



Post marketing surveillance

„Eucarbon®“ in Hungary

Final analysis in August 2006

F. TRENKA

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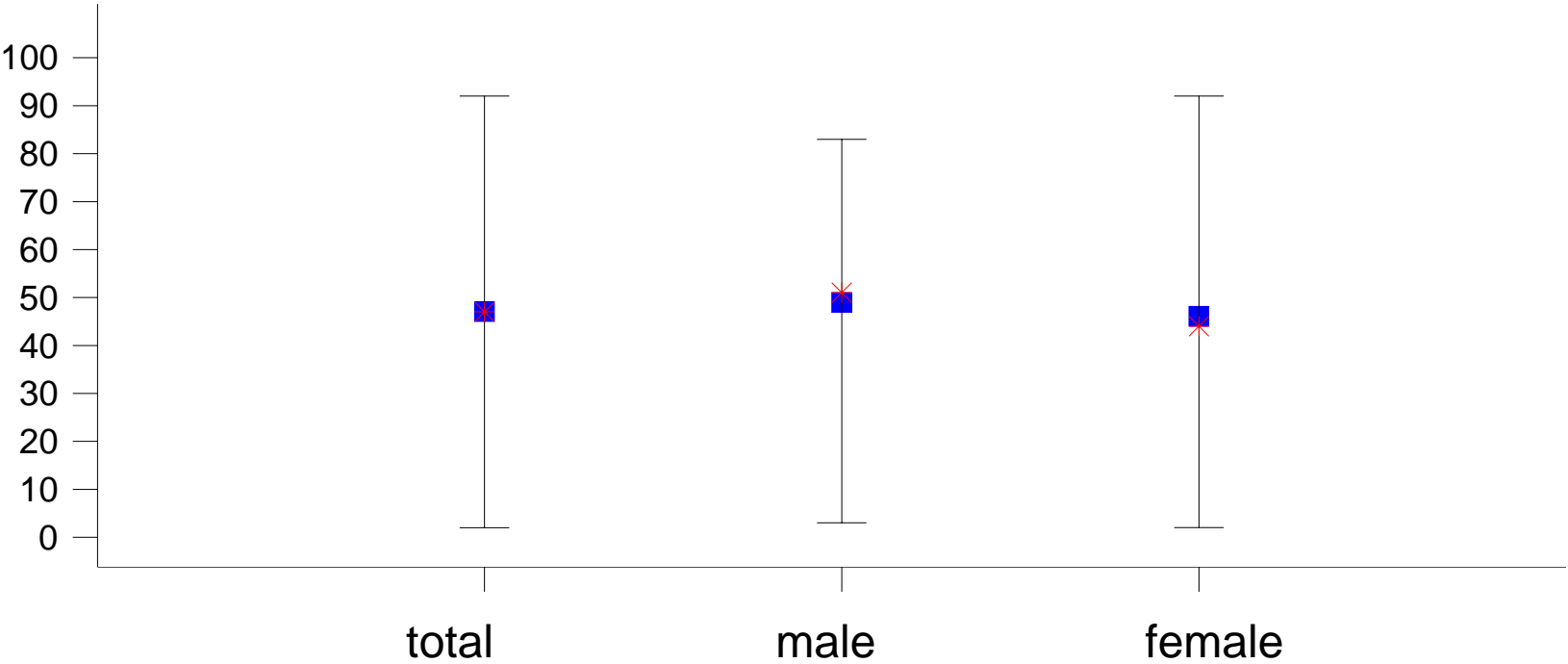
Dr. Robert Heinz & Partner GmbH
Medical Consulting

