PLAY VIDEO

AmLexin™ is a plant-based proprietary combination of Acacia catechu heartwood extract and Morus alba root bark extract. AmLexin™ has demonstrated the ability to help protect cartilage from breaking down in human clinical trials.

PRODUCT PROFILE SHEET

What Makes AmLexin™ Unique?

There are many ingredient options available in the joint health market space, but very few that take a proactive, protective approach for joint cartilage breakdown. AmLexin™ has been shown to be effective in an ex vivo GAG assay, at reducing Glycosaminoglycan (GAG) released by articular cartilage.

Clinical trial results demonstrated statistically significant reduction of uCTX-II, a type II collagen biomarker of joint cartilage break down.

This indicates a protective quality that may help reduce the degradation of joint cartilage.

The discovery

Unigen has a collection of more than 12,000 plants and marine samples with documented human consumption. After completing an extensive literature and legacy search, 132 plant extracts with historical usage related to arthritis and discomfort indications were selected for screening on in vivo analgesic models.

A total of 34 plant extracts were confirmed with in vivo efficacy that were carried forward for biological assay guided active isolation and identification.

More than 10 standardised extracts were developed after chemical and functional profiling.

Combinations of two or more active extracts were further developed and evaluated in in vitro and in vivo assays independently to discover novel and effective natural ingredients with solid efficacy in joint protection and the improvement of joint function.

This research program successfully led to the discovery of the composition AmLexin™ (*Acacia catechu + Morus alba*).

Product Advantages

- ✔ **100% Natural & Clean Label**
- ✔ **Scientifically studied**
  Plant-based composition with multiple peer review publication.
- ✔ **Discovered and developed through phenotypic screening**
  Unigen PhytoLogix® library.
- ✔ **Supports clinically meaningful articular cartilage protection**
- ✔ **Supports quick recovery from delayed onset muscle soreness**
- ✔ **Safe**
  Due to the constituent's historical safe human consumption and further supported by clinical safety data.

Research

1. Pre-clinical data

Unigen has published multiple peer reviewed preclinical data for AmLexin™ highlighting its cartilage protection, anti-discomfort, anti-inflammatory & antioxidation properties:

- Dose-dependent inhibition of the enzymatic activities of COX and LOX with IC50 values of 20.9 µg/mL, 49.2 µg/mL, and 11.1 µg/mL in COX-1, COX-2, and 5'-LO, respectively.[1]
- Statistically significant improvement in visceral pain, hyperalgesia and suppression of paw edema similar to known NSAIDs.[1]
- Statistically significant improvements in arthritis severity markers, including uCTX-II, serum IL-1β, TNF-α, and IL-6 levels as well as matrix degrading enzyme such as synovial MMP-13 in CIA model.[2]
- Mitigated knee joint histopathology data well aligned with the severity score of arthritis indicating the cartilage sparing activity in CIA model.[2]
- Demonstrated a 31.5%, 50.0%, and 54.8% inhibitions of proteoglycan degradations at 50, 100, and 200 µg/mL, respectively, in ex vivo proteoglycan protection model.[3]
- Synergistic proteoglycan protection activity indicating the merit of combining two bioflavonoid standardized extracts from *catechu* and *M. alba*.[3]
- Reductions of 17.5%, 29.0%, 34.4%, 33.5%, and 40.9% through week 1–5 in pain sensitivity, statistically significant improvements in articular cartilage matrix integrity, and minimal subchondral bone damage in MIA model.[3]

PLAY VIDEO

2. Human studies

Joint Cartilage Degradation Support (OA)

A randomized placebo and active comparator controlled clinical study was conducted to determine AmLexin™'s efficacy on reducing joint cartilage degradation. In this study 135 adults, aged 35 to 75 years, who had symptoms of knee discomfort were enrolled after signing the informed consent.

