

Scientific Information - Joint Supplements (Nutraceuticals)

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SCIENTIFIC RESEARCH SUPPORTS THE EASYGAIT FORMULA

The Easygait formulation is the result of a comprehensive and detailed evaluation of all the available scientific research on joint supplements. Easygait is a combination of 3 ingredients that have the best scientific evidence for effectiveness and are very safe.

These ingredients are: Glucosamine sulfate, MSM, and Vitamin C

Our goal is to make an effective joint supplement available to the average horse owner at the lowest possible cost. We will attempt to keep up with the latest scientific findings in these areas, and will modify our supplement accordingly. We also solicit your input for information we have missed, and would definitely like to learn about your experience with nutritional supplements used on your horses.

We have reviewed research studies conducted in the laboratory, as well as clinical studies that examine whether or not a supplement actually helps reduce lameness, stiffness, and/or pain in the real world. We also provide references to the original research data published in the scientific literature. In the following section, we present guidelines for assessing the reliability of nutraceutical research, and a summary of these research findings.

What is the difference between a nutraceutical and a prescription drug?

The health of our joints affects every aspect of our lives and the pain and loss of mobility can be crippling. The same applies to the animals in our lives. Our horses and dogs are seriously affected by joint disease as well, so it is no surprise that joint health is a popular area of research – both in human and veterinary medicine. The use of nutritional supplements (called “nutraceuticals”) has been popular for over a decade, but the scientific basis for their use has been somewhat limited. Not surprisingly pharmaceutical prescription “drug” treatments have been given the most attention.

It is important to understand the practical differences between drugs and nutraceuticals. Drugs are defined as substances intended to affect the structure or any function of the body of man or other animals.. Drugs are developed, patented, and marketed by pharmaceutical companies. The drug manufacturer must prove scientifically, with laboratory and clinical studies, that a drug is safe and effective, before they can sell it. Nutraceuticals are substances derived from foods or other relatively unprocessed natural materials. Nutraceuticals can certainly have effects on the body as well, but the nutraceutical industry in the US has managed to keep their products “unregulated” by the FDA. In 1994 nutraceutical companies convinced the US Congress to pass a law entitled “The Dietary Supplement Health and Education Act. DSHEA manufacturers do not need to register their products with FDA nor get FDA approval before producing or selling dietary supplements, As a result of this law, anyone can sell a nutraceutical without ever proving it is safe and effective.

A second and equally important consequence of this law is that, while a nutraceutical does not have to be approved by the FDA, neither can it be patented. As a consequence, and because anyone can sell it, many companies compete for sales, so prices can be very low, and the profits of the nutraceutical company low as well.

In the US, a drug patent means that only the drug company who originally developed the drug can sell it for a number of years, until the patent expires. Since there is no price competition from “generic” versions during the patent period, drug prices are high.

While many of the policies and profits of pharmaceutical companies are often questionable, the reality is that they are forced in spend hundreds of millions of dollars to develop and test a single drug in order to get FDA clearance for marketing. The high drug prices resulting from patent protection allow them to recoup these development costs, as well as make a profit.

This is a tradeoff. In exchange for high prices, we know more about the effectiveness and safety of an FDA regulated drug than we do about nutraceuticals. In fact, few new drugs would be developed without this system.

The patent situation is very different in many other countries. In countries like Germany, patents may be issued for nutraceuticals as well as for drugs, so it becomes financially feasible for drug companies to sponsor nutraceutical studies. This is the case with glucosamine sulfate, which is the main ingredient in many

joint supplements. Glucosamine sulfate has been extensively studied by Rotta Pharmaceutical in Italy, and their product is patented, and sold exclusively by them.

In the United States, the good news for us as animal owners is that nutraceuticals are more easily and cheaply available than prescription drugs. Anyone can sell them, no prescription and no FDA regulatory requirements. The bad news is that there is no requirement for safety or effectiveness testing.

Are nutraceuticals such as joint supplements safe and effective?

There is no easy answer. Unfortunately US nutraceutical companies are just as interested in profit as anyone else, and often take advantage of the lack of FDA regulation. Very few nutraceuticals in the United States are tested either before or after they are sold to us.