Demography

Age in Years



Age years
Mean (Min-Max)
x=Median

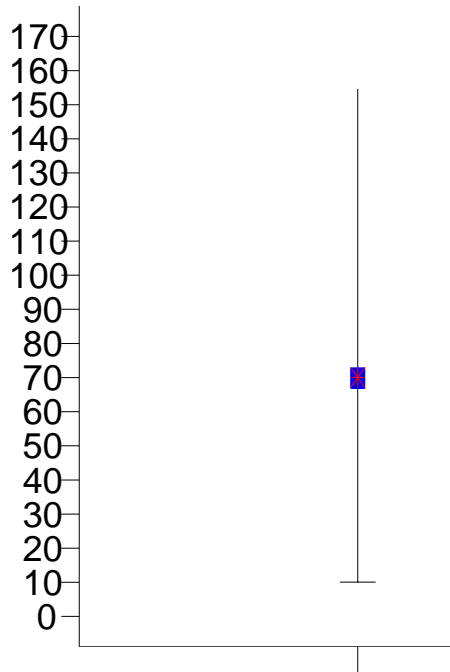




Demography

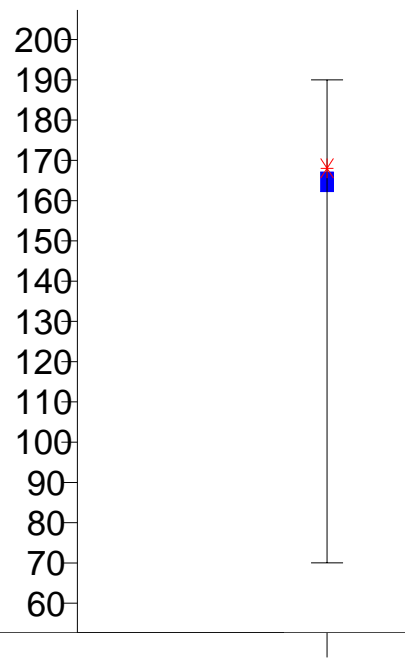
Weight, Height

Weight
Mean (Min-Max)
x=Median



Weight kg

Height
Mean (Min-Max)
x=Median

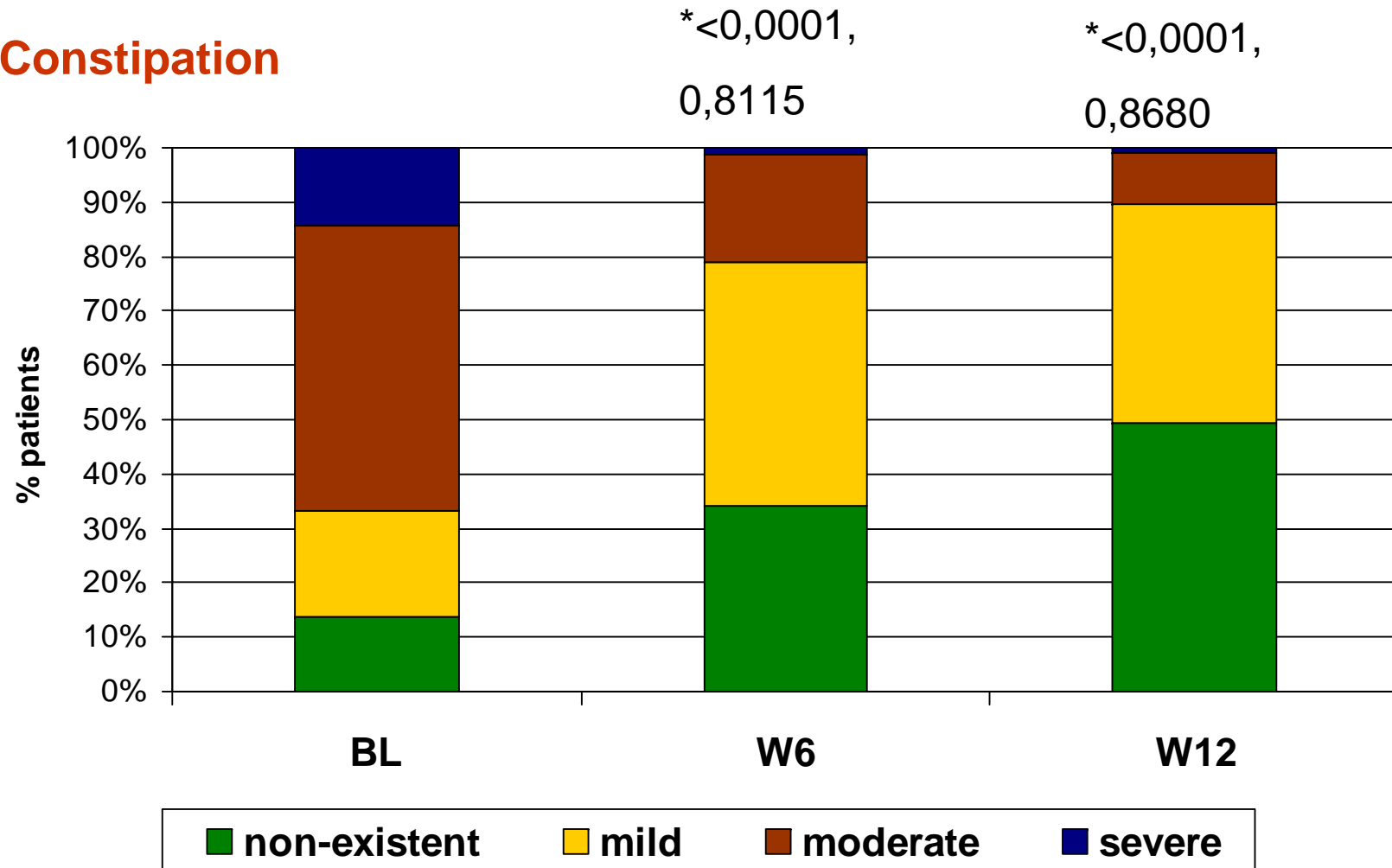


Height cm



Actual condition

Constipation



*Veränderung von BL



Mann-Whitney Values

Large superiority	0,71		
Medium superiority	0,64	→	relevant
Small superiority	0,56		
Equality	0,50		
Small inferiority	0,44		
Medium inferiority	0,36	→	relevant
Large inferiority	0,29		

