MOMAID

Patented postpartum dietary supplement to support healthy recovery after delivery

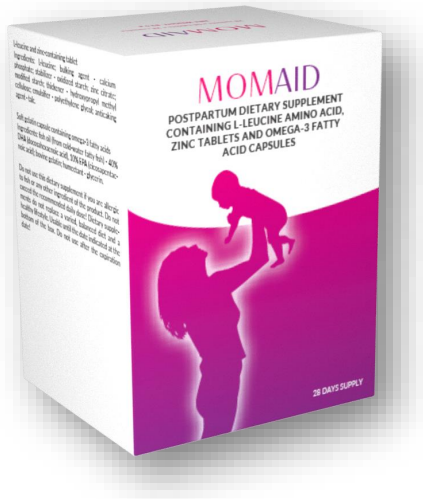
At a Glance

Unmet need
Pregnancy and birth places increased stress on the pelvic floor leaving the muscles fatigued and weak causing incontinence and sexual disfunctions. Pelvic floor dysfunctions affect about a quarter of the population in the developed world.

Market
3.7 million births in the USA. There is a thriving market for maternity vitamins both prenatal and postnatal. Currently no preventative measure, nor treatment is known to significantly decrease the rate of pelvic floor muscle injury during labor.

Target
The term 'fourth trimester' is getting more and more attention in the USA. The American College of Obstetricians and Gynecologists (ACOG) suggest that it is just as important for a mother's health as the first three trimesters. Women who get their child in a later age tend to focus more on their own body's recovery. Product is directed at women after giving birth either through vaginal delivery or C-section.

Solution
Our solution - MOMAID - contains a unique combination of Zinc, Leucine and Omega-3 fatty acids and directed at women after giving birth either through vaginal delivery or C-section to aid the restoration of muscular injuries.



Safety and efficacy
Used by thousands of women since 2018 with no complaints.

The chance of weak pelvic floor muscle strength decreased by 52% .

IP protection
US Patent entitled "Pharmaceutical Composition for Postpartum Recovery and Treatment of Pelvic Floor Dysfunction" (Publication Number: US-2021-0346427-A1; Publication Date: 11.11.2021).

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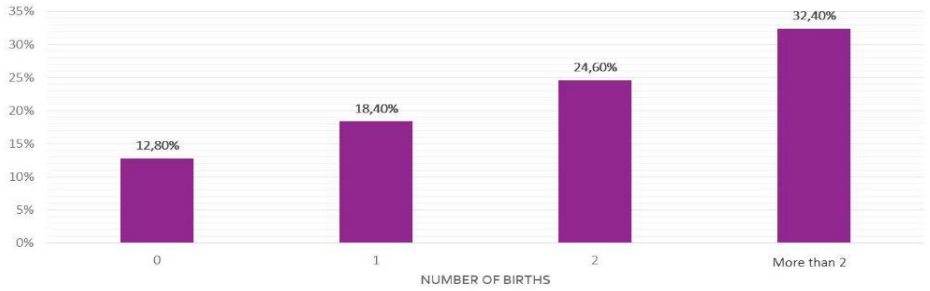
Unmet need

- Pelvic floor dysfunctions affect about a quarter of the population in the developed world. It is caused by weakened or damaged pelvic floor muscles.

- Pregnancy and birth are the main cause of muscle and tissue damages.

Probability of developing pelvic floor disorders after pregnancy / birth



Nygaard et al. Prevalence of symptomatic pelvic floor disorders in US women. JAMA. 2008 Sep 17;300(11):1311-6

The likelihood of developing muscle injuries in relation to maternal age*

*Dietz HP1, Simpson JM. Does delayed child-bearing increase the risk of levator injury in labour? Aust N Z J Obstet Gynaecol. 2007 Dec;47(6):491-5.

- No pharmaceutical treatment is currently known to help to repair the damaged muscles.

Postpartum Market

- Number of birth in the USA exceeded 3.7 million in 2022.
- It is recommended that all pregnant women take prenatal vitamins to ensure they receive essential nutrients for their own health and the development of their baby. According to a study published in JAMA Network Open in 2018, approximately 75% of pregnant women in the United States reported using prenatal vitamins.
- It is generally recommended that women continue taking prenatal vitamins or switch to postnatal vitamins after giving birth, especially if they are breastfeeding. A survey conducted by the Centers for Disease Control and Prevention (CDC) in 2015-2016 revealed that approximately 65% of breastfeeding women in the United States reported taking a postnatal dietary supplements.
- This results a huge market, therefore many companies offer postnatal vitamin food supplements in the USA such as Bayer, Church & Dwight, New Chapter (a P&G company), Ritual, etc. All currently marketed postnatal products target lactation only.
- Currently there is no treatment available on the market targeting the recovery of muscles injured during delivery.

