Clinical Study Synopsis for Public Disclosure

This clinical study synopsis is provided in line with **Boehringer Ingelheim's *Policy on Transparency and Publication of Clinical Study Data***.

The synopsis - which is part of the clinical study report - had been prepared in accordance with best practice and applicable legal and regulatory requirements at the time of study completion.

The synopsis may include approved and non-approved uses, doses, formulations, treatment regimens and/or age groups; it has not necessarily been submitted to regulatory authorities.

A synopsis is not intended to provide a comprehensive analysis of all data currently available regarding a particular drug. More current information regarding a drug is available in the approved labeling information which may vary from country to country.

Additional information on this study and the drug concerned may be provided upon request based on **Boehringer Ingelheim's *Policy on Transparency and Publication of Clinical Study Data***.

2. SYNOPSIS

Name of company: Boehringer Ingelheim		**Tabulated Study Report**		**(For National Authority Use only)**
Name of finished product: Ginsana® capsules				
Name of active ingredient: Standardised G115 Ginseng extract, adjusted to 4% ginsenosides		**Page:**	**Number:**	
Ref. to Documentation:	**Volume:**	**Page:**	**to**	**Addendum No.:**
Report date: 12 May 2000	**Number:**	**Study period (years):** March 99 to October 99		

Title of study:	Efficacy of Ginsana® in improving half-time haemoglobin re-oxygenation in recreational sportspeople: a double-blind, placebo controlled pilot study
Investigator:	[redacted]
Study centres:	2
Publication (reference):	
Clinical phase:	II
Objectives:	To assess the efficacy of Ginsana® in improving half-time haemoglobin re-oxygenation in healthy, recreational sportspeople and to assess the safety of the product.
Methodology:	Randomised, double-blind, placebo-controlled, parallel group design according to international Good Clinical Practice (GCP)
No. of subjects entered:	
total:	29
each treatment:	Placebo 14; Ginsana® 15
Diagnosis and main criteria for inclusion:	Volunteer recreational athletes, aged 18 to 40, of either sex, who took part in physical activity of moderate intensity.
Test product:	**Ginsana® capsules**
dose:	1 x 100mg capsule twice daily (b.i.d.) (200 mg/day)
mode of admin.:	per os (p.o.)
batch no.:	828115
Duration of treatment:	12 weeks
Reference therapy:	Placebo
dose:	1 capsule b.i.d.
mode of admin.:	p.o.
batch no.:	835209

Name of company: Boehringer Ingelheim		**Tabulated Study Report**		**(For National Authority Use only)**
Name of finished product: Ginsana® capsules		**SUPPLEMENTARY SHEET**		
Name of active ingredient: Standardised G115 Ginseng extract, adjusted to 4% ginsenosides		**Page:**	**Number:**	
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Criteria for evaluation:

Efficacy:	**Primary Endpoint:** Baseline-adjusted change in half-time haemoglobin re-oxygenation as measured by the Near Infra Red Spectroscopy (NIRS) methodology at day 84
	Secondary Endpoint: Baseline-adjusted change in half-time haemoglobin re-oxygenation as measured by the NIRS methodology at days 21, 42 and 63
	Maximum endurance time and respiratory threshold
	Thiobarbituric acid (TBARS), Glutathione Superdismutase/Glutathione Superdismutase Oxidised (GSA/GSSG)
Safety:	Adverse event reporting, general clinical assessment at the start and end of the study; laboratory screen of haematology and blood chemistry
Statistical methods:	Descriptive statistics; t-tests of all the primary and secondary endpoints, Wilcoxon rank-sum tests where the assumptions of normality were not satisfied; Fisher's exact test for the global assessment of tolerability; tabulation of incidence, severity and causal relationship of all adverse events.

SUMMARY - CONCLUSIONS:

Efficacy results:

There were small improvements in the Ginsana® group compared to the placebo group on the parameters half-time to re-oxygenation, maximum endurance time and respiratory quotient. (For the Intent-To-Treat population the change from baseline to Visit 5 for half-time haemoglobin re-oxygenation was a reduction of 3.2 seconds for the placebo group compared to 4.2 seconds for the Ginsana® group. The maximum endurance time increased by 0.2 minutes for the Ginsana® group whilst for the placebo group it reduced by 0.1 minutes. The respiratory quotient reduced by 0.039 in the placebo group whilst the Ginsana® group showed an increase of 0.072.) There was also a considerable placebo effect on some measures. In general, improvement in both groups was maximal at visit 2 and tended to wear off. Overall there were only small differences between active and placebo treatments, often smaller than the placebo change from baseline.

Safety results:

The safety result entirely confirmed the benign safety profile of ginseng, and raised no concerns at all.

Conclusions:

The effect seen on athletic performance was very small, but if consistent might still be regarded as useful by some athletes. Since the safety profile was entirely clean, the risk to benefit ratio was entirely in the direction of benefit.