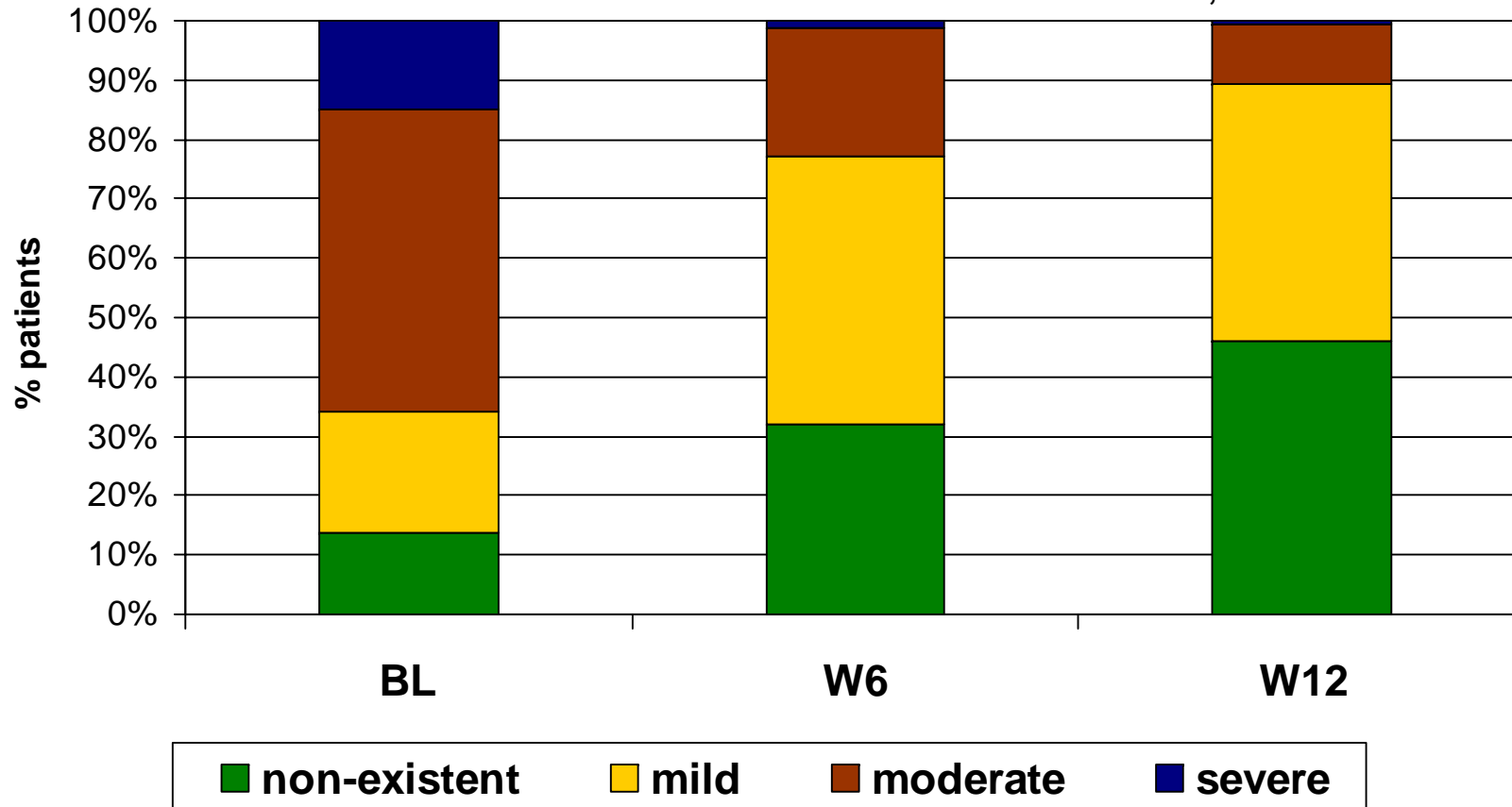


Actual condition

Hard stool

*<0,0001,
0,8024

*<0,0001,
0,8622



*Veränderung von BL

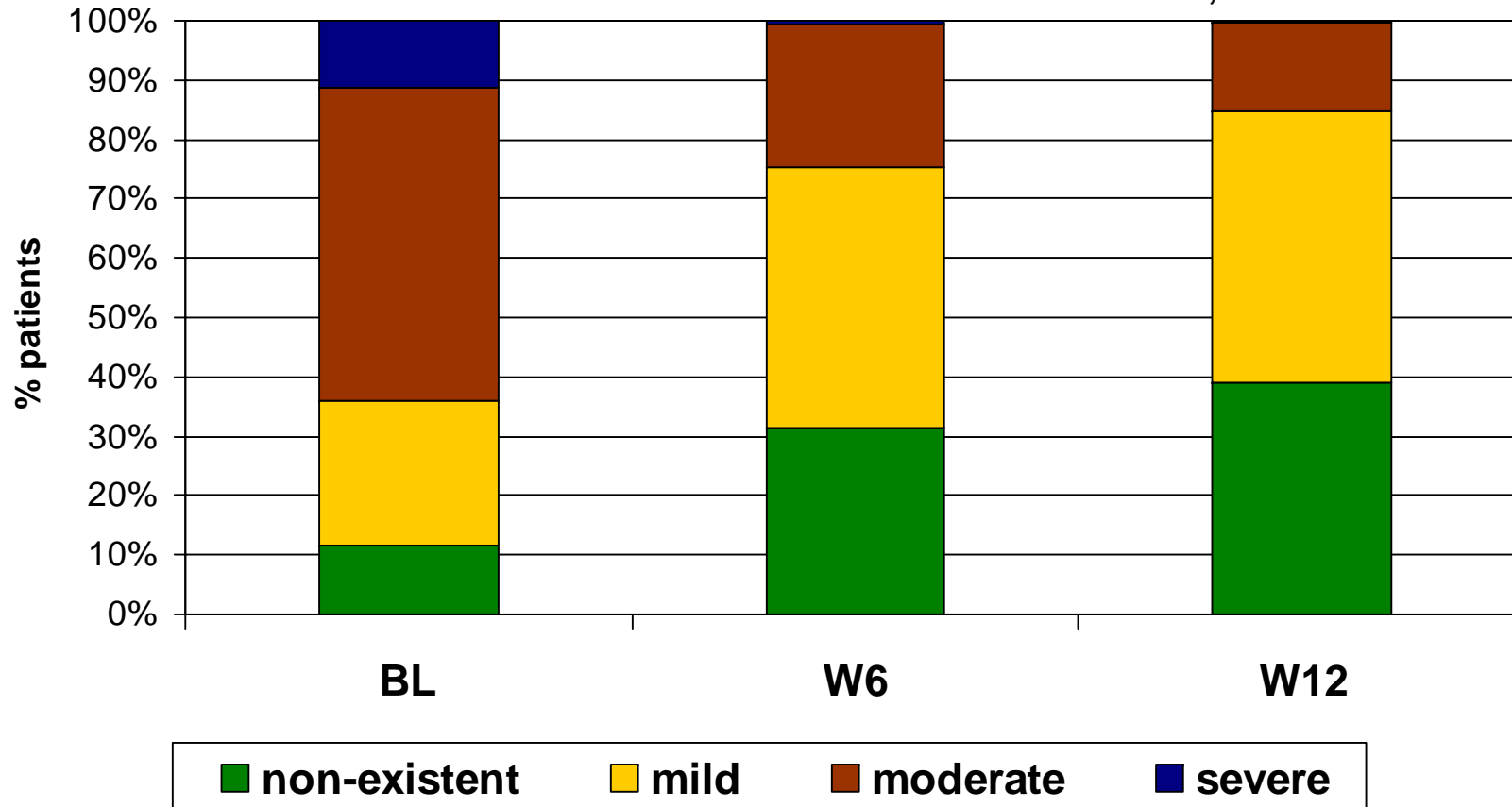


Actual condition

