts of T3 to T4 secreted by the human thyroid gland, however it is well documented that Armour® is often more effective and is better tolerated than synthetic preparations of T4, T3 and T4/T3 combination.[20] This is because the T3 in natural thyroid extract is absorbed more slowly than synthetic (purified, unbound) T3.[21]

The normal thyroid gland contains approximately 200 mcg of T4 per gram of gland, and 15 mcgs of T3 per gram. The ratio of these two hormones in the circulation does not represent the ratio of the thyroid gland, since about 80% of peripheral T3 comes from monodeiodination of T4. Peripheral monodeiodination of T4 also results in the formation of reverse T3, which is iatrogenically inactive.[22]

A similar ratio can be obtained by prescribing both Armour® and synthetic thyroxine, although clinical response and symptom control should take precedence over a theoretical ideal. Perhaps the ultimate form of thyroxine for difficult patients is whole thyroid extracted from animals, such as Armour thyroid tablets.[22, 23, 24]
The long history of successful use thyroid extract in America has seen natural thyroid extract products successfully compete with the heavily promoted synthetic T4 and T3 preparations. Not only are whole glandular extracts often superior to T4 for the treatment of hypothyroidism, but there is evidence to suggest that such products are also superior to combined T4/T3 preparations.[25, 26] Shames and Shames report a patient who was treated unsuccessfully with a combination of T4 and T3 who experienced a dramatic improvement when switched to Armour® thyroid extract.[26] When synthetic T4 and T3 first became available, Arem reports the considerable difficulties he experienced when switching patients from thyroid extracts to the new synthetic preparations.[25] According to Arem, "The new treatment was seldom entirely successful." Arem continues "Once switched from these natural T4/T3 tablets to T4 tablets, patients complained of sluggishness, decreased memory, impaired concentration, and a host of symptoms of ill-being. This was in spite of having reached normal blood levels of thyroid hormone and TSH."

Since at least a third of treated hypothyroid patients whose blood tests have been restored to "normal" continue to have symptoms, therefore modern thyroid treatment is often unsuccessful, a fact which is hardly surprising given the fact that triiodothyronine (T3) is the crucially important active thyroid hormone; and the commonly seen failure to convert T4 to T3 (and also, to a lesser extent T2) will result in an unsatisfactory treatment outcome. [25, 26, 27, 28]
This underlines the urgent need to rethink methods of thyroid treatment. Clearly, much greater priority must be given to a symptomatic approach and the importance of how the patient feels, given the relative ineffectiveness of T4 and the dubious usefulness of the serum TSH test alone for diagnosis. Over reliance on laboratory tests, without clinical evaluation, may lead to considerable diagnostic errors.[29, 30, 31, 32]

Hypothyroid patients who remained polysymptomatic on T4 treatment who were switched to Armour thyroid extract became biochemically euthyroid and completely symptom-free.[33]

Since thyroid replacement therapy should aim to reproduce as closely as possible the natural secretions of the thyroid gland, there should be more support for the use of whole thyroid extracts. To this end the effectiveness of whole thyroid extract versus synthetics should be compared in clinical trials, especially involving problematic patients.

BTA Statement:

B. The concentration of thyroid hormones in Armour Thyroid USP is regulated by the manufacturer to United States Food and Drug Administration (FDA) standards. Despite this, there have been significant problems with the stability of Armour Thyroid in recent years, prompting a massive recall of tablets[1]. Because of these stability problems with Armour Thyroid, there is potential for fluctuations in thyroid hormone levels in the blood of patients treated with Armour Thyroid. These fluctuations may be unpredictable and have adverse effects on patients' health.

In a 2005, sample testing of several batches of Armour® found that some of the samples were not maintaining full potency.[34] These were manufactured between March and August 2003, and were set to expire between March and August of 2005. To avoid potential problems, it was decided to recall all the Armour® made during that timeframe in 2003. A Forest Pharmaceuticals spokesperson stated that very little of the recalled product remained in circulation at that time. Interestingly though, other evidence has shown variation of T4 in synthetic thyroxine to be greater than 30% in some batches.[34]

In a 1980 study, a number of manufacturers *other* than Forest Pharmaceuticals had versions of desiccated thyroid that were found to be unreliable in potency. The amounts of T4 and T3 in Armour® Thyroid, USP were found to be constant. Moreover, two-year old and fresh tablets of Armour® Thyroid contained similar amounts of T4 and T3.[16]

