

**SOUTH AFRICAN ADULT HOSPITAL LEVEL ESSENTIAL MEDICINES LIST
CHAPTER 5: GYNAECOLOGY**

ESTIMATED CONSUMPTION OF TRANEXAMIC ACID, ORAL 500 MG TABLETS IN PUBLIC SECTOR

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Background:

Cost effectiveness analysis for LNG-IUS model was presented at the Adult Hospital Level meeting on 16 August 2018. The model suggests that LNG-IUS may be cost effective, if used for prolonged period of time for menorrhagia. The capital outlay estimated to be approximately R 800 million, may not be feasible.

However, concerns were raised regarding the acceptability by both health care workers and women, that impacts the uptake of this intervention. Currently, there is no local epidemiological data available to answer this question.

Recommendations:

Thus, it was recommended that:

1. RSA Pharmadatabase supplier data be sourced for tranexamic acid, oral consumption figures to try and determine an estimated number of women who may possibly require LNG-IUS intervention.
2. Possibility of a feasibility survey be investigated.

RSA Pharmadata supplier consumption data:

For the period: 01/08/2016 to date (i.e. approximately 24 months), it was estimated that 67,651 units of 100's were supplied to public sector depots. This equates to 6765100 x 500 mg tablets over a period of 24 months – 3382550 x 500 mg tablets over 12 months.

Current STGs and EML recommendations:

Adult Hospital Level STGS and EML, 2015

- 5.2 Uterine bleeding, abnormal: Tranexamic acid, oral, 1g 6 hourly on days 1–4 of the cycle (32 tabs).
- 2.10.1 Haemophilia A and B - Mucous membrane bleeds in haemophilia A and B: Tranexamic acid, oral, 1 g, 6 hourly (5 to 7 days) (56 tabs)
- 2.10.1 Von Willebrand's disease - Mild bleeding: Tranexamic acid, oral, 1 g 6 hourly (5 to 7 days) (56 tabs).

Assumptions and projected number of patients modelled to require LNG-IUS (over 12 months):

We cannot delineate the use of TXA for the above-mentioned indications, so assumptions were made, approximating the percentage of TXA use that would be specifically for 'abnormal uterine bleeding' in three scenarios:

Percentage of TXA used for 'abnormal uterine bleeding'	TXA 500 mg tablets (supply over 12 months)	TXA courses/ number of women
100%	3382550	105700
80%	2706040	84560
60%	2029530	63420

An important limitation of the above is that it is presumed that a woman would only require one course of TXA. Though, this may not be relevant in a real-world clinical setting.

Subsequent literature search:

To answer the prevalence question, a further literature search was done and epidemiology study was retrieved and reviewed - Harlow et al ¹reported that 11-16% reported of patients in developing countries reported abnormal uterine bleeding to their physician (assuming seeking treatment) (Harlow et al, 2004). The LNG-IUS costing model² used prevalence rates similar to these to determine the cost-effectiveness of LNG-IUS compared to current standard of care recommendations in the Adult Hospital Level STGs and EML, 2015 (that includes TXA, oral).

Price of TXA, oral 500 mg:

With the review of the cost analysis of LNG-IUS for AUB, concern was raised regarding the high contract price of TXA, oral. An investigation ensued, and it was determined that since the start of the last tender³ (awarded in 2016), there have been 2 generics released on the SA market, which happens to be cheaper than the current contract price - originator product, Cyklokapron® awarded at 70% lower than SEP (R281.32)⁴.

TXA 500 mg tablets currently listed on the SEP database includes:

- Morwak 500mg (100's) - R197.06
- Tranic 500mg (100's) - R266.44
- TXA Medwich 500mg (100's) - R623.81
- Cyklokapron T 500mg (100's) - R1003.74

It is noted that the oral formulation was not listed on the current WHO EML model list, amended August 2017, or in the International Medical Products Price Guide (<http://mshpriceguide.org/en/home/>).

Other international prices are listed below:

Country	Medicine	Price (country of origin)	Currency conversion rate ⁵	Price for 100 tabs (ZAR)
Turkey (ex manufacturer) ⁶	Transamine 500 mg 50 film tablet	39.67 TL	2.888	R 114.25
Australia (Pharmaceutical benefits scheme) ⁷	Tranexamic acid 500 mg 100 tablets (base dispensed price)	AUS\$ 43.85	9.715	R 426.00
Canada (Ontario Drug Benefit (ODB) Program) ⁸	Tranexamic acid 500 mg, unit benefit price	CAN\$ 0.8071	9.944	R 802.58

This analysis has shown that market intelligence is important, not only prior to awarding of pharmaceutical tenders, but this should be reviewed continuously during the lifetime of a tender cycle.

¹ Harlow S and Campbell O. Epidemiology of menstrual disorders in developing countries, a systematic review. British Journal of Obstetrics and Gynaecology. 2004. 111;6-16

² Levonorgestrel Intra-uterine System (LNG-IUS) Health Economics and Budget Impact Analysis, 1 September 2018

³ HP09-2016SD

⁴ SEP database, 28 August 2018

⁵ OANDA Average exchange rate (Jan 2018 to Sep 2018). <https://www.oanda.com/currency/average>

⁶ <http://www.ilacabak.com/>

⁷ www.pbs.gov.au

⁸ http://www.health.gov.on.ca/english/providers/program/drugs/odbf_mn.html