Flatulence

*<0,0001,
0,7866

*<0,0001,
0,8320



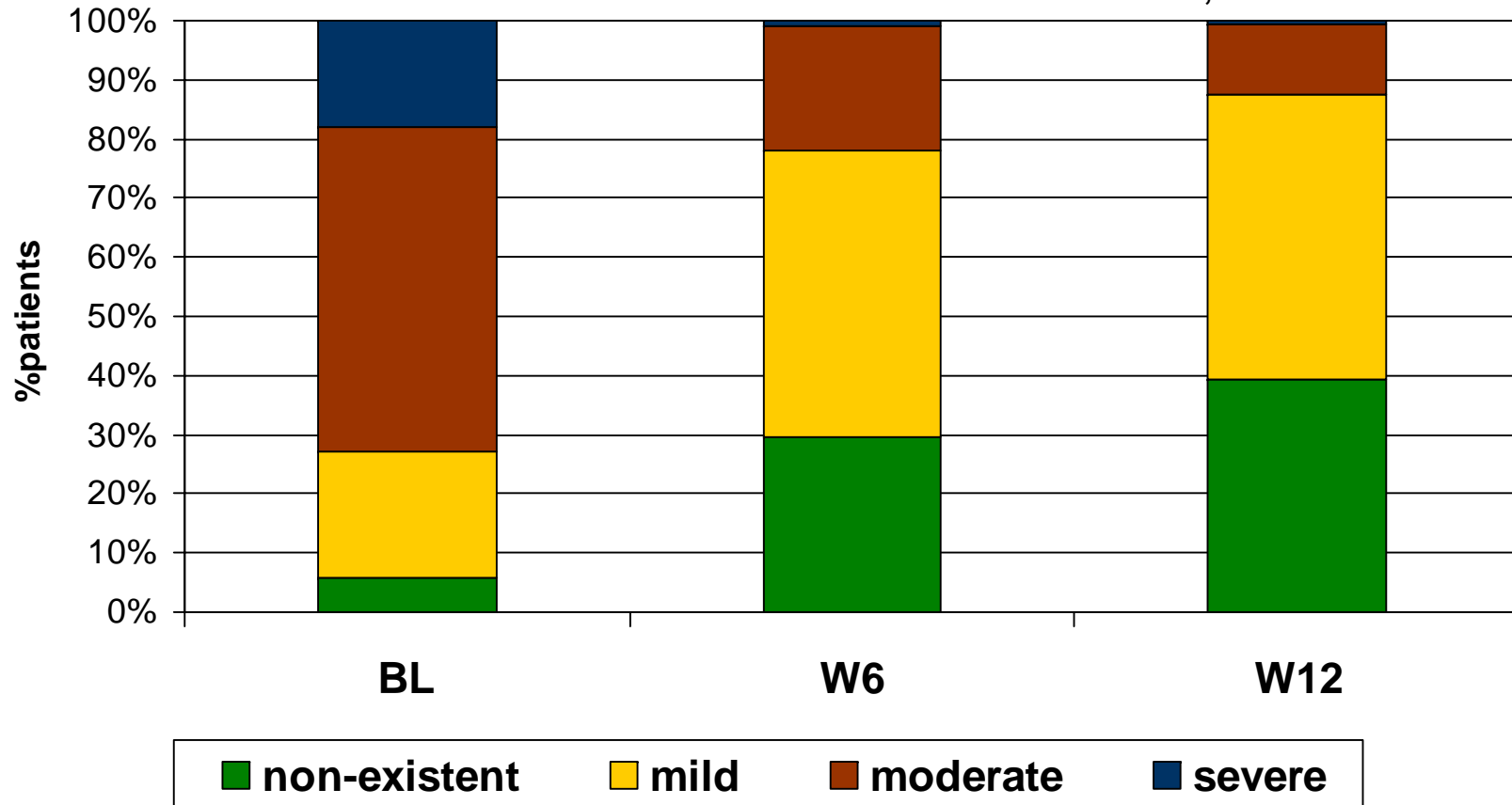
*Veränderung von BL



Actual condition abdominal distension

* $<0,0001$,
0,8402

