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## CASE AND RESEARCH LETTER

### Low-Dose Oral Minoxidil Severe Adverse Effects as a Consequence of Compounding Errors



#### Efectos adversos graves por minoxidil oral como consecuencia de errores de formulación magistral

To the Editor:

Low doses of oral minoxidil (LDM) (0.5–2 mg daily in women and 2.5–5 mg daily in men) is an emergent off-label therapeutic approach for hair disorders such as androgenetic alopecia.<sup>1</sup> Unfortunately, the availability of this drug greatly varies between countries and while doses between 1.25 and 5 mg can be obtained easily by halving or quartering the marketed drug (Loniten®, Pfizer), lower doses usually require to be compounded in the pharmacy per medical prescription. Published data shows that LDM has an excellent safety and effectiveness profile as its more common adverse effect is hypertrichosis.<sup>1</sup> Rare adverse effects such as fluid retention or periorbital oedema usually appear with higher doses or in warm climates, and mainly in women. Due to its ever-increasing use worldwide, reports of severe adverse effects have been recently published, but usually fail to specify the drug origin (i.e., compounded vs. commercially available).<sup>2,3</sup>

We recently published an article in which we collected all the cases of severe adverse effects that we observed in patients receiving LDM, including hypotensive syncope, generalized oedema, myocardial infarction and ischaemic stroke.<sup>4</sup> All of these adverse effects were related to the vasodilator capacity of the drug at doses much higher than LDM. In all cases of severe adverse effects, the medication was compounded, and a very significant error was detected in the composition of the drug sold to the patient (for example, up to 100 times the prescribed dose).

For this reason, in patients who develop a significant adverse effect, it is highly recommended to ask them for a sample of their pills in order to verify the dose at the

laboratory and check if it matches with the one prescribed by the doctor. So far, we have not detected any significant severe adverse effect with marketed oral minoxidil (Loniten®, Pfizer) at the doses used for hair disorders.

To further consolidate correct evidence of the use of LDM in trichology we recommend that the publication of cases of adverse effects include the origin of the drug (compounded or marketed). We encourage a critical reading of publications that do not include this information.

We believe that pharmacists should know the doses of oral minoxidil used for hair loss and should take care in order to correctly compound the drug. In addition, dermatologists should be aware that compound dose mistakes are not uncommon and may explain severe adverse effects of minoxidil. Finally, clinical trials should be performed to correctly establish the characteristics of this drug in hair disorders treatments, its medical indication and hopefully, an easily available commercialized oral or sublingual drug tailored to its new dermatologic use.<sup>5</sup>

#### Conflict of interests

The authors declare that they have no conflict of interest.

#### References

- Vañó-Galván S, Pirmez R, Hermosa-Gelbard A, Moreno-Arrones OM, Saceda-Corralo D, Rodrigues-Barata R, et al. Safety of low-dose oral minoxidil for hair loss: A multicenter study of 1404 patients. *J Am Acad Dermatol.* 2021;84:1644–51, <http://dx.doi.org/10.1016/j.jaad.2021.02.054>.
- Trüeb RM, Caballero-Urbe N, Luu NNC, Dmitriev A. Serious complication of low-dose oral minoxidil for hair loss. *JAAD Case Rep.* 2022;30:97–8, <http://dx.doi.org/10.1016/j.jdc.2022.09.035>.
- Dlova NC, Jacobs T, Singh S. Pericardial, pleural effusion and anasarca: a rare complication of low-dose oral minoxidil for hair loss. *JAAD Case Rep.* 2022;28:94–6.
- Moreno-Arrones OM, Rodrigues-Barata R, Morales C, et al. Serious adverse effects from compounding errors with low-dose oral minoxidil for alopecia treatment. *Actas Dermosifiliogr.* 2022;113:725–7, <http://dx.doi.org/10.1016/j.ad.2021.03.003>.

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5. Bokhari L, Jones LN, Sinclair RD. Sublingual minoxidil for the treatment of male and female pattern hair loss: a randomized, double-blind, placebo-controlled, phase 1B clinical trial. *J Eur Acad Dermatol Venereol*. 2022;36:e62–6, <http://dx.doi.org/10.1111/jdv.17623>.

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