



# **PRODUCT PROFILE SHEET**

## What makes Univestin<sup>®</sup> Unique?

The Univestin<sup>®</sup> plant extracts are standardised for two distinct types of bioflavonoids that the manufacturer, Unigen (USA) discovered to inhibit the pro-inflammatory enzymes COX and LOX and to also neutralize inflammatory reactive oxygen species (ROS).

Univestin<sup>®</sup> is a patented plant-based concept, derived from roots of *Scutellaria baicalensis* and heartwood of *Acacia catechu*, scientifically researched for its capacity to alleviate joint discomfort and stiffness. Alone or in combination with other joint care ingredients, it has been shown to **successfully provide fast-acting joint relief support**.

#### The discovery

Over 1230 medicinal plants from Unigen's PhytoLogix  $^{\odot}$  library were screened to identify natural substances with COX and LOX dual inhibitory activity.

The Univestin<sup>®</sup> bioflavonoids, baicalin from *Scutellaria baicalensis* and catechins from *Acacia catechu (Senegalia catechu*), were identified as the active components of the most effective extracts tested both in vitro and in vivo.

The combination of these two extracts produced a synergistic analgesic and antiinflammatory effect in vivo with regard to both onset and duration. A more detailed accounting of the Univestin<sup>®</sup> discovery process is available upon request.

Health Canada has recognized and approved symptom-relief claims for  $\mathsf{Univestin}^{\circledast}$  on Osteoarthritis population.

#### **Product Advantages**

history of safe human consumption.

 Scientifically studied plant-based combination derived from roots of Scutellaria baicalensis and heartwood of Acacia catechu.

Univestin<sup>®</sup> is a natural, plant-based composition, researched to alleviate joint

discomfort within 3-7 days. Univestin<sup>®</sup> is composed by carefully identified and

assessed plant extracts standardised to 2 specific bioflavonoids, with a long

- Fast-Acting (3-7 days) scientific results on joint stiffness
- ✓ Natural actives screened and selected from over 1230 medicinal plants from Unigen's PhytoLogix™ library.
- Over a dozen research studies Including human clinical trials.
- Safe

The botanical extracts used in this composition have a long history of safe human use including preclinical safety with results published in 8 peer-reviewed journals.

✓ Water Extraction Solvent Free

#### ✓ 100% Plant Based and Clean Label

- On Trend
  Natural and Plant Based.
- ✓ Allows combination with other ingredients
- ✓ 4 years shelf life

## Research

#### Pre-clinical data

Extensive pre-clinical data has shown the beneficial effects of Univestin<sup>®</sup> related to alleviate joint discomfort. The bioflavonoid components of Univestin<sup>®</sup> were discovered as inhibitors of the pro-inflammatory COX and LOX enzymes. The IC50 for inhibition of COX-1 by Univestin<sup>®</sup> was calculated to be 0.2 µg/mL/unit of enzyme and the IC50 for inhibition of COX-2 was calculated to be 0.4 µg/mL/unit of enzyme. Scientific data demonstrated that Univestin<sup>®</sup> was also an effective inhibitor of the LOX pro-inflammatory pathway.

The IC50 of Univestin<sup>®</sup> for inhibition of the LOX pathway was 25 µg/mL in the LPS stimulated THP-1 cells. Chondrocytes and inflammatory cells, e.g., neutrophils and macrophages, produce high amounts of ROS such as superoxide anion, H2O2 and HO-that are causally linked to cartilage degradation.<sup>1,2</sup>

Research demonstrates that Univestin<sup>®</sup> is a potent antioxidant having an oxygen radical absorbance capacity (ORAC) 36 times higher than that the commonly used antioxidant Citrus Bioflavonoids. Three experimental systems<sup>3</sup> were utilized to evaluate Univestin<sup>®</sup> for regulation of pro-inflammatory gene expression: human peripheral blood monocytes (hPBMCs), the human monocytic cell line 28SC, and the mouse macrophage cell line RAW 264.7.



