

Thyroid Patient Advocacy

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To all UK medical practitioners.

FACTS ABOUT ARMOUR THYROID TO USP

There are serious misconceptions amongst the medical profession concerning the use of natural desiccated porcine thyroid extract (Armour Thyroid to USP) as an alternative to thyroxine, where, amongst a significant number of patients and their medical practitioners, find the synthetic product to be ineffective in restoring their optimal health.

Although the following information may not be relevant to your current patients, I would urge you to keep it for reference for the benefit of any future patients who do not thrive on T4 only. Thyroid extract is often the most suitable medication for patients who complain of feeling unwell, even though their TFT's may show acceptable levels of hormone whilst taking T4 only.

Thyroid patients are desperately seeking an understanding and partnership with their NHS doctors to get the best treatment possible. We believe that every patient has the right to optimal treatment. Given that a number of thyroid patients do not respond well to thyroxine alone and continue to have many of the debilitating clinical symptoms of hypothyroidism, we feel that NHS doctors should be made aware that they can prescribe Armour Thyroid within the NHS to those patients who do not regain their normal health on thyroxine. **Many practitioners believe wrongly that they are not allowed to do this. THIS IS NOT THE CASE.**

There are a number of misconceptions about Armour Thyroid, which we would like to rectify, as it is important that all medical practitioners are given the correct information.

1. Medical Practitioners believe they cannot prescribe Armour – UNTRUE

Armour Thyroid is the brand name of natural, desiccated porcine thyroid extract. Armour is authorised by the FDA as medicine that is standardised to the specification of the USP. The MHRA has not objected to the importation of Armour thyroid, as it is an FDA authorised prescription medicine, standardised to the USP and is for the treatment of patients with thyroid disease, for whom the UK licensed thyroxine is unsuitable. Consequently it can be prescribed to patients who need it, subject to it being prescribed by a doctor.

I have pasted below a copy of a letter from the MHRA regarding the prescribing of natural thyroid extract (Armour Thyroid to USP) within the NHS.

2. Armour quality is not consistent – UNTRUE

On their respective websites, the British Thyroid Association and the British Thyroid Foundation suggest that:

"Armour is prepared from desiccated animal thyroid and the preparation and purification of this product may not be at the same rigorous standards of more modern medications"

This is either erroneous or a deliberate attempt to mislead UK medical practitioners and patients.

Forest Pharmaceuticals state that the amount of thyroid hormone present in the thyroid gland may vary from animal to animal, and to ensure that Armour tablets are consistently potent from tablet to tablet and lot to lot, analytical tests are performed on the thyroid powder and on the tablets to measure actual T4 and T3 activity. Different lots of thyroid powder are mixed together and analysed to achieve the desired ratio of T4 to T3 in each lot of tablets. This method ensures that each strength of Armour will be consistent with the USP official standards.

The current USP monograph for thyroid tablets has an Assay to measure the quantities of liothyronine and levothyroxine, a content uniformity test, a disintegration test and microbial limits.

Standards are set by an expert committee with open public comment. You can see citations to two references that discuss the stability of thyroid tablets and preparations at http://www.armourinfo.freeuk.com/document_1.html The first paper does not indicate that stability or uniformity were major issues in thyroid preparations. Copies of these papers can be obtained, as well as copies of the USP monograph on Thyroid Tablets from any medical or pharmacy school library.

3. Armour Thyroid is made from bovine extracts - UNTRUE

I contacted the Drug Information Pharmacist of the Professional Affairs Department at Forest Pharmaceuticals, who state that Armour Thyroid comes from United States grain-fed pig thyroid. The pigs are domestic. Armour Thyroid does not come from bovine thyroid. The reason some confusion may have arisen could be because many years ago, the manufacturers did produce a thyroid product, called 'Thyrar' (not to be confused with Thyrolar), that was made from bovine thyroid. Please see Annex for full list of Armour Ingredients

The disease status of porcine animals born, raised, and slaughtered in the USA or Canada can be accessed through the World Health Organization, Office Internationale des Epizooties (OIE) website at <http://www.oie.int> Here you will find that the USA and Canada are classified as being free of List 'A' porcine diseases including foot-and-mouth disease, hog cholera, swine vesicular disease, and African swine fever. This disease information can also be confirmed through USDA Animal Plant and Health Inspection Service (APHIS) Armour is a natural preparation of USP grade desiccated thyroid powder derived from porcine thyroid glands.