* $<0,0001$,
0,9003



*Veränderung von BL

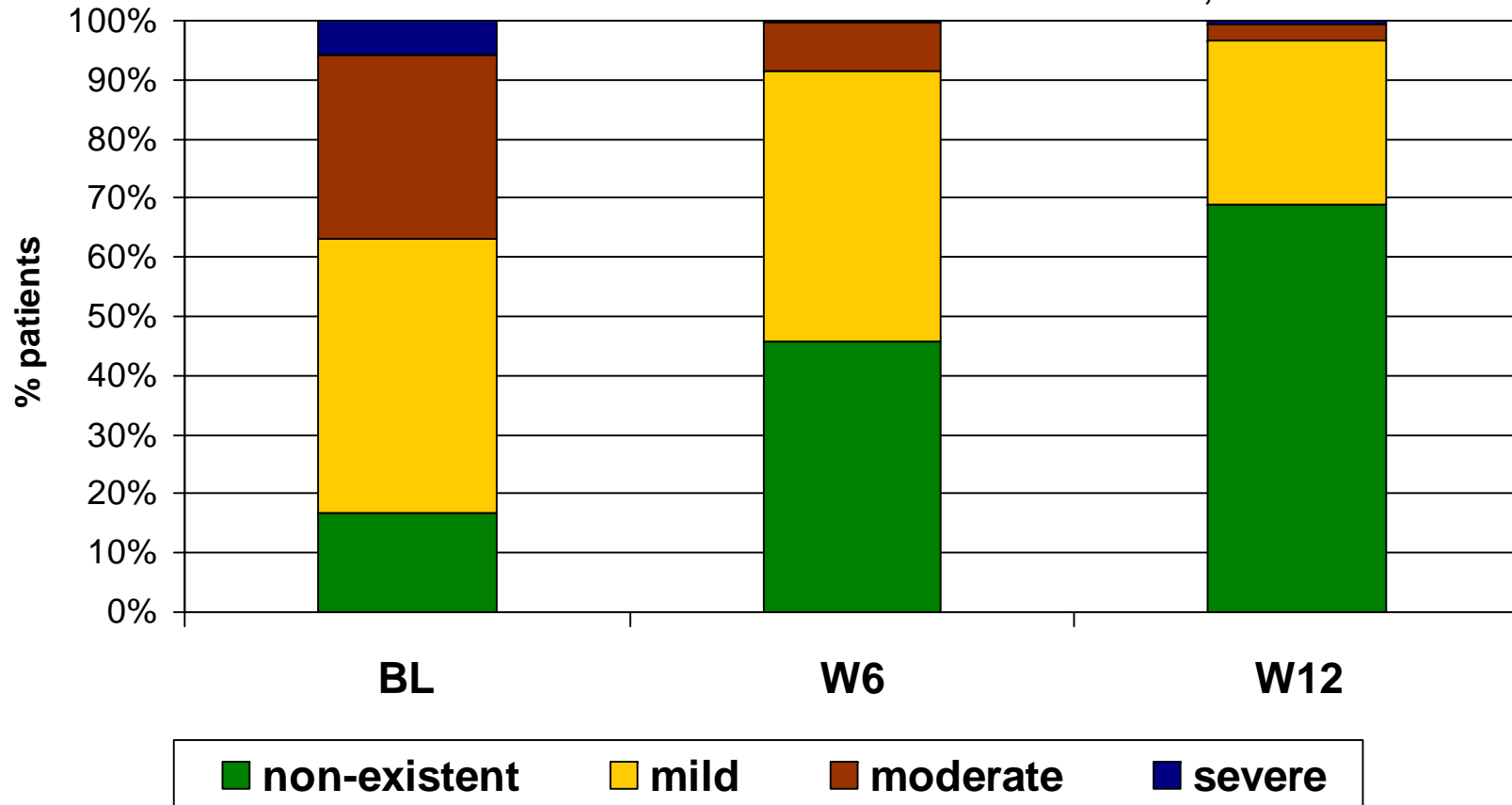


Actual condition

Pain

*<0,0001,
0,8402

*<0,0001,
0,9003



*Veränderung von BL



**Actual conditions/discomforts
without clinical relevant changes during
investigation**

- **diarrhoea**
- **soft stool**
- **liquid stool**
- **abrupt impulse to defecate**
- **abdominal press (W6)**

