

New positive results for Quercefit™, Indena quercetin Phytosome®

After demonstrating its activity, efficacy and safety profile in the field of sports nutrition, a pilot non-interaction study confirms the high tolerability of Quercefit™ in individuals assuming antiplatelet agents, anticoagulants or living with diabetes.

Milan, January 10th, 2019 – New recent studies suggest positive results for <u>Quercefit™</u>, the <u>Indena</u>'s unique <u>Phytosome</u>® formulation of quercetin, in terms of bioavailability, efficacy and high tolerability.

Quercefit™ is standardized in quercetin and formulated with Phytosome®, the food grade delivery system able to synergize the biological absorption of certain compounds, such as flavonoids. According to a published human pharmacokinetic study comparing the Indena extract to unformulated quercetin extracts, it proved to be up to 20-fold more bioavailable and able to be used at lower dosages, preserving its profile of natural ingredient. [1]

Furthermore, the **effectiveness** of 250mg (twice a day) of the ingredient emerged in a controlled human study conducted on amateur athletes practicing triathlon according to "Sprint" format (100 minutes for swimming 750 m + cycling 20 km + running 5 km). [2] Quercefit[™] statistically maintained the body resistance, by optimizing performance and recovery, offering acceptable muscle wellbeing after physical activity.

To further confirm the positive safety profile of Quercefit™, a pilot non-interference clinical study was conducted in order to investigate any interaction of this complementary and natural approach with common standard synthetic drugs, preventing any possible harmful effect. Even if additional studies should be needed to confirm the positive results, the clinical outcomes suggest that Quercefit™ does not alter the antiplatelet activity of the most common antiplatelet agents, has no impact on the international Normalized ratio (iNr) values in stable patients treated with warfarin or dabigatran and does not influence the metabolic control of diabetic patients treated with metformin. [3] The interaction with the antiplatelet therapy was assessed through the bleeding time (BT) test in 30 patients treated with acetylsalicylic acid, ticlopidine or clopidogrel before and after 10 days of supplementation with QuercefitTM. Interaction with anticoagulants was evaluated by measuring the iNr in 20 patients using warfarin or dabigatran before and after 20 days of supplementation with QuercetfitTM. Lastly, glycaemia and glycated hemoglobin were measured in 12 diabetic patients treated with metformin and restricted diet before and after 20 days of supplementation with QuercefitTM. After 10 days of supplementation no significant difference was observed in mean BT in patients treated with acetylsalicylic acid, ticlopidine or clopidogrel at standard dosages. Similarly, after 20 days of supplementation, the iNr level among patients assuming warfarin or dabigatran was not statistically different from baseline. Lastly, no statistically significant difference in mean levels of glycaemia and glycated hemoglobin was reported before and after 20 days of complementary administration of QuercefitTM in diabetic patients treated with metformin and restricted diet.



"Flavonoids, especially quercetin, are very important biological molecules with proven multiple activities, that potentially may be used to treat several human health conditions. However, the use of Quercetin (QC) has been limited by its low bioavailability until today. — commented Antonella Riva, Product Research Manager Indena — Our daily commitment in finding innovative solutions took us again beyond the poor availability of a precious substance. This effort led us not only to formulate a quercetin extract with the highest profile of bioavailability as Quercefit™, but also to prove scientifically and clinically its activity, efficacy and safety profile, as confirmed by this last study".

"Once again - added Cosimo Palumbo, Indena Marketing Director - Indena's Phytosome[®] delivery system has been successfully applied to one of the best-known and important flavonoids, quercetin. Exploiting its benefits in the sports nutrition category, the safety profile of a Phytosome[®] formulation is once more proven, taking a step forward adding specific evidence in cases of concomitant use of certain medications. Indena confirms to be a reliable partner to count on, a quality-driven producer of outstanding extracts, that are the benchmark in the market".

Quercefit™ is available as a fine powder, it presents good technological properties, it is easy to formulate as stand-alone, in combination with multi-component formulations and versatile in terms of formulative options.

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REFERENCES

- [1] Riva A. et al. Improved Oral Absorption of Quercetin from Quercetin Phytosome[®], a New Delivery System Based on Food Grade Lecithin. Eur J Drug Metab Pharmacokinet. 2018 Oct 16. doi: 10.1007/s13318-018-0517-3.
- [2] Riva A. et al. Quercetin phytosome[®] in triathlon athletes: a pilot registry study Minerva Medica 2018 august;109(4):285-9.
- [3] Riva A et al, Interaction study between antiplatelet agents, anticoagulants, diabetic therapy and a novel delivery form of quercetin. Minerva Cardioangiol. 2018 Sep 13. doi: 10.23736/S0026-4725.18.04795-3.

Indena

Indena is the leading company dedicated to the identification, development and production of high quality active principles derived from plants, for use in the pharmaceutical, health food and personal care industries. Backed up by almost a century of botanical experience, the company holds more than 120 primary patents, has published more than 700 scientific studies and co-operates with the world's most prestigious universities and private research institutions. Indena employs about 800 staff, investing around 10% of its annual turnover in research, making this activity the key to its success. Headquartered in Milan, Indena has 5 production sites and 5 international branches throughout the world and manages sales in more than 80 countries. The Company's experts communicate and interact constantly with the major international regulatory authorities such as WHO, EMA, FDA and ESCOP, and cooperate on the update of all the main pharmacopoeias.

Today, Indena supplies also capacity and expertise for custom manufacturing services and related key technologies. In particular, the company expands its offering with a new kilolab to handle semisynthetic and total synthetic APIs that require high containment (OEL of 20 ng/ m³).



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These statements have not been evaluated by the Food and Drug Administration.

This product is not intended to diagnose, treat, cure, or prevent any disease.