Psychological Elements

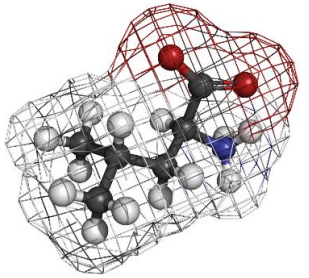
- The term ‘fourth trimester’ is getting more and more attention in the USA. The American College of Obstetricians and Gynecologists (ACOG) suggest that it is just as important for a mother’s health as the first three trimesters.
- Women who get their child in a later age tend to focus more on their own body’s recovery.
- Women after giving birth often experience lose vagina which degrades their sexual life.
- Many women experience incontinence and prolapse symptoms even in a younger age. Incontinence became a well-known problem among women.
- The aim of MOMAID is to make women aware that pregnancy and childbirth put increased pressure to their pelvic floor muscles.
- Awareness that such symptoms appear with child delivery are less known and, thus, less recognized.
- Once she is aware of that, she will know that there is a very good solution that can assist her: MOMAID

Solution

- Our solution - MOMAID - contains a unique combination of Zinc, Leucine and Omega-3 fatty acids and directed at women after giving birth either through vaginal delivery or C-section to aid the restoration of muscular injuries.

- ZINC is the second most common trace mineral in the human body. Zinc is involved in a large variety of metabolic processes, accelerates the regeneration of connective tissues and the healing of wounds. It contributes to maintaining the normal condition of hair, skin and nails.

- OMEGA-3 fatty acid can increase the production of muscle proteins, thereby enhancing muscle strength. They are beneficial both for the baby and the mother. After birth, they are important for babies in visual as well as mental development. Our solution contains both DHA and EPA omega fatty acids.



- LEUCINE is an essential amino acid (cannot be made by the body, it must come from food). Leucine is the only nutritional amino acid capable of stimulating the synthesis of muscle proteins. It enhances regeneration and prevents muscle tissue from degradation.

Mechanism of Action: Zinc

- In human vaginal smooth muscle cells, zinc has a beneficial effect on the production of extracellular components produced by the muscle at 20 µM zinc tissue level, thereby increasing the amount of collagen and elastin production and the amount of smooth muscle.[1]

- In humans, tissue zinc levels are significantly lower in patients with all types of hernia. The risk factors associated with hernia are similar to those involved in the development of prolapses.[2]

- Even if there is no absolute zinc deficiency in pregnant women, the risk of peripartum and postpartum complications is still increased at a zinc level at the lower end of the normal zinc serum level range.[3, 4, 5]

- In a report, the effect of delivery mode (cesarean section or vaginal delivery) was studied on maternal and newborn Mg and Zn blood serum levels. While maternal Mg and Zn levels did not differ before delivery, the plasma Zn level significantly decreased in women who underwent vaginal delivery, relative to the zinc levels of women with caesarean section. This is probably due to the high stress of skeletal muscles and uterine muscles during childbirth. In another study, plasma zinc levels lower than average were associated with complications during pregnancy and during labor and delivery.[6, 7]

1 Takacs P, Zhang Y, Candiotti K, Jaramillo S, Medina CA. Effects of PPAR-delta agonist and zinc on vaginal smooth muscle cells collagen and tropoelastin production. Int Urogynecol J. 2012;23(12):1775-1779.

2 Ozdemir S, Ozis ES, Gulpinar K, et al. The value of copper and zinc levels in hernia formation. Eur J Clin Invest 2011;41(3):285Y290

3 Schulpis KH, Karakonstantakis T, Vlachos GD, et al. Maternal-neonatal magnesium and zinc serum concentrations after vaginal delivery. Scand J Clin Lab Invest. 2010;70(7):465-469.

4 Lazebnik N, Kuhnert BR, Kuhnert PM, Thompson KL. Zinc status, pregnancy complications, and labor abnormalities. Am J Obstet Gynecol. 1988;158(1):161-166.

5 Caulfield LE, Zavaleta N, Shankar AH, Merialdi M. Potential contribution of maternal zinc supplementation during pregnancy to maternal and child survival. Am J Clin Nutr. 1998;68(2 Suppl):499S-508S.

