

SUMMARY

Safety & Performance



Product **Weight Wise Supplements**

Suggested Serving Size

Three 750mg Capsules twice daily, with lunch and dinner.

Description

Weight Wise Supplements provide new possibilities to support portion control, calorie control, and hunger control.

Weight Wise works through superabsorbent technology — absorbing fluid in your stomach and transforming into a zero-calorie, non-digestible gel that runs its natural course through the body like any food and is eliminated.

Substantive evidence provides a reasonable assurance of safety for human use.

Polymer Safety

Recognition of the safety of the material by national and international regulatory organizations provides validation that **Weight Wise Supplements** are safe for human use:

- Included in the Priority-Based Assessment of Food Additives (PAFA).
- Recognized by the Codex Alimentarius Commission of the World Health Organization (WHO) as a food additive.
- Not classified as hazardous by the Globally Harmonized System (GHS).
- Recognized as safe, non-toxic, and non-carcinogenic by the National Toxicology Program (NTP), International Agency for Research on Cancer (IARC), and Occupational Safety and Health Administration (OSHA).

Numerous studies on safety are available in public literature that also support reasonable assurance that the superabsorbent material in **Weight Wise Supplements** is known to be biocompatible and safe.

POLYMER SAFETY

Recognized as Safe Based on Biological and Toxicological Data

Conclusions about the safety for human consumption of the superabsorbent material in **Weight Wise Supplements** were drawn from safety pharmacology and toxicity testing.

Conclusions from in vivo and ex vivo safety testing for the superabsorbent material in **Weight Wise Supplements** show:

- No long-term negative effects of use.
- Well tolerated with no GI irritation or inflammation.
- No effects on the central nervous system, cardiovascular system, renal system or gastrointestinal system.
- No related effects on fertility or maternal or embryo/fetal toxicity.
- Non genotoxic in vitro or in vivo. No evidence of gene mutations, chromosome damage or cytotoxicity.

The data provides the basis for a conclusion that there is a reasonable expectation of safety under the proposed conditions of use of the product.

Clinically Tested for Safety in Adults

The product has been tested for safety, tolerability, and efficacy in healthy adults in accordance with International Conference on Harmonisation Good Clinical Practice guidelines and other applicable regulatory requirements and laws.

Two studies conducted in healthy adults provide a reasonable assurance of safety of **Weight Wise Supplements** for use as a gel that induces satiety:

- **Study 1:** Multiple dose pilot study to assess the safety, efficacy, and tolerability of encapsulated superabsorbent material given to healthy adults.
- **Study 2:** Multiple dose study to assess the safety, efficacy, and tolerability of encapsulated superabsorbent material given to healthy adults.

In general, product use is well tolerated with low frequency of self-limiting gastrointestinal events. All adverse events were dose-dependent, mild to moderate in severity, transient, and resolved without intervention. In Study 2, there were no adverse events reported in any participants.

History of Safe Use

This product does not contain a new dietary ingredient. Rather, there is a history of use and other evidence of safety establishing that the dietary ingredient in **Weight Wise Supplements** was present in the food supply as an article used for food. In other words, the dietary ingredient that has been present in the food supply as an article used for food is the same chemical in the dietary supplement. The dietary supplement will reasonably expected to be safe under the conditions recommended or suggested in the labeling.

Performance

Weight Wise Supplements support hunger control as an innovative appetite suppressant. **Weight Wise** works by forming a zero-calorie, three-dimensional gel that makes you feel full. When taken in combination with food, it can help you control portion size and calorie intake.

These statements not evaluated by the United States Food and Drug Administration.
This product not intended to diagnose, treat, cure, or prevent any disease.

Thank You!

Look for Weight Wise Supplements exclusively on Kickstarter.
Reach us anytime: contact@myweightwise.com