A few nutraceutical companies voluntarily conduct safety testing of their product, and are careful about the purity of their ingredients. Some companies also adhere to the “Good Manufacturing Practices” required by the FDA. Nutraceuticals are subject to some oversight by the FDA, and there are some restrictions on labeling and advertising, but this is rarely enforced.

Fortunately, there are a few government agencies in the US that will sponsor nutraceutical research. The National Institutes of Health has recently conducted a study on glucosamine for joint health. Some non-profit private foundations or academic institutions sponsor relevant research as well – but this a small part of total research efforts.

It is important for animal owners who use nutraceuticals to learn how to assess safety and effectiveness of nutraceuticals. No one is doing it for you.

Aren't “natural” supplements always safe?

Because nutraceuticals aren't regulated, many companies may shamelessly exploit fads and misinformation. The best example is the use and abuse of the term “natural.” Many companies (also food and cosmetic manufacturers) describe their product as “natural,” implying that this makes their product somehow safe, of high quality, and is somehow “better” than “synthetic.” This is misleading. Consider, for example, thyroid medication for people with low thyroid hormone output from their own glands, or who have had their entire thyroid gland removed surgically because of cancer. Replacement thyroid hormone is available in two

basic forms: “Synthroid” is identical to the hormone made by your own human thyroid gland, even though it is produced “synthetically” in the laboratory. The other kind is “Armour” thyroid. This is “natural” since it comes from pigs, but not only is it slightly different from human hormone in its molecular structure, but it is manufactured from highly stressed slaughterhouse pigs, and different batches have different strengths. Which would you prefer?

It is simplistic to believe that natural is better. Many things from nature are not safe. There are relatively few plants that humans can safely eat. Look at any forest or grassland and count the number of plants you see, then consider how many are edible. In fact, most plants are quite indigestible and many are highly toxic to humans. Don’t be taken in by “natural.”

What kind of research has been done on joint supplements/ nutraceuticals for horses and humans?

Many scientific studies have been conducted on joint supplements. There are dozens of laboratory studies that evaluate the effect of supplements in samples of joint tissue or blood, outside of the body. These studies give us some idea of how the joint supplement ingredients may affect biochemical reactions in the body. For example, does a supplement increase growth of the cartilage in a piece of joint tissue in a laboratory culture? Is the supplement well absorbed from the digestive tract and actually found in the blood, or in the fluid taken from the joint itself? Does the supplement inactivate the biochemicals found in the bloodstream that cause inflammation and tissue damage?

While laboratory studies are useful and informative, they don’t always accurately predict that the supplement will do when used in the real world. They don’t really answer the question, “Will a joint supplement actually help the lameness in my horse.

The best way to tell if something is helpful is to do a clinical trial. This is a study where the substance in question is actually tested on the animal (human or equine) in real world conditions. Clinical studies which are considered very well designed from a scientific perspective are called comparative, placebo-controlled studies. That is, they usually have two or more groups or subjects (peoples or horses or dogs or...). One group (experimental group) is given the substance being tested. The other group (control group) takes a placebo. A placebo is a

substance that looks and tastes the same as the test substance, but is missing the active ingredient.

Then the study tries to keep everything else about the two groups the same (“controlled”). That is, the number of geldings or mares identical in each group, they should also be the same ages, receive the same feed, shelter, exercise, have the same health history, and identical general care and attention.

Ideally, the best clinical studies are also “blinded,” which means that the investigator, the person(s) who actually conduct the study, knows which animals are taking the test substance and which are taking placebo. This helps prevent any personal bias from affecting the study results. They are “blinded” to this information. It is difficult enough to conduct such these carefully designed studies with human subjects, who can choose to cooperate,, but even more difficult to do with horses. It is also very expensive. As a result, there are relatively few such blinded, comparative, controlled studies in horses.

Another study design is a longitudinal study. Here, horses with stable arthritis or some other injury are given a nutraceutical for some months to see if they improve, then it is stopped to see if the symptoms come back. This can be helpful, but the problem is they might have improved anyway – because of weather changes, or simply because joint problems can come and go without apparent explanation.