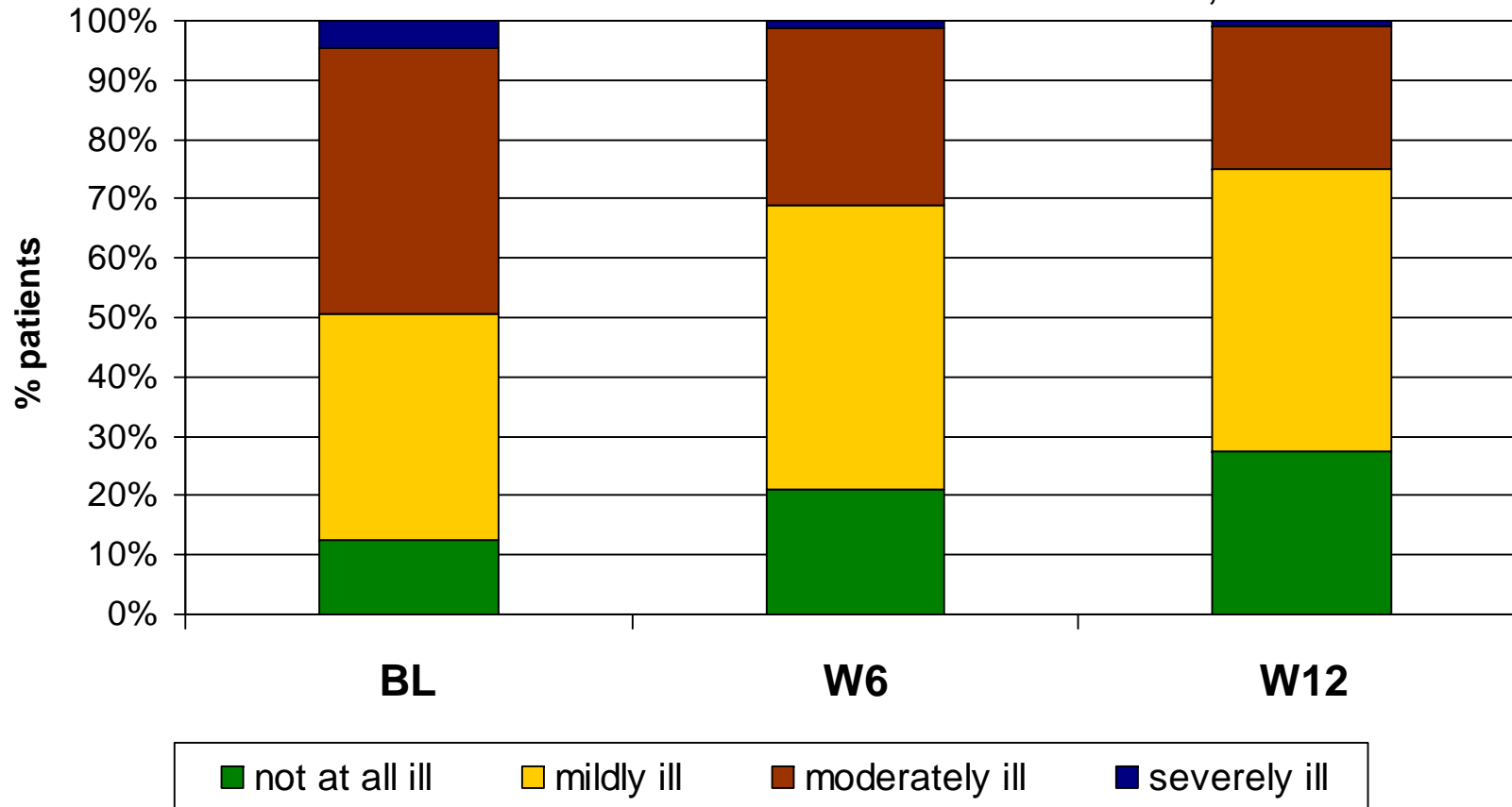


Severity of illness

Done by the physician

* $<0,0001$,