The study participants were supplemented with AmLexin™ at 400 mg/day and an active comparator (Glucosamine: 1500 mg and Chondroitin: 1200 mg Combination per day) for 12 weeks. Urinary levels of uCTX-II were measured and standardized to the total urine creatinine. As seen in Figure 1, there was a statistically significant difference between the changes of uCTx-II for AmLexin™ (UP1306) and placebo groups after 12 weeks product use (p=0.029).[4]

Participants in the AmLexin™ group showed an 8.9% reduction in the uCTX-II while there was a 25.1% increase in the uCTX-II level for the placebo group. The Glucosamine/chondroitin group showed only 0.5% changes from baseline.[4]

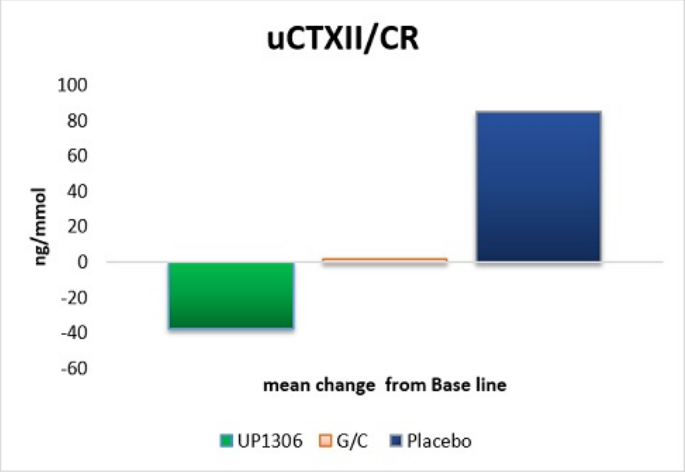

Figure 1. AmLexin™ significantly reduces uCTX-II Levels vs. Placebo

Post-Exercise Recovery Support

A double-blind placebo-controlled clinical trial was carried out over 9 weeks in a single centre. Thirty physically active male and female subjects within 18–70 years of age were randomized into AmLexin™ (mean age = 42.92 ± 2.48 and gender 7/5, male/female, respectively) and placebo (mean age = 41.15 ± 3.5 and gender 10/3, male/female, respectively) groups.

Subjects were supplemented with 400 mg of AmLexin™/day or a look-alike placebo during an 8-week training program, and for one week following a 13.1-mile half-marathon.

Results showed that AmLexin™ group experienced significantly lower levels of post-exercise pain on day 1–3 following the half-marathon compared to the placebo group. The AmLexin™ group also showed lower post-exercise oxidative stress and higher antioxidant capacity on days 1 and 6 following the half-marathon.[5]

These results demonstrated the rapid benefits of AmLexin™ on pain and oxidative stress within 1–6 days post-exercise.[5]

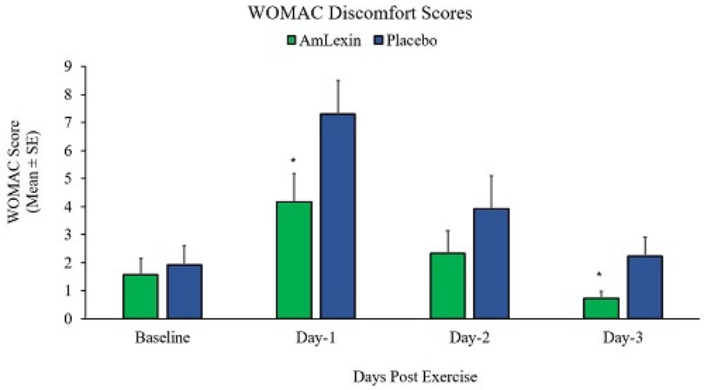

Figure 2. AmLexin™ reduced WOMAC discomfort scores as of day 1 post exercise

The anti-oxidation activity of AmLexin™ was assessed using the RedoxSYS diagnostic system. The system measures the oxidation-reduction potential (ORP) such as static ORP (sORP), and the capacity ORP (cORP). While sORP values represent oxidative stress level, the cORP is the measure of available antioxidant.

In the current study, there were clear evidences favouring the beneficial effects of AmLexin™ on the level of oxidative stress (as measured by sORP) (decreased after supplementation) and anti-oxidant reserve (as measured by cORP) (increased after supplementation).[5]

AmLexin™ and Univestin® Synergy to Support Osteoarthritis

Research has been conducted to investigate the potential benefits of AmLexin™ and Univestin® for joint support (pain relief and cartilage protection), specifically as a combination treatment for Osteoarthritis (OA)[6]. Results show that when combined in a formula both ingredients work efficiently in reducing (significantly) pain sensitivity. Not only this but according to the study the combination also helped to preserve the articular cartilage matrix integrity composition and showed a statistically significant reduction in uCTX-II level (the most well-validated biomarker in osteoarthritis).

