

## Evidenze scientifiche sui principi attivi - Linea Ferachel

- Akzo Nobel Functional Chemicals October 5, 2007. APPLICATION FOR THE APPROVAL OF FERRAZONE® FERRIC SODIUM EDTA AS A SOURCE OF IRON FOR USE IN THE MANUFACTURE OF PARNUTS PRODUCTS, FOOD SUPPLEMENTS AND FORTIFIED FOODS
- World Health Organization. (2006). Guidelines on food fortification with micronutrients / edited by Lindsay Allen et al.
- EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS); Scientific Opinion on the use of ferric sodium EDTA as a source of iron added for nutritional purposes to foods for the general population (including food supplements) and to foods for particular nutritional uses. EFSA Journal 2010;8(1):1414. [32 pp.]. doi: 10.2903/j.efsa.2010.1414.
- Evaluations of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) 2007.
- Giliberti A. et al., Comparison of Ferric Sodium EDTA in Combination with Vitamin C, Folic Acid, Copper Gluconate, Zinc Gluconate, and Selenomethionine as Therapeutic Option for Chronic Kidney Disease Patients with Improvement in Inflammatory Status, *Nutrients*, 2022, 14, 2116.
- Di Lullo L. et al., The best therapeutic option for oral treatment of secondary anaemia in chronic kidney disease: role of Ferric Sodium EDTA, in association with Vitamin C, Folic acid, Copper gluconate, Zinc Gluconate and Selenomethionine, *Nephrol Renal Dis*, 2021, Vol. 6: 1-6.
- Gatti G. et al. Short study on the use of oral Ferric Sodium EDTA in association with vitamin C, folic acid, copper gluconate, zinc gluconate and selenomethionine, in patients with advanced Chronic Kidney Disease, *Nephrol Renal Dis*, 2021, Vol. 6: 1-3.
- Marchitto N. et al. A pilot study on secondary anaemia in “frailty” patients treated with the Ferric Sodium EDTA in combination with vitamin C, folic acid, copper gluconate, zinc gluconate and selenomethionine: safety of treatment explored by HRV non-linear analysis as predictive factor of cardiovascular tolerability. *Eur Rev Med Pharmacol Sci*, 2020, 24: 7776-7783.
- Marchitto N. et al. Role of Ferric Sodium EDTA associated with vitamin C, folic acid, copper gluconate, zinc gluconate and selenomethionine administration in patients with secondary anaemia. Effects on hemoglobin value and cardiovascular risk. *Health Sci J*. 2019, 13 (5), 682.
- Marchitto N. et al. Effect of Ferric Sodium EDTA administration, in combination with vitamin C, folic acid, copper gluconate, zinc gluconate and selenomethionine, on cardiovascular risk evaluation: exploration of the HRV frequency domain. *Clinical Practice*, 2019, 16(5), 1245-1251.
- Curcio A. et al. Efficacy and Safety of a New Formulation of Ferric Sodium EDTA Associated with Vitamin C, Folic Acid, Copper Gluconate, Zinc Gluconate and Selenomethionine Administration in Patients with Secondary Anaemia. *J Blood Lymph*. 2018, 8:3, 224.
- Alessandra Graziottin. Ferro (NaFe<sub>3</sub>+EDTA), Lattoferrina, Vitamina C e Vitamina B12: sinergie farmacologiche: Per ottimizzare prevenzione e cura dell’anemia prima, durante e dopo la gravidanza.
- Ai Guo Ma et al. Supplementation of iron alone and combined with vitamins improves haematological status, erythrocyte membrane fluidity and oxidative stress in anaemic pregnant women. *British Journal of Nutrition* (2010), 104, 1655-1661.
- Hallberg L. et al. The role of vitamin C in iron absorption. *Int J Vitam Nutr Res Suppl*. 1989;30:103-8.