Armour Thyroid meets all the requirements set by the USP for thyroid medications and manufacturing specifications are tightly controlled, contrary to the BTA and BTF's current misconceptions about desiccated thyroid. The natural porcine thyroid powders are not sterile products nor are they designed to be such. The finished lots are tested for and meet all USP compendial requirements including those for the absence of Salmonella and E.coli pathogens. The manufacturers also verify that the Total Aerobic Plate Count (TAPC) does not exceed 10,000 Colony Forming Units per gram (CFU/g). The entire thyroid process is performed in accordance with the Food & Drug Administration (FDA) Current Good Manufacturing Practices (cGMP) requirements. After processing, the thyroid products are packaged, stored, and handled in a manner to prevent any cross-contamination.

SO WHY THE CONTINUED MISCONCEPTIONS?

The BTF Statement on Armour Thyroid has incorrect information regarding the reasons why Armour Thyroid is not currently licensed in the UK. They also give out incorrect information about the reason it was withdrawn after synthetic thyroxine had been developed in the 1970's. This was NOT due to quality control problems; the suggestion that it was is blatantly untrue, and there are NO studies to support it.

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. Before marketing a drug, firms had to prove safety and effectiveness for the product's intended use. The requirement was applied retroactively to 1938, when the 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. 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 retains its 'grandfathered' status since no evidence to the contrary has developed concerning its safe and effective status.**

As Armour Thyroid has never been licensed in the UK, it has never been withdrawn. The falling demand was the result of assertions by certain drug manufacturers and medical authorities that the synthetic thyroxine was, by definition, better, and that porcine thyroid was greatly inferior. There have been NO studies to support this and BTF are seriously in error when making these assertions.

Interestingly, in a 1980 study, a number of generic versions of desiccated thyroid were found to be unreliable in potency. The amounts of T4 and T3 in Armour, on the other hand, were found to be constant (ref 1). Moreover, two-year old tablets of Armour Thyroid contained similar amounts of T4 and T3 as did fresh tablets.

The following quote from the bible of thyroid treatment, Goodman and Gilman's "The Pharmacological Basis of Therapeutics", sheds some light on this question. The reason why 'other' brands of desiccated porcine thyroid extract were withdrawn is:

" Several years ago (1963), a large batch of material came into the hands of a number of distributors

in the United States and Europe and, although of proper iodine content, it later proved not to be thyroid extract at all. This episode gave desiccated thyroid a bad name because several publications about the unreliability of thyroid extract appeared before the hoax was uncovered".

A further allegation from the BTF state that the use of Armour causes "*substantial fluctuations to T3 levels*". This is once again quite unsupported by evidence. Doctors using natural desiccated thyroid (NDT) have found that over time T3 levels sometimes rise to a small degree without any significant consequence. The assertion that these so-called minor variations in T3 can cause strokes and osteoporosis is again completely without foundation or supportive evidence.

We are all aware that over dosage with T4 and T3 is undesirable, but Armour is no more likely to cause such problems than is synthetic T4 and T3. Splitting the daily dose would obviate any potential concern about transient elevations of T3 levels.

All thyroxine, whether made by the thyroid itself, or given exogenously, has to be converted to the active T3; and the thyroid produces just the right combination of T4 and T3 (and T2 and T1 and other unspecified hormones) that are available in Armour thyroid. Since T4 and T3 have been released together by the thyroid gland in all mammals (and many other species) throughout evolutionary history, it is absurd for the BTF to suggest that this combination is potentially damaging. Desiccated thyroid has been used for a century in hypothyroid patients with great benefit and no harm, and the suggestion, again by the BTA and BTF that the long-term effects are not known are patently incorrect. This is how nature does it and Armour is almost identical to human thyroid.

