

FACTS ABOUT NATURAL THYROID EXTRACT (ARMOUR THYROID, ERFA 'THYROID', NATURE THROID AND WESTHROID)

There are serious misconceptions amongst the medical profession concerning the true facts about Natural Desiccated Porcine Thyroid Extract (NDT) such as Armour Thyroid, Erfa 'Thyroid', Nature Throid and Westhroid as an alternative to thyroxine (T4) only therapy, where 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, 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 Thyroid Function Tests 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 natural thyroid extract 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. UNTRUE

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

Medical Practitioners believe they cannot prescribe NDT UNTRUE

Armour Thyroid, Nature Throid, Westhroid and Erfa 'Thyroid' are the brand names of natural, desiccated porcine thyroid extract. Branded NDT is authorised by the United States Federal Drug Administration (FDA) as medicine that is standardised to the specification of the United States Pharmacopeia. The Medicines and Healthcare Products Regulatory Agency has not objected to the importation of NDT, 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. Please see letter and Emails from MHRA to TPA regarding this.

2. Thyroid extract 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, the manufacturer of Armour Thyroid, state that the amount of thyroid hormone present in the thyroid gland may vary from animal to animal. 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 (T3) and levothyroxine (T4), • 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, Nature Throid, Westthroid and Erfa 'Thyroid' are made from bovine extracts – UNTRUE

We contacted the Drug Information Pharmacist of the Professional Affairs Department at Forest Pharmaceuticals, who state that Armour Thyroid comes from United States grain-fed domestic pig thyroid. The thyroid extracts do 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 'Thyral' (not to be confused with Thyrolar), that was made from bovine thyroid.

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, swine cholera, swine vesicular disease, and African swine fever. This disease information can also be confirmed through United States Department of Agriculture USDA Animal Plant and Health Inspection Service (APHIS). Armour is a natural preparation of USP grade desiccated thyroid powder derived from porcine thyroid glands.

The above named NDT meets all the requirements set by the USP for thyroid medications and manufacturing specifications are tightly controlled, contrary to the BTA and RCP'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 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 BTA Statement on natural desiccated porcine thyroid extract has incorrect information regarding the reasons why NDT is not currently licensed in the UK. They also give out incorrect information about the reason NDT 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.

In the United States, Armour and several other thyroid medications were 'grandfathered' in when the US 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 Federal Food, Drug, and Cosmetic Act was passed. Pre-1938 products 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 New Drug Application process. The NDT brands

mentioned here retain their **'grandfathered' status since no evidence to the contrary has developed concerning their safe and effective status.**

As NDT 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 BTA 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
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 BTA state that the use of NDT causes "*substantial fluctuations to T3 levels*". This is once again quite unsupported by evidence. Doctors using 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 NDT 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 (as well as T2 and T1 and other unspecified hormones) that are available in NDT. 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 BTA 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 that the long-term effects are not known are incorrect. This is how nature does it and natural thyroid extract 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 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 NDT because it works and actually makes them feel better. It is also quite untrue for the BTA to suggest that blood testing in patients taking NDT is less than satisfactory; indeed, it presents no difficulties of any kind.

It appears that there has not been ANY attempt to empirically evaluate the evidence regarding the use of thyroid extract. Its wholesale dismissal by the BTA and RCP represents, at least in part, a biased attitude. TPA 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 being refused a choice of treatment if the one and only levothyroxine therapy doesn't make them well. Hypothyroidism is also one of the few medical conditions where people are joining Internet support groups to find the information being denied them by their doctor. The current situation, whereby hypothyroid patients are being left consider alternative medication, owing to their misconceptions about NDT is unacceptable.

There are valuable lessons to be learned by endocrinologists and GP's on these support groups.

Since natural desiccated porcine thyroid extract has been available since 1894, long before synthetic T4, and has been 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 seeking to work in partnership with our medical practitioners to get the best treatment for hypothyroid sufferers. Getting the correct thyroid medication 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. I would welcome your suggestions as to how we might work together to increase general awareness and understanding of the issues

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.

Idis and Pharmarama, as importers and suppliers, have to prove that Armour Thyroid, Erfa 'Thyroid', Nature Throid or Westhroid is being supplied for the permitted indication, and a spokesperson for Idis and Pharmarama has agreed that doctors now only need to write on the prescription "required for the treatment of hypothyroidism".

PLEASE SEE THE LETTER and EMAILS RECEIVED FROM MHRA on the TPA website.