Dear Healthcare Professional,

Recently there have been some comments made on and shared through social media about Toxaprevent, a product that we distribute in Australia and New Zealand. We understand that these comments have generated some concern; accordingly, we would like to clear up some of the confusion. The statements made on social media misrepresent how Toxaprevent works – it does not get absorbed into the body. To clarify:

1. **Toxaprevent is not a supplement or a food; it does not get absorbed into the body and it is registered on the ARTG as a Medical Device (not as a Listed Medicine or Food).**
   - A Medical Device is very different from a supplement in that a supplement breaks down for release in the body; a Medical Device is exactly the opposite – it is designed NOT to break down OR be absorbed into systemic circulation; Medical Devices pass out of the body WHOLY INTACT via the stool.
   - As a Medical Device, therefore, Toxaprevent enters the GIT through the mouth and exits intact via the stool, carrying with it toxins which have been attracted to the mineral charge of the clinoptilolite.
   - It has been proven that Toxaprevent is NOT absorbed across the GI barrier. Studies have shown that NONE of the Toxaprevent is absorbed and that it travels INTACT all the way through the digestive tract without any absorption.

2. **The safety of Toxaprevent has been proven, allowing it to be sold across the world and extensively within the EU.**
   - EU regulations regarding Medical Devices are particularly stringent and require that all Medical Devices that come into direct contact with the human body must fulfill their intended function and be free from undesirable side effects for the user.
   - Medical Devices approved for sale in the EU must therefore be subjected to extensive biological assessments to evaluate their interactions with tissues, cells and body fluids. The main motivation for assessing the biocompatibility of a Medical Device is to protect the user from possible biological risks.
   - The German manufacturers of Toxaprevent have done all of the required assessments and confirm that Toxaprevent adheres to the very stringent EU safety requirements for Medical Devices, including:
     - DIN EN ISO 10993-1: 2010-04 - Biological evaluation of medical devices, Part 1: Assessment and testing as part of a risk management process.
     - DIN EN ISO 10993-11: 2009-08 - Biological assessment of medical devices: Tests for systemic toxicity (acute).
   - The biological assessments of the clinoptilolite raw materials used and of the end product itself are carried out in accordance with the EU risk management standard “DIN EN ISO 14971: 2013-04 - Application of risk management to medical devices”.
   - These safety reviews demonstrate that Toxaprevent products are high-quality products that comply with the stipulated standard and regulations for Medical Devices in accordance with EU Directive 93/42/EEC.

3. **Toxaprevent has been proven to improve heavy metal clearance, and not to add to the body’s heavy metal burden.**
   - There are many clinical trials, as well as animal studies, that have demonstrated the benefits of clinoptilolite for support of heavy metal clearance. Some of these studies are included in Appendix A attached.
   - In one study, for example, clinoptilolite removed lead from the blood and brain at a level comparable to the chelating agent EDTA (a synthetic chelator). It did NOT add to the lead burden in the blood or the brain, but rather significantly removed lead from the body.
   - If you would like of any these studies sent to you, please contact our Technical Support team at support@biopractica.com.au

Please rest assured that we will be investigating these claims further and will continue to work to ensure the quality of our formulations. It is really important that, as a healthcare practitioner, you feel confident in the quality and efficacy of the Medical Devices and Listed Medicines you recommend. We hope, therefore, that this information helps clear up some of the confusion or concerns the recent social media commentary has generated. If you would like any further information on Toxaprevent, please contact our Technical Support team at support@biopractica.com.au.

Kind regards,
Peter Ochsenham
Managing Director – Bio-Practica

APPENDIX A: SUPPORTIVE EVIDENCE FOR HEAVY METAL BINDING, SAFETY AND THERAPEUTIC APPLICATION OF CLINOPTILOLITE

Selected published human clinical trials/reviews supporting safety and efficacy of clinoptilolite.

- Cutovic, M., Lazovic, M., Vukovic-Dejanovic, V., Nikolic, D., Petronic-Markovic, I., & Cirovic, D. (2017). Clinoptilolite for treatment of dyslipidemia: preliminary efficacy study. The Journal of Alternative and Complementary Medicine, 23(9), 738-744. Doi:10.1089/acm.2016.0414
- Flowers, J. L., Lonky, S. A., & Deitsch, E. J. (2009). Clinical evidence supporting the use of an activated clinoptilolite suspension as an agent to increase urinary excretion of toxic heavy metals. Nutrition and Dietary Supplements, 1, 11-18.
- Ivkovic, S., Deutsch, U., Silberbach, A., Walraph, E., & Mannel, M. (2004). Dietary supplementation with the tribomechanically activated zeolite clinoptilolite in immunodeficiency: Effects on the immune system. Advances in Therapy, 21(2), 135–147. Doi:10.1007/bf02850340
- Kraljević Pavelić, S., Micek, V., Bobinac, D., Bazdulj, E., Gianoncelli, A., Krpan, D., … Pavelić, K. (2020). Treatment of osteoporosis with a modified zeolite shows beneficial effects in an osteoporotic rat model and a human clinical trial. Experimental Biology and Medicine, 153537022096875. Doi:10.1177/1535370220968752
- Kraljević Pavelić, S., Simović Medica, J., Gumbarević, D., Filošević, A., Pržulj, N., & Pavelić, K. (2018). Critical Review on Zeolite Clinoptilolite Safety and Medical Applications in vivo. Frontiers in Pharmacology, 9. Doi:10.3389/fphar.2018.01350
- Lamprecht, M., Bogner, S., Steinbauer, K., Schuetz, B., Greilberger, J. F., Leber, B., et al. (2015). Effects of zeolite supplementation on parameters of intestinal barrier integrity, inflammation, redoxbiology and performance in aerobically trained subjects. Journal of the International Society of Sports Nutrition, 12(1). Doi:10.1186/s12970-015-0101-z
- Mastinu, A., Kumar, A., Maccarinelli, G., Bonini, S. A., Premoli, M., Aria, F., ... & Memo, M. (2019). Zeolite clinoptilolite: Therapeutic virtues of an ancient mineral. Molecules, 24(8), 1517. Doi:10.3390/molecules24081517