WHERE NEXT?

Despite an extensive literature search we can find no scientific evidence to support the fact that synthetic thyroxine is superior to natural desiccated thyroid extract. These studies have quite simply not been done. The logic of supplementing a failing thyroid has to be that it is as close to nature as possible; giving T4 alone is not and accounts for the unsatisfactory results in many patients. There is a growing body of scientific evidence that shows that many patients often do not regain a true sense of well being on pure synthetic thyroxine and prefer Armour because it works and actually makes them feel better. It is also quite untrue for the BTF to suggest that blood testing in patients taking Armour is less than satisfactory; indeed, it presents no difficulties of any kind.

It appears that conventional medicine has not made ANY attempt to evaluate the evidence regarding the empirical use of Armour. Its wholesale dismissal by the BTA and BTF represents, at least in part, a biased attitude. TPA-UK would like to see the instigation of a properly conducted prospective randomised control trial as soon as possible.

Hypothyroidism is one of the few medical conditions where people are joining Internet support groups, and ending up self-prescribing and feeling better. There are valuable lessons to be learned by endocrinologists on these boards.

Since natural desiccated porcine thyroid extract has been available since 1894, long before synthetic T4, and making patients better, it is up to such medical authorities to prove, on the contrary, that synthetic T4 is as good, safe and reliable as Armour.

We are keen to work with medical practitioners to get the best treatment for sufferers of hypothyroidism. Getting the thyroid medication right for the patient improves quality of life, and has helped many sufferers to return to work, relinquish state benefits and contribute towards the nation's wealth.

The current situation, whereby hypothyroid patients are being left to self-diagnose, self-treat, and self-monitor because most practitioners are unwilling to consider alternative medication, owing to their misconceptions about Armour, is unacceptable. We are seeking to work in partnership with our medical practitioners.

I would welcome your comments as to how we might work together to increase general awareness and understanding of the issues.

Yours sincerely



Sheila Turner
Thyroid Patient Advocate

Reference: 1) Rees-Jones RW, Rolla AR, Larsen PR. Hormonal content of thyroid replacement preparations. JAMA 1980;243:549-550.

Annex 1

Armour Ingredients

Active Ingredients:

Armour ThyroidT Tablets, USP contain the labelled amounts of levothyroxine (<http://www.armourthyroid.com/glossary.html#sodium>) and liothyronine (<http://www.armourthyroid.com/glossary.html#liothyronine>), as established by the USP. The ratio of Armour Thyroid T4 to T3 is 4.22:1 (4.22 parts of T4 to one part of T3).

Inactive Ingredients:

1. Thyroid Powder, USP
2. Dextrose, Anhydrous
3. Microcrystalline Cellulose, NF
4. Sodium Starch Glycolate, NF
5. Calcium Stearate, NF
6. Opadry White (titanium dioxide used as a whitening agent)

Armour ThyroidT does not contain gluten or lactose.

You can find confirmation of their ingredients and their quality control procedures on the manufacturers website: <http://www.armourthyroid.com/>

Annex 2

If Armour thyroid were labelled as USP it would be expected to meet the requirements of the USP monograph throughout its shelf life. The current USP monograph for thyroid tablets has an Assay to measure the quantities of liothyronine and levothyroxine, a content uniformity test, a disintegration test and microbial limits. Standards are set by an expert committee with open public comment. Citations to two references that discuss the stability of thyroid tablets and preparations can be seen at http://www.armourinfo.freeuk.com/document_1.html The first paper does not indicate that stability or uniformity were major issues in thyroid preparations. Copies of these papers as well as copies of the USP monograph on Thyroid, Thyroid Tablets can be seen at any medical or pharmacy school library.

The onus is on Idis, as importer and supplier, to prove that Armour is being supplied for the permitted indication, and a spokesperson for Idis has agreed that doctors now only need to write on the prescription “required for the treatment of hypothyroidism”.

TPA-UK has no financial interest in any pharmaceutical company nor do they have any competing interest to declare.