

Pursuant to Article 5, paragraph 1, item 5 and Article 37 of the Law on Drugs and Medical Devices (Official Gazette no. 106/07,88/10. 36/11 and 53/11, 136/11, 11/12, 14713, 27/14 and 43/14), considered the request from Inter-evrogeneks Ltd., Novo Selo for registration of traditional herbal medicinal product, the Ministry of Health –Agency of medicines shall make a

DECISION

1. TO RENEW THE APPROVAL of the registration of the traditional herbal medicine

Name of the medicine: VARUMIN 1® (ВАРУМИН 1®) oral solution
Manufacturer: INTER-EVROGENEKS Ltd. – Novo Selo, Republic of Macedonia
Pharmaceutical dosage form: herbal tea
Content:
100 ml solution contains:
Liquid extract of herbal drugs.....99,5 g
Dry standardized extract of aloe....0,30 g
Packaging: dark glass bottle x 50 ml/box

100 ml liquid extract contains:
Visci herba.....1,00 g
Propolis.....0,80 g

VARUMIN 2 (ВАРУМИН 2) oral solution

Content:
100 ml solution contains:
Liquid extract from herbal drugs.....99,0 g
Dry standardized extract of Aloe.....0,80 g

100 ml liquid extract contains:
Inulae radix.....1,60 g
Visci herba.....1,20 g
Cornus cortex.....0,60 g
Calendulae flos.....1,00 g
Milefolii herba.....0,40 g
Cynodon rhizome....1,50 g
Hyperici herba1,40 g

Package: dark glass bottle x 200 ml/box
Dispensing of medicine: The traditional herbal tea is released at a pharmacy without a prescription.

2. The summary of product characteristics, package leaflet and packaging is an integral part of this decision.
3. The approval for registration of the traditional medicine applies indefinitely.

Explanation

Inter-Evrogeneks Ltd. Novo Selo, has submitted request to Ministry of Health for a renewal of the approval for registration of the traditional herbal medicine under name, content, pharmaceutical dosage form and package, provided along with this Decision and in accordance to the Rules for renewal of the approval of the registration of herbal medicines (Official Gazette of RM, no. 65/08). Together with the application for marketing authorization, the manufacturer has submitted the necessary documentation. The Commission for traditional herbal medicines in Ministry of Health, considering the requirement of registration data found that data from the Article 44-a, from the Law determined that the data contained in the submitted documentation and made a proposal

to renew the approval of the registration and to put the medicine in further circulation for indefinite time.

Based on the opinion of the Commission for traditional herbal medicinal products, Ministry of Health –Agency for medicines made a decision in compliance with the Law for drugs and medical devices as in the enclosed documents.

The fee for this Decision is collected according to tariff number 67 of the Law of administrative fees (Official Gazette of RM, no. 6/10).

LEGAL ADVICE: Against this decision may be appealed within 15 days after receipt to the State Commission for deciding in administrative proceedings and procedure employed in the second degree in Government of Republic of Macedonia.

- SUBMITTED TO:
- The holder of the approval
 - Archive

Prepared by: M. Hadzihamza

Approved:

DIRECTOR OF BUREAU OF PUBLIC REMEDIES Mr. pharm. Special. Marija Darkovska Serafimovska /signed illegibly/ /blue seal affixed/	DEPUTY MINISTER Jovica Andovski /signed illegibly/ /official round blue seal of the Ministry of Health, affixed/
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I confirm that this translation from Macedonian into English language and vice versa is true to the original document presented.
I affix my official seal and signature.
Vesna Tanceva, authorized juridical translator from/into English language.

Потврдувам дека преводот од англиски на македонски јазик и обратно, е верен на оригиналниот презентирани документ.
Тврдам со својот потпис и службен печат.
Весна Танчева, постојан судски преведувач од/на англиски јазик.

Republic of Macedonia
Strumica, November 22nd, 2014
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Струмица, 22/11/2014
B. Tanceva