Generic in-vitro, water and animal studies on clinoptiloite for heavy metals (excluded are studies on amines, ammonia, mycotoxins, LPS, microbiota, mould, pesticides and other chemicals).

- Awuah, J. B., Dzade, N. Y., Tia, R., Adei, E., Kwakye-Awuah, B., Catlow, C. R. A., & de Leeuw, N. H. (2016). A density functional theory study of arsenic immobilization by the Al (III)-modified zeolite clinoptilolite. Physical Chemistry Chemical Physics, 18(16), 11297-11305.
- Basha, M. P., Begum, S., & Mir, B. A. (2013). Neuroprotective actions of clinoptilolite and ethylenediaminetetraacetic acid against lead-induced toxicity in mice Mus musculus. Toxicology international, 20(3), 201.DOI:10.4103/0971-6580.121666
- Burmanczuk, A., Rolinski, Z., Kowalski, C., Burmanczuk, N., & Markiewicz, W. (2015). Possible use of natural zeolites in animal production and environment protection. Journal of Elementology, 20(4).
- Elizalde-González, M. P., Mattusch, J., Wennrich, R., & Morgenstern, P. (2001). Uptake of arsenite and arsenate by clinoptilolite-rich tuffs. Microporous and Mesoporous Materials, 46(2-3), 277-286. doi.org/10.1016/S1387-1811(01)00308-0
- Erdem, E., Karapinar, N., & Donat, R. (2004). The removal of heavy metal cations by natural zeolites. Journal of colloid and interface science, 280(2), 309-314. doi.org/10.1016/j.jcis.2004.08.028
- Jovanovic, M., Rajic, N., & Obradovic, B. (2012). Novel kinetic model of the removal of divalent heavy metal ions from aqueous solutions by natural clinoptilolite. Journal of Hazardous Materials, 233-234, 57-64.
- Kristo, A. S., Tzanidaki, G., Lygeros, A., & Sikalidis, A. K. (2015). Bile sequestration potential of an edible mineral (clinoptilolite) under simulated digestion of a high-fat meal: an in vitro investigation. Food & Function, 6(12), 3818–3827. doi:10.1039/c5fo00116a
- Kyriakis, S. C., Papaioannou, D. S., Alexopoulos, C., Polizopoulou, Z., Tzika, E. D., & Kyriakis, C. S. (2002). Experimental studies on safety and efficacy of the dietary use of a clinoptilolite-rich tuff in sows: a review of recent research in Greece. Microporous and Mesoporous Materials, 51(1), 65-74. doi.org/10.1016/S1387-1811(01)00475-9
- Laurino, C., & Palmieri, B. (2015). Zeolite:“the magic stone”; main nutritional, environmental, experimental and clinical fields of application. Nutricion hospitalaria, 32(2), 573-581. DOI:10.3305/nh.2015.32.2.8914
- Malliou, E., Loizidou, M., & Spyrellis, N. (1994). Uptake of lead and cadmium by clinoptilolite. Science of The Total Environment, 149(3), 139–144. doi:10.1016/0048-9697(94)90174-0
- Smical, I. (2011). Properties of natural zeolites in benefit of nutrition and health. Human and Veterinary Medicine, 3(2), 51-57.
- Sprynskyy, M., Buszewski, B., Terzyk, A. P., & Namieśnik, J. (2006). Study of the selection mechanism of heavy metal (Pb2+, Cu2+, Ni2+, and Cd2+) adsorption on clinoptilolite. Journal of colloid and interface science, 304(1), 21-28. 10.1016/j.jcis.2006.07.068
- Vaca Mier, M., López Callejas, R., Gehr, R., Jiménez Cisneros, B. E., & Alvarez, P. J. . (2001). Heavy metal removal with mexican clinoptilolite: Water Research, 35(2), 373–378. doi:10.1016/s0043-1354(00)00270-0