The results of this combination study and individual studies on both ingredients support that AmLexin™ and Univestin® may potentially be an alternative natural and plant-based solution for the management of OA and/or its associated symptoms, by enhancing the anti-inflammatory and analgesic action of Univestin® with the cartilage degradation support from AmLexin™. To learn more about the synergy download here our specific presentation.

PLAY VIDEO

Product Safety

AmLexin™ was valuated in a 28-day repeated oral dose toxicity study administered at oral doses of 500, 1000 and 2000 mg/kg/day to rats for 4 weeks. A 2-week recovery group from the high dose (2000 mg/kg) and vehicle treated groups were included.

No morbidity or mortality was observed for the duration of the study. No significant differences between groups in body weights, food consumption, haematology, clinical chemistry, organ weights, gross pathology and histopathology were documented.

The no-observed-adverse-effect-level (NOAEL) was considered to be the highest dose tested, 2000 mg/kg/day, both for male and female rats.[7] Furthermore, no adverse effects were observed during clinical trials.

Product Range

Ingredient	Active Content	Grade	Mesh Size
Amlexin	Min 15% Catechins Min 2% Mulbberroside A	Powder	NLT 80% thru 80 mesh

Product Applications

Amlexin™ is mainly used in capsules and tablets, but can also be used in liquid applications. We suggest you use a strong flavour to cover the bitter taste when formulating liquid applications.

Product Dosage

According to clinical evidence, the recommended daily dosage for AmLexin™ is 400mg/day.

The Phytologix® Technology Platform

AmLexin™'s unique formulations are discovered and developed through Unigen's proprietary Phytologix® Technology Platform. This proprietary informatics database contains comprehensive botanical profiles on over 12,000 plants and data on more than 15,000 extracts and 300,000 HTP fractions.

Unigen scientists used these profiles to identify plants whose actives delivered the most effective health benefits.

About

Unigen focus on identifying and studying the unique bioactive natural products of medicinal botanicals and then developing them into reseach-driven, proprietary standardised extracts for use in nutraceutical, cosmetic, and pharmaceutical finished products.

References

1. *Yimam M, Lee YC, Jiao P, Hong M, Nam JB, Brownell L, Hyun E, Jia Q.* UP1306, a Botanical Composition with Analgesic and Anti-inflammatory Effect. *Pharmacognosy Res. 2016 Jul-Sep;8(3):186-92.*
2. *Yimam M, Horm T, Wright L, Jiao P, Hong M, Brownell L, Jia Q. UP1306:* A Composition Containing Standardized Extracts of Acacia catechuand Morus alba for Arthritis Management. *Nutrients. 2019 Jan 26;11(2):272.*
3. *Yimam M, Lee YC, Wright L, Jiao P, Horm T, Hong M, Brownell L, Jia Q.* A Botanical Composition Mitigates Cartilage Degradations and Pain Sensitivity in Osteoarthritis Disease Model. *J Med Food. 2017 Jun;20(6):568-576.*
4. *Kalman DS, Hewlings SJ.* The Effects of Morus alba and Acacia catechuon Quality of Life and Overall Function in Adults with Osteoarthritis of the Knee. *J Nutr Metab. 2017;2017:4893104. doi: 10.1155/2017/4893104. Epub 2017 Sep 11. PMID: 29085676; PMCID: PMC5612321.*
5. *Yimam M, Talbott SM, Talbott JA, Brownell L, Jia Q.* AmLexin, a Standardized blend of Acacia catechu and Morus alba, shows benefits to delayed onset muscle soreness in healthy runners. *J Exerc Nutrition Biochem. 2018 Dec 31;22(4):20-31.*
6. *Yimam M et al. (2017)* Cartilage Protection and Analgesic Activity of a Botanical Composition Comprised of Morus alba, Scutellaria baicalensis, and Acacia catechu, *Evid Based Complement Alternat Med. 2017 Aug 20;2017:7059068. doi: 10.1155/2017/7059068*
7. *Yimam M, Jiao P, Hong M, Brownell L, Hyun-Jin Kim, Lee YC, Jia Q.* Repeated dose 28-day oral toxicity study of a botanical composition composed of Morus alba and Acacia catechu in rats. *Regul Toxicol Pharmacol. 2018 Apr;94:115-123.*
8. Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers. *July 2005, J:\IGUIDANC\5541fnlcln1.doc*
9. *Anroop B. Nair and Shery Jacob.* A simple practice guide for sode convertion between animals and human. *March 2016-May 2016; 7(2): 27–31. doi: 10.4103/0976-0105.177703*