6 Kleopatra H. Schulpis et al. Maternal-neonatal magnesium and zinc serum concentrations after vaginal delivery. Scandinavian Journal of Clinical & Laboratory Investigation, 2010; 70: 465–469.

7 N. Lazebnik et al. Zinc status, pregnancy complications and labor abnormalities. Am J Obstet Gynecol. 1988 Jan;158(1):161-6.

Mechanism of Action: Leucine

- Numerous studies have shown leucine's beneficial role in enhancing muscle protein synthesis [1, 2]

- Leucine diet supplement in combination with resistance training showed moderately but greater changes in isometric leg muscle strength than the only physical training group.[3]

1 Rowlands DS, Nelson AR, Phillips SM, et al. Protein-leucine fed dose effects on muscle protein synthesis after endurance exercise. Med Sci Sports Exerc. 2015;47(3):547-555.

2 Luiking YC, Deutz NE, Memelink RG, Verlaan S, Wolfe RR. Postprandial muscle protein synthesis is higher after a high whey protein, leucine-enriched supplement than after a dairy-like product in healthy older people: a randomized controlled trial. Nutr J. 2014;13:9.

3 Trabal J, Forga M, Leyes P, et al. Effects of free leucine supplementation and resistance training on muscle strength and functional status in older adults: a randomized controlled trial. Clin Interv Aging. 2015;10:713-723.

Mechanism of Action: Omega-3

- It is known from animal experiments that omega-3 fatty acids stimulate protein anabolic processes.[1]
- Dietary intake of omega-3 fatty acid increases muscle anabolic signaling activity, thereby stimulating protein synthesis in muscle.[2]
- The beneficial effect of Omega-3 fatty acids in pregnancy is well-known, furthermore, its beneficial effect on growth is also proved in animals. In humans, it has been shown that Omega-3 fatty acid is able to increase the production of muscle proteins, thereby enhancing muscle strength.[3, 4, 5]

1 Poult Sci. 2017 Sep 1;96(9):3176-3187. doi: 10.3382/ps/pex147. Omega-3 polyunsaturated fatty acids provided during embryonic development improve the growth performance and welfare of Muscovy ducks (Cairina moschata). Baéza E1, Chartrin P1, Bordeau T1, Lessire M1, Thoby JM2, Gigaud V2, Blanchet M3, Alinier A3, Leterrier C4.

2 Smith GI, Atherton P, Reeds DN, et al. Dietary omega-3 fatty acid supplementation increases the rate of muscle protein synthesis in older adults: a randomized controlled trial. Am J Clin Nutr. 2011;93(2):402-412.

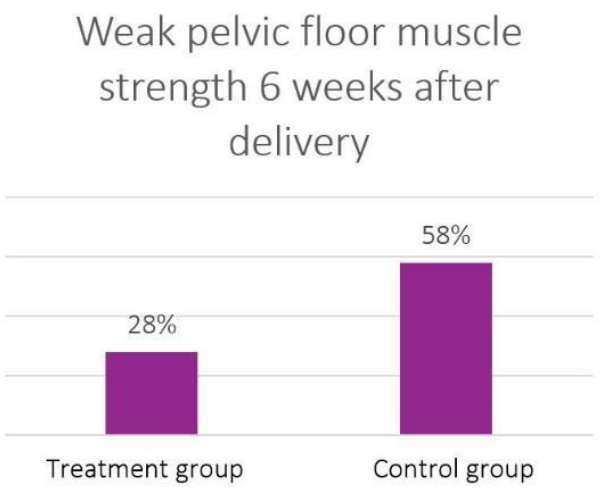
3 Smith GI, Julliand S, Reeds DN, Sinacore DR, Klein S, Mittendorfer B. Fish oil-derived n-3 PUFA therapy increases muscle mass and function in healthy older adults. Am J Clin Nutr. 2015;102(1):115-122.