The response by Richheimer and Jensen should serve to correct any misrepresentations (implied or otherwise) regarding the liothyronine and levothyroxine content in Armour® and the nature of the collaborative study for the U.S. Pharmacopeia. As determined by Armour® Pharmaceutical Company and other participating laboratories, the liothyronine and levothyroxine content in Armour® is well within the specifications set by the U.S. Pharmacopeia.[15]

The single reference the BTA executive has used to support their Statement on Armour® is the Federal Drugs Administration (FDA) withdrawal notice of Armour®. [34] If this withdrawal is evidence against the use of Armour® Thyroid, the same argument follows for synthetic thyroxine. There have been previous reports of many defects in the commercial T4 alone preparation over the years.[35, 36] The FDA's letter to the manufacturers of Synthroid (Eltroxin UK) summarises all the dangers of inconsistent dosing for hypothyroid patients. In particular, they state: *". . .* patients using Synthroid have experienced significant, unintended variations in their doses of levothyroxine sodium. . . these variations are not conducive to proper control of hypothyroidism."[36]

In 2005, endocrinologists had expressed concern about the performance of levothyroxine sodium. As a result, FDA requested product stability data from manufacturers of all approved products manufactured between July 2003 and June 2005. In 2006, FDA presented the data at a joint meeting of the Endocrine and Metabolic Drugs Advisory Committee and the Advisory Committee for Pharmaceutical Sciences. The purpose of the meeting was to discuss the potency and stability of marketed levothyroxine products. In October 2007, FDA announced that it was tightening its potency specifications for all levothyroxine sodium to ensure the drug retained its potency over its shelf life. The FDA has taken this action in response to concerns that levothyroxine sodium potency may deteriorate prior to its expiration date.[37]

Many millions of patients throughout the world have used and continue to use natural thyroid extract. Before the advent of the TSH test in the early 1970s, patients used these products in

much higher dosages than nowadays.[38] There is no evidence to show that patients were harmed by these higher dosages.

BTA Statement:

C. There is no evidence to favour the prescription of Armour Thyroid in the treatment of hypothyroidism over the prescription of thyroxine sodium, as supplied in the United Kingdom.

Armour Thyroid is a combination T4/T3 treatment and there is evidence that combinations of synthetic T4/T3, or T3 alone treatments, result in greater improvement of clinical symptoms than T4 only treatment, which therefore supports the argument in favour of treating with T4/T3 combination.[20, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50]

Further evidence of the potential benefits of a combined T4/T3 treatment protocol

- Adding T3 to T4 results in greater improvement of clinical symptoms and signs in hypothyroid patients.[58]
- When T3 and T4 are both added to the food simultaneously with goitrogens, a much better prevention of goitre is obtained than when T4 alone is added, even at 7 times higher concentration.[59]
- In humans, T4/T3 treatments have been shown to reduce serum cholesterol and increase the speed of the Achilles tendon reflexes better than T4 treatments alone.[60]
- Several studies in rats rendered hypothyroid show that cellular euthyroidism is only obtained in the target organs if T3 is added to the classic T4 medication.[61, 62]
- T3 is thought to be between four and five times as potent as T4.[63, 64] The absorption of oral T4 can be variable (50 to 73%), contrasting with that of T3 that is more constant and efficient (95%).[87, 88]

TPA-UK wish to highlight the many conditions that may reduce the conversion of T4 to T3, e.g. aging, obesity, disease, stress, exercise, malnutrition, etc., potentially reducing the efficacy of a T4 alone treatment, and in which a natural or synthetic T4/T3 treatment may be more effective.[51, 52, 53, 54, 55, 56, 57]

There are also toxic substances such as phenols, cadmium, and mercury and medications such as propranolol, amiodarone and several others that may interfere by inhibiting the T4 to T3 conversion.[65, 66, 67, 68, 69]

Deficiencies in hormones, such asT3 itself, TSH, growth hormone, insulin, cortisone and certain trace elements such as selenium, iron, zinc, copper, iodine partially block this essential conversion step for thyroid function.[70, 71, 72, 73, 74, 75, , 76, 77, 78, 79, 80, 81, 82, 83]

On the other hand, excess hormones such as glucocorticoids, ACTH, oestrogens and some trace elements may slow down the conversion of T4 to T3.[84, 85, 86]

The Third Thyroid Hormone: 3, 5-diiodo-l-thyronine (T2)

Many endocrinologists believe there is little (or no) information about the other thyroid hormones 3, 5-diiodo-l-thyronine (T2) and monoiodothyronine (T1). This is not the case. The manufacturers of Armour® Thyroid to USP (Forest Pharmaceuticals) have done no studies into the specific amount of T2, T1, calcitonin or any other 'T' hormones that are naturally occurring in the desiccated thyroid. Nothing has been removed in the processing.

