

**Main effects of the medicinal and preventive action of the dietary supplement “Water solution of hydrated C<sub>60</sub> fullerene”, (C<sub>60</sub>FWS), revealed in pre-clinical and clinical trials (January-June 2009).**

**Conclusions from pre-clinical trial reports**

“Investigation of the specific activity and toxic action of water solution of hydrated C<sub>60</sub> fullerene (C<sub>60</sub>FWS)” and “Trials of radioprotective influence of water solution of hydrated C<sub>60</sub> fullerene (C<sub>60</sub>FWS) in the experiment on rats” (National Pharmaceutical University of Ministry of Healthcare of Ukraine, Problem Laboratory of Morphofunctional Research, Head of the Department, Doctor of Sciences in Biology, Professor L.M. Maloshtan, and Grigoriev S.P. Institute for Medical Radiology of National Academy of Medical Science of Ukraine, Laboratory of Radioprotective Drugs, Head of the Laboratory, PhD in Biology, senior scientist Ye. M. Mamotyuk).

In the course of nonclinical trials in laboratory animals, the following is determined:

1. In case of continuous intragastric and oral administration, C<sub>60</sub>FWS neither leads to any signs of intoxication, nor disturbs locomotor activity.
2. Introduction (oral or intraperitoneal) of hydrated C<sub>60</sub> fullerene at doses 1000-folds exceeding the ones given as dietary supplement C<sub>60</sub>FWS, does not cause any toxic effects.
3. C<sub>60</sub>FWS demonstrates membrane-stabilizing and anti-cytolytic action, which is manifested by the decreased level of spontaneous haemolysis and peroxidation of cell membrane lipids.
4. C<sub>60</sub>FWS demonstrates cardioprotective action, suppresses the formation of myocardial doxorubicin toxicity, having evident normalizing action on the functional state of cardiac muscle. Increases processes of protein synthesis in it.
5. C<sub>60</sub>FWS suppresses stress strain at physical load, prevents the development of adrenal hypertrophy and improves physical capabilities of the organism.
6. C<sub>60</sub>FWS intake promotes improved physical stamina in animals and has evident adaptogenic action.
7. C<sub>60</sub>FWS has anti-inflammatory and anti-exudative action.
8. C<sub>60</sub>FWS demonstrates evident antiulcer and tissue regenerative action.

9. C<sub>60</sub>FWS promotes recovery of haemodynamics and trophic processes in liver against the background of subchronic toxic hepatitis, induced by tetrachloromethane and ethanol.
10. C<sub>60</sub>FWS does not produce any toxic effect on enzyme synthetic ability of the liver, does not act as cytolytic, but has evident hepatoprotective action.
11. C<sub>60</sub>FWS produces marked radiological defense (preventive and medicinal) and radioprotective action, as well as extends survival rate of animals, totally radiation-exposed to sublethal doses of X-radiation.
12. Only positive medicinal and preventive efficacy of C<sub>60</sub>FWS in all cases studied, one way or another, is connected with its powerful anti-oxidative properties, exceeding manifold those of well-known antioxidants, such as vitamin E, Quercetin, and Carsil.

Comparative analysis of C<sub>60</sub>FWS application in pre-clinical trials demonstrated that having comparative or even better medicinal and preventive action, total doses of hydrated C<sub>60</sub> fullerene (in the form of C<sub>60</sub>FWS) were on average 4-5 orders of magnitude less than those of reference drugs conventionally used at therapy of the selected pathology models.

Full texts of reports on pre-clinical trials can be found [here](#).

### **Conclusions from clinical trial reports:**

“Efficacy of fullerene application in complex therapy of patients with ulcerative disease” and “Efficacy of application of biologically active supplement “Water Solution of Hydrated C<sub>60</sub> Fullerene” in complex therapy of patients with chronic hepatitis of toxic genesis” (Kharkov National Medical University, 3-nd Department of Internal Medicine, headed by: Honored Worker of Science and Technology of Ukraine, Doctor of Sciences in Medicine, Professor V. N. Khvorostinka).

In the course of clinical trials the facts revealed in nonclinical trials have been confirmed, and the following is determined:

1. C<sub>60</sub>FWS is devoid of any harmful effects, including toxic ones, on the human organism.
2. C<sub>60</sub>FWS has evident immunotropic effects and is devoid of any toxic effects on hematopoietic system.
3. C<sub>60</sub>FWS demonstrates stimulating influence on macrophage function.
4. C<sub>60</sub>FWS demonstrates potentiating action on restoration of hepatocyte functional state.
5. C<sub>60</sub>FWS demonstrates «wise» and long-term antioxidative activity due to regulation of free radical level in the nidus of inflammation, as well as activates own endogenous antioxidative systems of the organism.
6. C<sub>60</sub>FWS provides increased metabolic potential of the organism.
7. C<sub>60</sub>FWS has powerful regenerative, wound-healing and bactericidal properties, which promotes more rapid processes of healing by granulation and scarring in ulcer patients.
8. Anti-inflammatory and regenerative properties of C<sub>60</sub>FWS are manifested in cooperation of immune, metabolic and microcirculation reactions of the organism, aimed at healing of duodenal ulcers.
9. C<sub>60</sub>FWS provides optimization of neurovegetative regulation mechanisms of stomach secretory function; and its inclusion into complex therapy in duodenal ulcer (DU) patients promotes restoration of acid-forming function of the stomach.

10. C<sub>60</sub>FWS promotes normalization of clinical blood analysis indexes in DU patients, which is associated with evident anti-inflammatory effect of the treatment and absence of any toxic effects of C<sub>60</sub>FWS.
11. C<sub>60</sub>FWS has evident antimicrobial activity against *H. pylori*; it also enhances susceptibility of *H. pylori* to conventional medicinal treatment.
12. C<sub>60</sub>FWS promotes more rapid decrease of asthenovegetative, dyspeptic and abdominal pain syndromes.
13. C<sub>60</sub>FWS provides effective humoral immune protection, which is connected both with completion of autoimmune reactions, and restoration of own barrier properties of intestine mucous. The latter effect is interrelated with restoration of drainage properties of the mucous at the level of gastrointestinal cell membrane glycocalix.
14. C<sub>60</sub>FWS enhances the activity of proliferative processes against the background of decreased autoimmune aggression and improves identification of own antigenic determinants of the organism of the patient.
15. Alteration of immunoglobulin level is associated with *H. pylori* elimination, decrease in inflammation phenomena and normalization of identification processes of own antigens. In other words, C<sub>60</sub>FWS promotes restoration of identification of cells by type “friend-or-foe” and inhibition of autoimmune graft-versus-host reaction.
16. C<sub>60</sub>FWS application has positive effect on hepatocyte functions, restoration of protein, lipid and enzyme exchange, improves metabolic and oxidation-reduction processes in the organism, reduces inflammatory and fibrosing processes in the liver.
17. C<sub>60</sub>FWS is capable to destroy protective structural barriers of pathogenic microorganisms; it promotes activation of phagocytic reaction and this way it promotes overcoming of drug resistance of pathogenic agents in human.
18. C<sub>60</sub>FWS application accelerates 2-3-folds the term of convalescence at concomitant use with traditional treatment regimens.

Full texts of reports on clinical trials can be found [here](#).