The request of preparing the ADDITION TO THE EXPERT’S REPORT for traditional herbal medicine VARUMIN® - 2 was submitted by Inter-evrogeneks, Novo Selo, Republic Macedonia.

On the base of decision of the Expert collegiums of the Department of Preclinical and clinical Pharmacology and toxicology at Medical Faculty in Skopje, I was chosen to make an EXPERT’S REPORT for traditional herbal medicine VARUMIN® - 2, submitted by Inter-evrogeneks, Novo Selo, Republic Macedonia.

After the study of the submitted documentation to me and other relevant information I suggest to the Expert collegiums of the department to accept this text like EXPERT’S REPORT for traditional herbal remedy VARUMIN® - 2.
1.0 FORM AND COMPOSITION

Form: solution for oral administration

2.0 GENERAL INFORMATION FOR THE PRODUCT

Varumin® 2 is traditional herbal medicine (solution for oral administration), which in his composition contains water extract from herbal drugs and aloe dry extract, which are in fact their main active components of the herbal remedy. Varumin® 2 in combination with Varumin® 1 is assigned for improving the general state of the organism when exhausted, for increasing the power of resistance, like adjuvant therapy to the standard therapy in various acute and chronic illnesses, malignant diseases, anemias and in other positions which are characterized with lessen immunity and bad general condition.

7.0. EFFECTS OF THE PRODUCT USE

Varumin 2 is traditional herbal remedy for improving of the general state of the body if exhausted, for increasing of the resistance, like adjuvant in standard therapy of acute and chronicle diseases, malignant diseases, anemia and other states that are characterized with lessen immunity and bad general state.

8.0. DOSING AND POSOLOGY

VARUMIN® 1 is assigned for oral combine use with product VARUMIN® 2 as on the scheme:

VARUMIN® 1: at the beginning of the therapy, drink the whole amount (50 ml) of VARUMIN® 1. After 6 hours begin to take VARUMIN® 2.

VARUMIN® 2: to take 4 times a day, one soupspoon before meal.
9.0. PRECAUTION OF THE PRODUCT USE

(Joanne Barnes 2002; PDR for Herbal Medicines 2002; WHO 1999).

VARUMIN® 1 must not be used at:

- Persons extremely sensitive to some of the components of the preparation;
- Children under than 10 years
- Persons with intestinal obstruction;
- Persons with inflammatory intestinal illnesses (Khron disease, ulcer colit);
- Inflammatory of the appendix (appendicitis) and stomach-ache with enigmatic etiology;
- During pregnancy,

9.2. Interactions

Long term use of aloe preparations together with cardiac glycosides and anti-arrhythmic drugs can take to excessive lose of potassium and to assignee the effect of cardiac glycosides and antiarytmic drugs.

Parallel use of the aloe preparations with tiazide diuretics and corticosteroids increases the possibility of potassium deficient.

Drugs that contain Viscum album can stress the effect of the cardiac glycosides, anti hypertensive, anti-depressives and anti-coagulants.

Patients who use at the same time selective inhibitors of the overtaking of the serotonin (exam. sertralin) and preparations based on St John’s worth the increasing of the level of serotonin is registered. All the knowledge suggested that St John's have affection on the hepatic citochrom P450 system, by enlarging of the activity of the isoenzyme CYP3A4, worth may reduce the activity of some medicaments which are used at the same time known as the replacements of that enzyme, lake no sedative antihistamines, oral contraceptives, amprenavire, some antiretroviral medicaments, antiepileptic, Ca-blocators, cyclosporine, some chemotherapeutics, macrolititic, antibiotics and certain antifungal medicaments.

9.3. The measures of precaution and warning

Prolonged use of preparations that contain aloe can provoke:

- hypersensitive reactions which manifest themselves with papular dermatitis and eczematous formations;
- losing of electrolytes (especially potassium), which can result in hyperaldosteronism, inhibition of the intestinal motility and stressing the activity of the cardio active medicaments;
- gastrointestinal difficulties, heart arrhythmia and nephropathies (in rare circumstances);
- albuminuria and chematuria
9.4. Adverse effects

Stomach-ache and spasms can appear in application even if one dose of preparations that contain aloe. Chronicle use of laxatives (like the extract of aloe) can provoke electrolytic misbalance (hypo potassium and hypocalcaemia), metabolite acidosis, and malabsorption; lose in weight, albuminuria and chematuria. Weakness and orthostatic hypotension can be expected in aged patients, after long-term of use of extracts of aloe. Steatorea and gastroenteropathy with hypoalbuminemia are registered at some patients on aloe therapy. Malanotics pigmentation on the colon mucosa (pseudomelanosis coli) is registered at patients who take antrahinon laxatives for long period of time. This pigmentation is from reversible character and is withdrawn after 4-12 months after the interruption of the therapy.

10.0 RATIONALITY OF THE COMBINATION

Varumin® 2 is traditional herbal medicine (solution for oral administration), which in his composition contains water extract from herbal drugs and aloe’s dry extract, which are the main active components of the herbal remedy. In the sufficient literature there is lots of information which lead to the wide applications of these compounds in traditional and homeopathic, also in scientific medicine. In the elaborated literature there are no data about the possible interactions or incompatibilities between the composing components of the product.

11.0 PACKAGING

- Glass bottle with 200 ml solution for oral use.
12.0 CONCLUSION

Varumin® 2 is preparation (solution for oral administration), which in his composition contains water extract from herbal drugs; aloes dry extract and propolis, which are the main active components of the herbal remedy.

Varumin® 2 is traditional herbal medicine which in combination with Varumin® 1 is assigned for improving of the general state of the body if exhausted, for increasing of the resistance, like adjuvant in standard therapy of acute and chronic diseases, malignant diseases, anemia and other states that are characterized with lessen immunity and bad general state.

In the sufficient literature for the active compounds of the herbal remedy there are many data which lead to the wide applications of these compounds in traditional and homeopathic, also in scientific medicine. The active ingredients of the product have laxative, anti-inflammatory, anti-microbe, immune-stimulative, detoxificative, citotoxic, diuretic, anti-depressive and other actions. These pharmacodinamic characteristics of the some compounds of the Varumin 2 justified the purposed field of action.

On the base of the above mentioned in this Expert report, I consider that Varumin 2 – product of the company Inter-evrogeneks, Novo Selo, R. Macedonia, fulfilled the conditions on his composition and characteristics, directed for the traditional herbal medicines of that kind and can be registered in R. Macedonia.

The Expert report is made by

Prof. d-r Stojmir Petrov
The Expert collegiums of the Department of Preclinical and clinical Pharmacology and toxicology, on his meeting on the 18.12.2009, make an overview on the text of the EXPERT’S REPORT for traditional herbal medicine VARUMIN® - 2, a product of the company Inter-Evrogeneks, Novo Selo, Republic of Macedonia and it has been adopted.

Director
Prof. d-r Petar Milosevski
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