There may be advantages to using Armour® that are not related to its T3 content. Broda Barnes observed some patients treated with syntheticT4/T3 combination continued to experience residual symptoms, particularly dry skin and oedema. Both symptoms resolved in 1-2 months when the treatment was changed to Armour®.[89] This observation suggests a third active substance is secreted by the thyroid gland. The most likely candidate is diiodotyrosine(T2). Although little was known about the function of this compound in humans, the widely held assumption that it is metabolically inert may be incorrect. In a study of guinea pigs, oral administration of T2 prevented alterations in thyroid and pituitary function induced by oophorectom.[90] Administration of T2 also accelerated the metamorphosis of tadpoles and enhanced the growth of the protozoan *Tetrahymena*.[91, 92]

Whole thyroid extracts contain T4 and T3, and also T2 and T1, which also have hormonal activity.[26, 28, 93, 94, 95, 96, 97, 98 .99 ,100, 101, 102, 103, 104] Notably, as we have seen, T2 is very active in its metabolic effects.[26]

T2 has been shown to increase hepatic oxygen consumption by about 30%. The authors of the study discovered that out of T4, T3 and T2, only T2 was active in stimulating rapid hepatic oxygen consumption. They concluded that it acts rapidly and directly through activation of the mitochondria.[28]

In another study, T3 and T2 were compared in terms of Resting Metabolism (RM) and on the oxidative capacity of tissues that are metabolically active (liver, muscle tissue, brown adipose tissue or BAT, and heart). What they found was that T2 had a dose-dependent effect, which increased RM and oxidative capacity. They found the greatest response to T2 was in the liver and in BAT. The effects again occurred rapidly and independently of protein synthesis. They stated that their results suggested isomers like T2 could be direct mediators of thyroid hormone regulation on energy metabolism.[93, 94] A further study found increased hepatic oxidative capacity and thought this was due to a direct action upon the mitochondria by T2.[95] Other studies had similar findings.[96, 97]

Yet another study showed the same thing: increased oxidative capacity and energy expenditure, causing the authors to suggest that T2 and T3 displayed similar effects.[98] T2 was also shown to have a similar effect to that of T3 on lipid metabolism with T2 actually doing a little better in some tissue.[99]

Although there is little research in humans, some *does* exist. In one study, using human mononuclear blood cells, it was found that T2 increased the rate of respiration significantly.[105] So, the efficacy appears to have been established. Can it significantly inhibit TSH like T3 and T4? The studies are conflicting, but one thing seems to be prevalent amongst them all — TSH inhibition isn't nearly as severe with T2 as it is with T3.[100]

One study showed that T2 is 13% less inhibitory on TSH levels, as compared to T3.[101]
In yet another study, T3 and T2 suppressed TSH to similar levels; however, it took 15 mcg/100g body weight per day of T3 to accomplish this, while it took 200 mcg/100g body weight per day of T2 to accomplish the same thing. This means it took about 13 times more T2 to exert the same effect on TSH as T3.[102]

When researchers in another study administered 100 ug/kg of T3 and 800-1600 ug/kg of T2 the following occurred: T3 rapidly decreased serum TSH levels to within minimal levels after 24 hours. Seventy-two hours after application, TSH levels were still significantly lower than control levels. As far as the T2, TSH levels were transiently reduced and reached their lowest point at 24 hours and increased afterwards. Basal levels were reached 72 hours after an application. What they found after analysing the data was that there seemed to be a trend for a dose-dependent suppression of TSH by T2, which did not reach statistical significance. Furthermore, it appears as though it took 100 times more T2 than T3 to finally exert the same amount of TSH inhibition. Even using 400 times more T2 than T3, it appears that T3 only allows TSH to be inhibited to just a slight degree less than T2.[103]

BTA Statement

D. There has never been a direct comparison of these two treatments. The BTA committee cannot recommend a treatment with possible side effects, when a safe and equally well-established treatment exists.