- Reeves P.G. et al. Dietary Copper Deficiency Reduces Iron Absorption and Duodenal-Enterocyte Hephastin Protein in Male and Female Rats. *J Nutr.* 2005, 135(1):92-8.
- National Institutes of Health, Office of Dietary Supplements, (2006), "Dietary Supplement Fact Sheet: Selenium"
- Phuong Nguyen, Ruben Grajeda, Paul Melgar, Jessica Marcinkevage, Rafael Flores, Usha Ramakrishnan, and Reynaldo Martorell. Effect of Zinc on Efficacy of Iron Supplementation in Improving Iron and Zinc Status in Women. *Journal of Nutrition and Metabolism*, Volume 2012.
- Munro I.C., SODIUM IRON EDTA, CanTox Inc., Mississauga, Ontario Canada. 796. Sodium iron EDTA (WHO Food Additives Series 32)
- Appel, M.J.; Kuper, C.F.; Woutersen, R.A. 2001. Disposition, accumulation and toxicity of iron fed as iron (11) sulfate or as sodium iron EDTA in rats. *Food Chem Toxicol* 39(3):261-269.
- Scholl, TO., 2005, Iron status during pregnancy: setting the stage for mother and infant, *Am J Clin Nutr*, vol. 81(5 suppl), pp. 1218S-1222S.
- Wang, B., Siyan, Z., Yinyin, X., and Liming, L., 2008, Effect of sodium iron ethylenediaminetetraacetate (NaFe<sub>3</sub>+EDTA) on haemoglobin and serum ferritin in iron-deficient populations: a systematic review and meta-analysis of randomised and quasi-randomised controlled trials, *Br J Nutr*, vol. 100, pp. 1169-1178.
- Anupam Aditi et al. Vitamin C, Gastritis, and Gastric Disease: A Historical Review and update. *Dig Dis Sci.* 2012, 57:2504-2515.
- Rodrigo R. et al. Cardioprotection against ischaemia/reperfusion by vitamins C and E plus n-3 fatty acids: molecular mechanisms and potential clinical applications. *Clin Sci (Lond).* 2013, 124(1):1-151968.
- Ryszard Rutkowski et al. Vitamin C: is it time to re-evaluate its role in health and disease? *Postep. Derm. Alergol.* 2012; XXIX, 6: 456-460.
- Select Committee on GRAS Substances (SCOGS) Opinion: L-ascorbic acid
- Padayatty S.J. et al. Vitamin C pharmacokinetics: implications for oral and intravenous use. *Annals of Internal Medicine* 2004; 140:533-7.
- Rumbold A, Ota E, Nagata C, Shahrook S, Crowther CA-Vitamin C supplementation in pregnancy.
- Scheers N. Regulatory Effects of Cu, Zn, and Ca on Fe Absorption: The Intricate Play between Nutrient Transporters. *Nutrients* 2013, 5(3), 957-970.
- López de Romaña D. et al. Risks and benefits of copper in light of new insights of copper homeostasis. *Journal of Trace Elements in Medicine and Biology*, 25 (2011) pp. 3-13.
- Select Committee on GRAS Substances (SCOGS) Opinion: Copper (cupric) sulfate.
- Hazra, A. Tripathi, S.K. Folic Acid Revisited. *Indian Journal of Pharmacology*, 2001,(5), pp.322-342
- Letter Regarding Dietary Supplement Health Claim for Folic Acid With Respect to Neural Tube Defects (Docket No. 91N-100H).
- Lumley J. et al., (2001). Periconceptional Supplementation with Folate and/or Multivitamins for Preventing Neural Tube Defects. *Cochrane Database Syst.Rev* 2011.

