

Téatrois® (tiratricol, Triac)

Repositioned as an orphan drug under the name “Emcitate” in 2020

Téatrois is an “old” drug, its marketing authorization in France was granted on 25 June 1974 (AMM N° 317 373.5). Until 2020, it was manufactured by **Cenexi** and marketed by **DB Pharma** (the former owner was **Theranol-Deglaude**). The indications were “**resistance to thyroid hormones**” and “**TSH suppression**” (in particular after thyroid cancer).

Manufacturer : **CENEXI**, 17, rue de Pontoise, 95520 Osny, France - <http://www.cenexi.com/contact>

Marketed (until 2020) by **DB Pharma**, 1bis Rue du Commandant Rivière, 94210 La Varenne Saint Hilaire, France
Contact : François Deutsch, DB Pharma, db-pharma@db-pharma.com, 01 48 83 25 14

Informations about Téatrois, in the French public drug data base, medicaments.gouv.fr :
<https://base-donnees-publique.medicaments.gouv.fr/extrait.php?specid=63030409>

It’s marketing has totally stopped since April 1st, 2020.

Until then, in France (only country where Téatrois was on the market), it was taken by very few patients (mostly hypothyroid patients, in combination with levothyroxine), **approx. 300 to 400 boxes per month** (plus some orders sent to French pharmacies by patients from other countries), and not reimbursed by French social security – the price, in the last few years, had gone up from approx. 35€ to approx. 65€ for 100 pills.

In 2014, Dutch researchers started a **clinical trial (NCT02060474, “Triac Trial I”**, on patients with **MCT8 deficiency** (Allan-Herndon-Dudley syndrome, AHDS), a rare disease which affects less than 500 patients in Europe: <https://clinicaltrials.gov/ct2/show/NCT02060474>

The results showed that Téatrois was very efficient in the affected patients, improving key clinical and biochemical features, without serious adverse events. A new trial (**Triac Trial II**), on affected young boys (< 30 months) started in the end of 2020: <https://clinicaltrials.gov/ct2/show/NCT02396459>

The rights for Téatrois were bought by **RTTI, Rare Thyroid Therapeutics**, in 2017. They gave it a new name, “**Emcitate**”, and obtained an “orphan drug” designation by the EMA in October 2018, and by the FDA in January 2019:

<https://www.ema.europa.eu/en/medicines/human/orphan-designations/eu3171945>
<https://www.accessdata.fda.gov/scripts/opdlisting/opd/detailedIndex.cfm?cfgridkey=666618>

According to RTTI (and the society representing them in France, **Bluedil**), they choose this “repositioning” because “*Téatrois was authorized only in France, the active ingredient was difficult to find, the former owner was not willing to do any investments or to do new studies (requested for a European marketing authorization) for a drug with such a small market. “If we hadn’t bought the drug and made the necessary modernizations in the production line, it would have been disappeared.”*

Rare Thyroid Therapeutics International AB (RTTI), 3 Teatergatan, SE-111 48, Stockholm, Sweden,
info@rarethyroid.com

Directeur : Peder Walberg, peder.walberg@rarethyroid.com (RTTI was recently acquired by PledPharma)

Representative in France: Mr Sylvain Forget, **Bluedil**, 06 70 98 43 23, sylvain@bluedil.fr

Since **October 12, 2020**, Emcitate has a “**nominal temporary authorization**” (“ATU nominative”) granted by the French medicines agency ANSM: <https://ansm.sante.fr/tableau-atun/emcitate-350-microgramme-comprime>

It can be prescribed only by endocrinologists, oncologists and pediatrics based in a hospital (not in private praxis). It is delivered only by hospital pharmacies, the price is **880€ per 60 pills** (with a nominative ATU prescription, the cost is paid by the hospital).

The indications, in the French marketing authorization, are MCT8 deficiency – but also (following the discussions between the French patient organization VST and RTTI/Bluedil and the ANSM) the former indications for Tétratis, “thyroid hormone resistance” and “TSH suppression/thyroid cancer”.

According to RTTI, they “*have requested a European marketing authorization*” (but this request still hasn’t been officially submitted?) – and, in the meantime, are “*very willing to help patients in need, all over Europe, to access the drug, if they cannot get it paid by their national health insurance system.*”

Regarding the increase in price, they say that this was necessary because of the “*modernization of the production line*” at the manufacturer Cenexi, but also to “*finance the clinical trials*” (even if the first line, Triac Trial I, was financed by the Dutch public health system... and the 2nd trial only started at the end of 2020...)

According to one of the French specialists who has worked a lot with Tiratricol over many years, **Professor Claude Jaffiol**, Montpellier, honorary president of the French academy of medicine: c.jaffiol@orange.fr, Triac has several advantages, and should be used more widely :

- 1 Triac is very efficient in suppressing TSH, much better than levothyroxine, with a better cardiac tolerance
- 2 Triac can be used for a wide range of thyroid pathologies, certain life-threatening, e.g. thyroid cancer.
- 3 Triac is very well tolerated, and improves the quality of life of the concerned patients
- 4 There is no misuse of Triac "to lose weight" (which has been the case in other countries, e.g. among bodybuilders), because it has been forbidden for this indication, and its prescription is strictly limited.

But with the tremendous increase price, the difficulties to find the product and its total marketing stop in spring 2020, and the new very strict prescription conditions, it is totally impossible for a hypothyroid patient to obtain Emcitate - all concerned hypothyroid patients had to switch to other treatments (levothyroxine alone or levothyroxine + liothyronine), even if this caused a lot of adverse effects and widely affected their quality of life.

It is difficult to find out how many patients are concerned by this repositioning and marketing stop – our patient organization tried to make an inquiry via our website, with an online survey, but for the moment there are only approx. 40 respondents. Many of them have been taking Tétratis for many years (15, 20, sometimes 30 years), and are very shocked and disappointed by the present situation.

Patient questionnaire: <https://fr.surveymonkey.com/r/VST-Teatrois>

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