Armour® Thyroid is no more likely to cause side effects than is a synthetic T4/T3 combination.[151] Splitting the daily dose of Armour® would obviate any potential concern about transient elevations of T3 levels.[19]

Thyroxine was introduced without any comparison with natural thyroid extract. The Medicines Control Agency (MCA) has continued its use without review. Given that levothyroxine is the cheaper medication **(**see below for cost of Armour®), one has to question why the manufacturers would not wish to demonstrate equal effectiveness. Natural thyroid extract has been making patients better since 1894, long before the introduction of synthetic thyroxine. Thus, the burden of proof lies with the synthetic product to demonstrate it is as safe, effective and as consistent as Armour.[15, 16]

BTA Statement:

E. Armour Thyroid is not on the British National Formulary and is not a licensed therapy in the UK. Mr. G. Matthews, the Pharmaceutical Assessor of the Medicines and Health Care Products Regulatory Agency, in a letter sent to BTA dated 19 October 2005, has clarified that "The regulations on medicine allow doctors to prescribe an unlicensed medicine for a patient to meet such a special clinical need, on their own direct personal responsibility. Where these unlicensed medicines are not available in the UK they can be imported by appropriately licensed medicines wholesalers, for supply to a doctor or pharmacy, to meet these needs."

The MHRA does allow doctors to prescribe Armour Thyroid from Forest Pharmaceutical.[104] Armour® is a fully official FDA-registered drug in the USA, and appears in the Martindale Pharmacopoeia – page 1604.[105] It is legal to prescribe Armour® Thyroid to a patient in the UK and it can be delivered by UK pharmacies if there is a prescription from a licensed physician. Indeed, Armour® Thyroid can be obtained very simply on a named patient basis and Idis World Medicines will source this.[106]

Armour® and several other thyroid medications were 'grandfathered' in when Congress passed the Kefauver-Harris Drug Efficacy Amendments of 1962 to tighten control over drugs.[107, 108] Before marketing a drug, manufacturers had to prove the safety and effectiveness for the product's intended use. The requirement was applied retrospectively to 1938, when the Food, Drugs and Cosmetics (FDC) Act was passed. Pre-1938 drugs were allowed because they were generally recognised as safe and effective, provided no evidence to the contrary developed.[107, 108] Too much evidence to the contrary developed concerning the levothyroxine products and the FDA decided none was generally recognised as safe and effective, so these synthetic products lost their 'grandfathered' privilege and had to go through the NDA process. Armour® Thyroid continues to retain its 'grandfathered' status since no evidence to the contrary has developed concerning its safe and effective status.

BTA Statement:

F. The cost of Armour Thyroid may be up to £20 per month, compared to an equivalent cost of £1 per month for thyroxine. Furthermore, Armour Thyroid is not eligible to be claimed on the prescription exemption certificate (FP10).

The £20 quoted by BTA is unhelpful, since it is unrelated to dosage. Generic synthetic thyroxine may be of most variable potency, manufacturer to manufacturer. Thyroid experts are convinced that the method of determining bio equivalence is flawed, and that there may be important differences among preparations. Casually changing a patient to a new levothyroxine preparation could lead to over- or under-treatment, with possible adverse effects. An extreme case would be a change to a more potent preparation, causing atrial fibrillation and fatal embolism in a susceptible individual.[109] Most patients receiving thyroid medication have noticed that the effectiveness of their treatment frequently varies with the manufacturer. The choice of manufacturer by the chemist is not related to quality, but cheapness. The US FDA insists that doctors and pharmacists stay with the manufacturer

whose preparation was used initially, since the variations in potency are unacceptable.[19, 20, 21, 22, 23, 24, 25, 26, 32, 37, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 89]

Simon Stephenson (2007), Head of Medicines, Pharmacy & Industry Business Unit, Department of Health (July 2007) sent TPA-UK a breakdown of the actual cost of the different dose tablets of Armour®. The average cost per unit of the differing strengths of Armour® Thyroid dispensed in primary care over the course of the year April 2006 to March 2007 is outlined in the table below. A pharmacist stated the average cost of all prescriptions per patient, per calendar month is £20.00. The cost of Armour (apart from the 240mg tablet), is far below this.