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Univestin<sup>®</sup> significantly decreased pro-inflammatory II-1 $\beta$ , IL-6, and COX-2 gene expression and TNF- $\alpha$  secretion in human PBMCs treated with lipopolysaccharide. Univestin<sup>®</sup> significantly decreased LPS-induced expression of TNF- $\alpha$ , IL-1 $\beta$  and NF $\kappa$ b in human 28SC monocytic cells. Univestin<sup>®</sup> changed the expression of LPS-induced cytokines and chemokines in RAW 264.7. cells to more closely mimic untreated controls, as assessed by microarray.<sup>3</sup>

#### **Human Studies**

Two independent CROs performed two human clinical trials to demonstrate clinical efficacy of Univestin<sup>®</sup>. **A human clinical study** with Univestin<sup>®</sup> was conducted at Florida State University (Tallahassee, Florida, United States) in 2011. The clinical trial was a single-centred, randomized, double-blind, positive-controlled study. For this trial, a total of 80 subjects were randomized (40 per group) and were balanced by demographics, such as age, gender, and BMI. The data was analysed by an independent statistician and ANOVA techniques were used to assess effect of usage over time. The principle objective of this study was to examine the quick onset effects of a 1-week, daily supplementation with Univestin<sup>®</sup> at 500 mg/day on the indicators associated with OA as compared with a positive control supplementation – an NSAR drug (non-steroidal anti-inflammatory) with a dosage of 440 mg /day.<sup>4</sup>

The results suggested that Univestin<sup>®</sup> was superior with respect to the discomfort section of the WOMAC scale and possibly with respect to improving stiffness, thus providing greater relief than that of the NSAID drug when taken for one week. Additionally, the increase in ROM (Range of Motion) within the Univestin<sup>®</sup> group from baseline to day 7 day suggests that **Univestin<sup>®</sup> aids in joint flexibility and also supports the above findings of decreased discomfort and stiffness over one week of supplementation**.







Univestin<sup>®</sup> Significantly Improved Discomfort in 5 Days

**Univestin**<sup>®</sup> has demonstrated significant results in joint stiffness and function in another study conducted by JSS Medical Research Inc. (Montreal, Quebec, Canada) in 2003.<sup>5</sup> The clinical trial was a single-centred, randomized, double-blind, placebo and positive comparator-controlled study. Sixty subjects (n=60) with rheumatoid arthritis or osteoarthritis of the knee and/or hip were recruited for this study. Supplementation consisted of oral administration for 90 days of the placebo, Univestin<sup>®</sup>, or an active control NSAID drug (non-steroidal anti-inflammatory) according to the above dose schedule.

This study provided data to support that Univestin<sup>®</sup> at 250 mg/day and 500 mg/day was significantly more effective than Celecoxib 200 mg/day for the reduction of joint stiffness and joint function incapacity caused by osteoarthritis, within 30 days (p = 0.010) of use and Univestin<sup>®</sup> 500 mg/day was more effective than Celecoxib for reduction of discomfort at 30 days (p = 0.020).<sup>5</sup>



Univestin<sup>®</sup> Significantly Reduced Joint Stiffness

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Univestin<sup>®</sup> Significantly Improved Joint Function

### Univestin<sup>®</sup> and AmLexin<sup>™</sup> Synergy to Support Osteoarthritis

Research has been conducted to investigate the potential benefits of Univestin<sup>®</sup> and <u>AmLexin<sup>™</sup></u> 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 Univestin<sup>®</sup> and AmLexin<sup>TM</sup> 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<sup>®</sup> with the cartilage degradation support from <u>AmLexin<sup>TM</sup></u>. To learn more about the synergy <u>download here</u> our specific presentation.

## **Product Safety**

Acute toxicity, repeated toxicity, safety pharmacology, reproductive and developmental toxicity and genotoxicity in in vivo safety studies have demonstrated the safety of Univestin<sup>®</sup>. Furthermore, extensive human clinical safety studies were conducted on Univestin<sup>®</sup> at multiple dose levels and different durations. Dosages from 250 mg to 1,100 mg per day were administered orally in capsules without any adverse effect reported.<sup>7</sup> Univestin<sup>®</sup> has been proven to be safe for human consumption with more than 6 billion doses consumed at the recommended daily dosages.

## **Product Range**

Ingredient	Active Content	Grade	Mesh Size
Univestin	Min 60% Baicalin Min 10% Catechins	Powder	NLT 80% thru 80 mesh

## **Product Applications**

Univestin<sup>®</sup> is mainly used in capsules and tablets, but can also be used in liquid applications. We suggest you use flavouring (i.e berry) which will cover the slightly bitter taste when formulating liquid applications.

## **Product Dosage**

Recommended daily dosages are 250mg-500mg/day depending on the severity and health application.

## The Phytologix<sup>®</sup> Technology Platform



Univestin<sup>®</sup>'s unique formulations are discovered and developed through Unigen's proprietary Phytologix<sup>®</sup> 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

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

#### References

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