Even more variable is the opinion of “experts” (just like this article!). Simply having an academic degree (DVM, MD, PHD,) doesn’t really tell you anything about that expert’s actual expertise. Most experts also have some kind of bias. For example, we have done a study and defend our result, we “want” something to work, we are selling a product, or hired by a company that is selling a product, or we have an academic reputation to support.

And then there is “anecdotal” evidence. This is our own personal experience? What if we experience improvements in our own health when we take a new nutraceutical or drug or food? What if we see big improvements in our horses or dogs? What if our vet or personal physician believes a particular drug or nutraceutical has helped many of her/his patients? This is important information, and it too can be valid. But remember that there could be other reasons we or our horses felt better. Again, maybe a change in weather, feed, rest, or rehab exercises, physical therapy, fitness training, or just more TLC and

general attention could be helping the joint pain. Or maybe the arthritic attack just improved spontaneously.

How do I know a supplement is really safe and effective?

When you are evaluating use of nutraceuticals for yourself or your horses, or use of drugs or even foods, remember to assess and question the quality of the evidence;

- ARE THERE ANY CLINICAL TRIALS THAT USE YOUR PRODUCT'S INGREDIENTS?

Unfortunately the answer is often no. This should make you extremely cautious about any claims being made about that particular product.

- IS IT ANECDOTAL EVIDENCE ONLY?

- IS IT AN EXPERT'S OPINION? IF SO, DOES THE EXPERT BACK UP HER/HIS OPINION BY REFERRING TO RELIABLE STUDIES? WHAT IS THE EXPERT'S BIAS?

- IF THE NUTRACEUTICAL HAS BEEN TESTED WITH "CLINICAL TRIALS," ASK TO SEE STUDY DETAILS. MAKE SURE IT WAS ACTUALLY DONE ON HORSES, USING THE SAME INGREDIENTS FOUND IN THE PRODUCT YOU ARE EVALUATING.

- IS THE STUDY HIGH QUALITY? IS IT A CONTROLLED, COMPARATIVE STUDY, PUBLISHED AND EVALUATED BY OTHER EXPERTS? FINALLY,

- IF THE STUDIES ARE PUBLISHED, HOW ARE THEY PUBLISHED AND BY WHOM?

"Peer-reviewed" publications are generally the most reliable. In human health, *JAMA (Journal of the American Medical Association)* and *NEJM (New England Journal of Medicine)* are good examples, but someone's "Heath Newsletter" is probably just the opinion of one group within a University or Hospital or Veterinary College, or simply an individual who want to sell their Newsletter to you. In veterinary medicine, publications like *The Veterinary Journal* are peer-reviewed. Lay publications like *Equus* and *Practical Horseman* are not.

Just being on the Internet is obviously no guarantee of reliability. If information is published in a book or magazine, assess the reliability of the publication. Some books and articles are published by the author her/himself, and have not been evaluated by anyone else. Some magazines simply publish ideas that are interesting and entertaining, but no real basis in fact – just one

reporter's opinion. Many magazines will publish an article for you if you buy advertising space in their magazine.

If I decide to try a joint supplement, what's next?

First, be sure the nutraceutical supplement you buy is pure and that it has enough active ingredient in it to actually do some good. Recommended doses should be based on the best available studies that showed a positive effect. Many supplements do not add enough of the active ingredients to be effective (Vitamin C, MSM, glucosamine sulfate). EASYGAIT CONTAINS CONTAINS HIGH DOSES OF THESE INGREDIENTS, DOSES KNOWN TO BE EFFECTIVE IN CLINICAL STUDIES.

Be patient and be willing to try a supplement for at least 4 to 8 weeks longer deciding if it is helping.

Try to come up with a way to measure progress with careful observation of degree of obvious lameness, smoothness of gaits (preferably on both hard and soft surfaces), informal (or formal veterinary) flex test, voluntary movement at turnout, or any other improvement in either movement or overall behavior.

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