Strength	**Est. unit cost in pence:**	**Est. cost for one month supply**
Armour® Thyroid 240mg	79	£22.12
Armour® Thyroid 180mg	46	£12.88
Armour® Thyroid 120mg	43	£12.04
Armour® Thyroid 90mg	34	£9.52
Armour® Thyroid 60mg	31	£8.68
Armour® Thyroid 30mg	27	£7.56
Armour® Thyroid 15mg	19	£5.32

NB. Levothyroxine sodium 150 mcgs costs £1.52 per 28 days supply and is equivalent to about 120mg Armour® Thyroid costing £12.04 per calendar month.

The statement from the BTA that Armour® is not eligible to be claimed on the prescription exemption certificate (FP10) is false. The NHS Business Services Authority (Prescription Pricing Division) states that: "Myxoedema (underactive thyroid) or other conditions where supplemental thyroid hormone is necessary qualifies for an exemption certificate". A Medical Exemption Certificate means all prescriptions are free, whatever condition the medication is for.[110] Many members of Thyroid Patient Advocacy-UK are prescribed Armour by their doctors using an NHS prescription. As Primary Care Trusts are responsible for funding unlicensed drugs, doctors should first seek their permission.

Potential for significant savings in NHS expenditure

Whilst considering the costs of medication for hypothyroidism, we must consider the cost to the NHS of other medicines prescribed because the T4-only monotherapy does not fully resolve the patients' symptoms. Hypothyroid patients chronically used more prescription drugs, especially for diabetes, cardiovascular disease and gastrointestinal conditions.[14] These are of great financial burden to the NHS and an overwhelming burden to the quality of life of the tens of thousands of hypothyroid sufferers in the UK alone.

Irving Kirsch's recent Department of Psychology at the University of Hull study (25 February 2008) is the first to examine both published and unpublished evidence of the effectiveness of selective serotonin reuptake inhibitors (SSRIs), which account for 16 million NHS prescriptions a year. The largest study of its kind concluded that antidepressant drugs do not work. More than £291 million was spent on antidepressants in 2006, including nearly £120 million on SSRIs.[147]

Depression has an association with lower thyroid hormone levels[111, 112, 113, 114, 115, 116, 117, 118, 121, 19, 120] and research has shown that improvement can be achieved with thyroid hormone replacement.[117, 121, 122, 123, 124, 125, 126, 127]

There is an association with anxiety and lower thyroid hormone levels[128, 129, 130, 131, 132, 133] and again, research has shown improvement with thyroid treatment replacement therapy.[134, 135]

Memory loss and Alzheimer's disease likewise have an association with lower thyroid hormone levels.[136, 37, 138, 139, 140, 141, 142] Both these conditions have shown improvement with thyroid treatment.[143, 144, 145, 146]

TPA-UK takes the view that all doctors should have freedom of choice in prescribing T4 alone, combined synthetic T4/T3, T3 alone or Armour® Thyroid. The selection of treatment,

whether synthetic or natural, should be a matter between the patient and the doctor, both having freedom of choice in this respect. Medical practitioners should abandon the misconceptions that thyroid extract is inconsistent, dangerous, unreliable and/or outdated, and recognise that Armour® Thyroid meets the stringent guidelines laid down by the United States Pharmacopoeia (USP) and the FDA.

In addition, medical practitioners should be strongly encouraged to make a full assessment of the clinical presentation of patients already using Armour® Thyroid.

To quote one patient*:* "I have just tried Armour for a few weeks after being unsuccessfully treated with thyroxine for 2 1/2 years. Unfortunately I ran out of Armour, but for those few weeks my symptoms went, for the first time in years (and I'm only 20 so that's a large proportion of my life). No more muscle aches, joint pain, foggy non-thinking brain, tiredness, depression. Then when I ran out, I started thyroxine again. Now the dreaded symptoms have all come back. I now know how needed Armour is, and think it is verging on negligent that it can't be prescribed to me."[148]

TPA-UK has demonstrated the safety and efficacy of Armour Thyroid and its benefits for many patients. In thyroid medicines as with most things, one size does not fit all!

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The British Thyroid Association Reference.

1. An FDA enforcement removed more than half a million bottles of Armour Thyroid from US pharmacies in 2005 due to unstable concentrations of thyroid hormone in the preparation. [www.fda.gov/bbs/topics/enforce/2005/ENF00899.html]