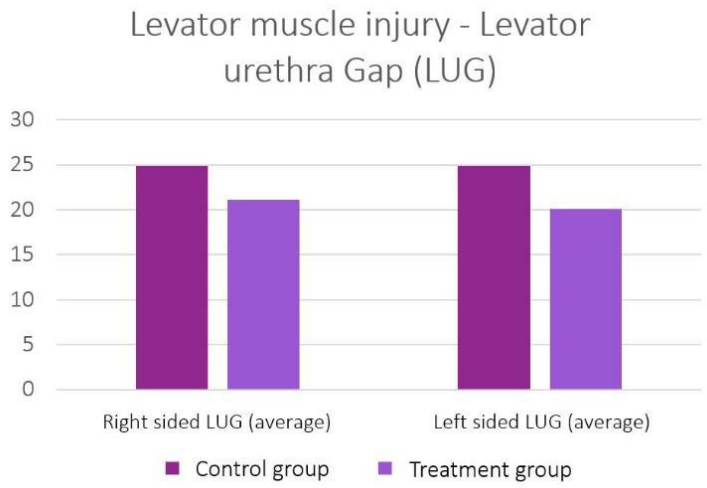
4 Gingras AA, White PJ, Chouinard PY, et al. Long-chain omega-3 fatty acids regulate bovine whole-body protein metabolism by promoting muscle insulin signalling to the Akt-mTOR-S6K1 pathway and insulin sensitivity. J Physiol. 2007;579(Pt 1):269-284.

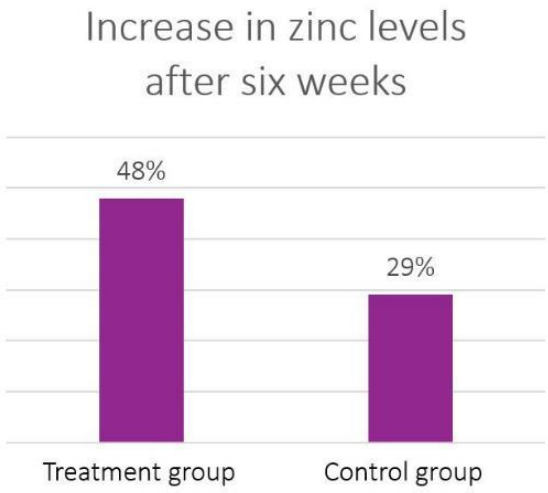
5 Di Girolamo FG, Situlin R, Mazzucco S, Valentini R, Toigo G, Biolo G. Omega-3 fatty acids and protein metabolism: enhancement of anabolic interventions for sarcopenia. Curr Opin Clin Nutr Metab Care. 2014;17(2):145-150.

Efficacy of MOMAID

- In order to examine the therapeutic effects of MOMAID, a seven-month long clinical study was conducted in 2018 at the Department of Obstetrics and Gynecology at the University of Debrecen in Hungary. The mothers who took part in the study received dietary supplement preparations immediately after giving birth. The therapeutic group was taking MOMAID for 6 weeks, while the control group received a standard postnatal vitamin.
- Gynecologists examined the regeneration of pelvic muscles 6 weeks after delivery, measuring the strength of pelvic floor muscles, muscle injury, blood zinc levels, and vaginal wall injury.
- The chance of weak pelvic floor muscle strength decreased by 52% in the MOMAID group compared to the control group 6 weeks after delivery.







Safety of MOMAID

- Used by thousands of women since 2018 with no complaints. There are no side effects reported at recommended doses. No serious adverse events have been reported with usage.
- MOMAID is manufactured in a GMP complying factory and the whole product lifecycle is managed under ISO 13485 QMS and ISO 22000 food safety management system.


TEQUA-ZERT
Minőségfejlesztési és Tanúsító Kft.

CERTIFICATE

The **Tequa-Zert Kft.** as the Hungarian certification partner of **TEQUA-Group** hereby certifies that it has audited the quality management system introduced by

FEMPHARMA Kft.

4024 Debrecen, Vígkedvű Mihály u. 21. II.em.5.

and operated in the areas of

Manufacturing and trade of medical devices

and it has established that the system captioned above is compliant with the requirements of the MSZ EN ISO 13485:2016 Standard.

The Certificate is valid until: 2026-06-20

Tequa-Zert MSZ EN ISO 13485:2016

Certificate-Nr.: CA 230221 FEMPHARMA
Berhida, 2023-07-01

Head of the certification department
TEQUA-Zert Kft. H-8182 Berhida, Orgona u. 6/7. Telefon: +36-88-456 079

ISO 13485:2016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Certificate

We hereby certify that

FEMPHARMA Kutatásfejlesztési Kft.

Headquarters: 4024 Debrecen, Vígkedvű Mihály u. 21. II. em. 5.
Site: 4029 Debrecen, Csigkid u. 22/A.

in the following fields

research and development, contract manufacturing of dietary supplements

Food chain category / subcategory (ISO/TS 22003:2013): C / CIV

has introduced and applied a Food Safety Management System which satisfies the requirements of **ISO 22000:2018**

Expiry Date: 18 04 2026
Registration Number: 01-20685/23-15298
Date of Issue: Budapest, 19 04 2023

Certificate is valid only with successful surveillance audits. Validity of Certificate may be confirmed by scanning QR code.