- Weekly Iron-Folic Acid Supplementation (Wifs) in Women of Reproductive Age: its Role in Promoting Optimal Maternal and Child Health. World Health Organization 2009, Who/Nmh/Nhd/Mnm/09.2.
- Richard D. Semba, Luigi Ferrucci, Anne R. Cappola<sup>4</sup>, Michelle O. Ricks, Amanda L. Ray, Qian-Li Xue, Jack M. Guralnik, and Linda P. Fried. Low Serum Selenium Is Associated with Anemia Among Older Women Living in the Community: The Women's Health and Aging Studies I and II.
- EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA).
- Select Committee on GRAS Substances (SCOGS) Opinion: Magnesium gluconate; Potassium gluconate; Sodium gluconate; Zinc gluconate.
- Chaffee BW, King JC. Effect of zinc supplementation on pregnancy and infant outcomes: a systematic review. Paediatric and Perinatal Epidemiology. 2012, 26 (Suppl. 1):118-137.
- WHO: e-Library of Evidence for Nutrition Actions (eLENA).
- Andrews NC. Forging a field: the golden age of iron biology. Blood 2008; 112(2): 219–230.
- Crichton R. Inorganic Biochemistry of Iron Metabolism – From Molecular Mechanisms to Clinical Consequences. 2nd edition. England: John Wiley & Sons, Ltd.; 2001.
- Dunn LL et al. Iron uptake and metabolism in the new millennium. Trends Cell Biol 2007;17(2): 93-100.
- Crichton R et al. Iron Therapy With Special Emphasis on Intravenous Administration. 4th edition. London, Boston: International Medical Publishers; 2008.
- Ovidio Brignoli Società Italiana di Medicina Generale. Anemia e terapia marziale I dati di Health Search - Società Italiana di Medicina Generale.
- “La carenza di ferro”, di Nevin S. Scrimshaw, pubbl. su “Le Scienze (Scientific American)”, num.280, dic.1991, pag.16-22.
- Triolo G. et al. Linee Guida per il trattamento dell’anemia nell’insufficienza renale cronica. Giornale Italiano di Nefrologia, 2003, 20, S-24, pp. S61-S82.
- Rockey DC. Occult and obscure gastrointestinal bleeding: causes and clinical management. Nat Rev Gastroenterol Hepatol 2010;7:265-79.
- Hershko C, Skikne B. Pathogenesis and management of iron deficiency anemia: emerging role of celiac disease, Helicobacter pylori, and autoimmune gastritis. Semin Hematol 2009;46:339-50.
- Clark SF. Iron deficiency anemia: diagnosis and management. Curr Opin Gastroenterol 2009;25.
- Pasricha SR, Flecknoe-Brown SC, Allen KJ, et al. Diagnosis and management of iron deficiency anaemia: a clinical update. Med J Aust 2010;193:525-32.
- Paesano R. et al. Ipoferremia e anemia da carenza di ferro in gravidanza. Il Ginecologo, 2008, 3 (Suppl 1), pp. 1-6.
- Van Thuy P, Berger J, Nakanishi Y, Khan NC, Lynch S, Dixon P. The use of NaFeEDTAfortified fish sauce is an effective tool for controlling iron deficiency in women of childbearing age in rural Vietnam.
- Xiu X Han MD, Yong Y Sun, Ai G Ma, Fang Yang, Feng Z Zhang, Dian C Jiang, Yong Li. Moderate NaFeEDTA and ferrous sulfate supplementation can improve both hematologic status and oxidative stress in anemic pregnant women.

- Saaka M. Combined Iron and Zinc Supplementation Improves Haematologic Status of Pregnant Women in Upper West Region of Ghana. Ghana Med J. 2012 Dec; 46(4): 225-233.
- Shubhada J. Kanani, Rashmi H. Poojara. Supplementation with Iron and Folic Acid Enhances Growth in Adolescent Indian Girls. J Nutr. 2000 Feb.
- Bier-Ulrich A.M. et al. The impact of intensive serial plasmapheresis on iron metabolism and Hb concentration in menstruating women: a prospective randomized placebo-controlled double-blind study. Transfusion 2003; 43:405-401.
- Kapur G. et al. Iron supplementation in children with celiac disease. Indian J Pediatr. 2003 Dec; 70(12):955-8.
- Yang Y. et al. Efficacy and safety of iron supplementation for the elderly patients undergoing hip or knee surgery: a meta-analysis of randomized controlled trials. The Journal of Surgical Research 2011, 171(2):e201-7.