ISO 22000:2018

Patients' Satisfaction

- Parallel to the clinical study we have performed a patient satisfaction survey on MOMAID dietary supplement.
- The main results of this anonymous survey were the following:
  - All patients were either satisfied (14%) or totally satisfied (86%) with the product
  - 32% of respondents said that MOMAID had a positive effect on their skin
  - 59% of respondents said that MOMAID had a positive effect on their hair
  - 72% of respondents said that MOMAID had a positive effect on their nails
  - 3% of respondents have reported side effects but none of these were serious
  - 100% of respondents said that they would recommend this product to their friends.

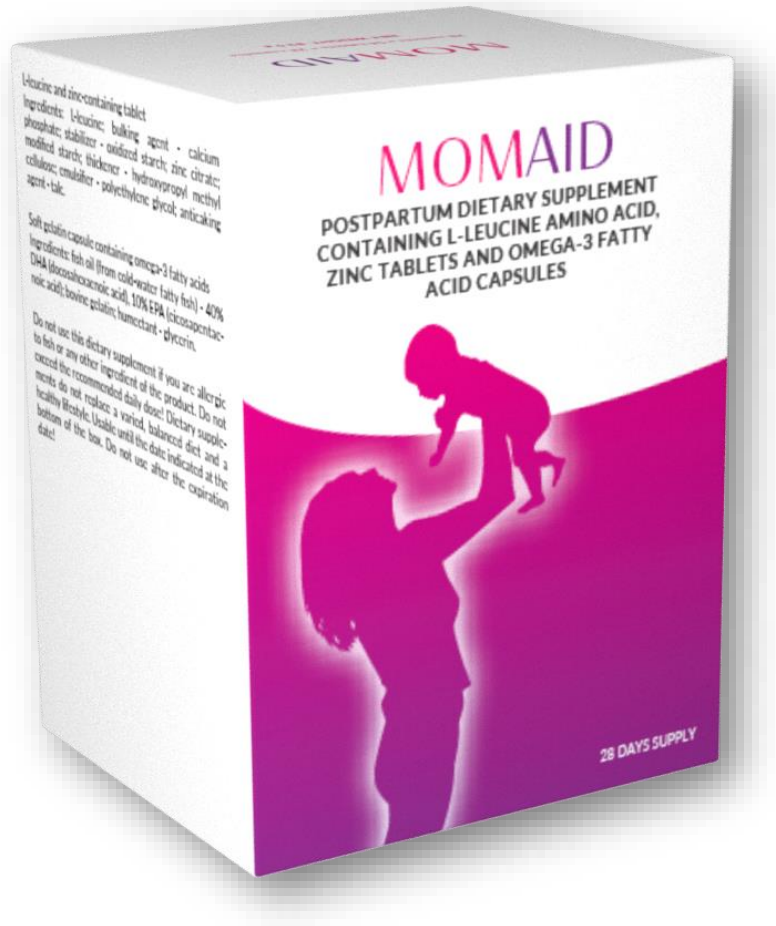
IP

- The scientific foundation for product development has been summarized under the US Patent entitled “Pharmaceutical Composition for Postpartum Recovery and Treatment of Pelvic Floor Dysfunction” (Publication Number: US-2021-0346427-A1; Publication Date: 11.11.2021).

Availability

- As part of a B2C pilot we have sold over 2000 boxes in Hungary. We learned valuable information about the customers' preferences, questions, focuses and satisfaction.
- In 2022, as part of an Exclusive Distribution Agreement, Gedeon Richter (European multinational pharmaceutical and biotechnology company headquartered in Budapest) has launched the product in 4 EU countries and will continuously launch it in 19 European countries altogether.

Product



- MOMAID is a dietary supplement for women, recommended from the day after delivery for 12 months.
- Two L-Leucine+Zinc tablets and one Omega-3 softgel capsule are packaged together in a daily sachet.
- 28 daily sachets are packaged in a carton box, together with an information leaflet.
- One sachet contain the recommended daily dose.

Ingredients	Amount per dose (1 softgel capsule and 2 tablets)	%NRV*
Omega-3 fatty acid (from which	500 mg	**
EPA	50 mg	**
DHA	200 mg	**
L-Leucine	1600 mg	**
Zinc	24 mg	240%

*Nutrient Reference Value.
** Nutrient Reference Value not established.

Net weight of 1 daily sachet/serving: 3,09g
Net weight: 86 g
Gross weight: 124 g

Contact us

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