0,6412

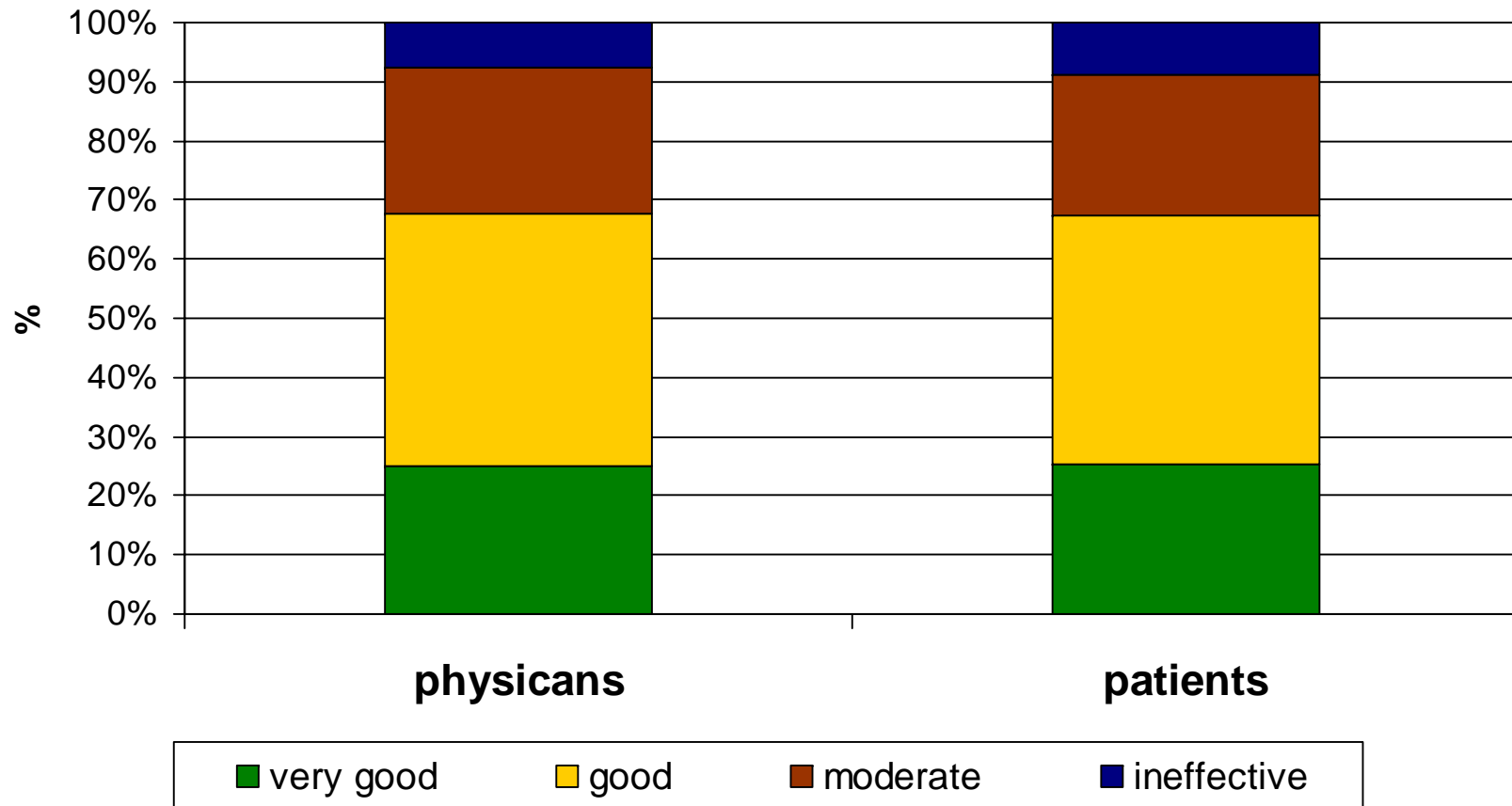
* $<0,0001$,
0,6852



*Veränderung von BL

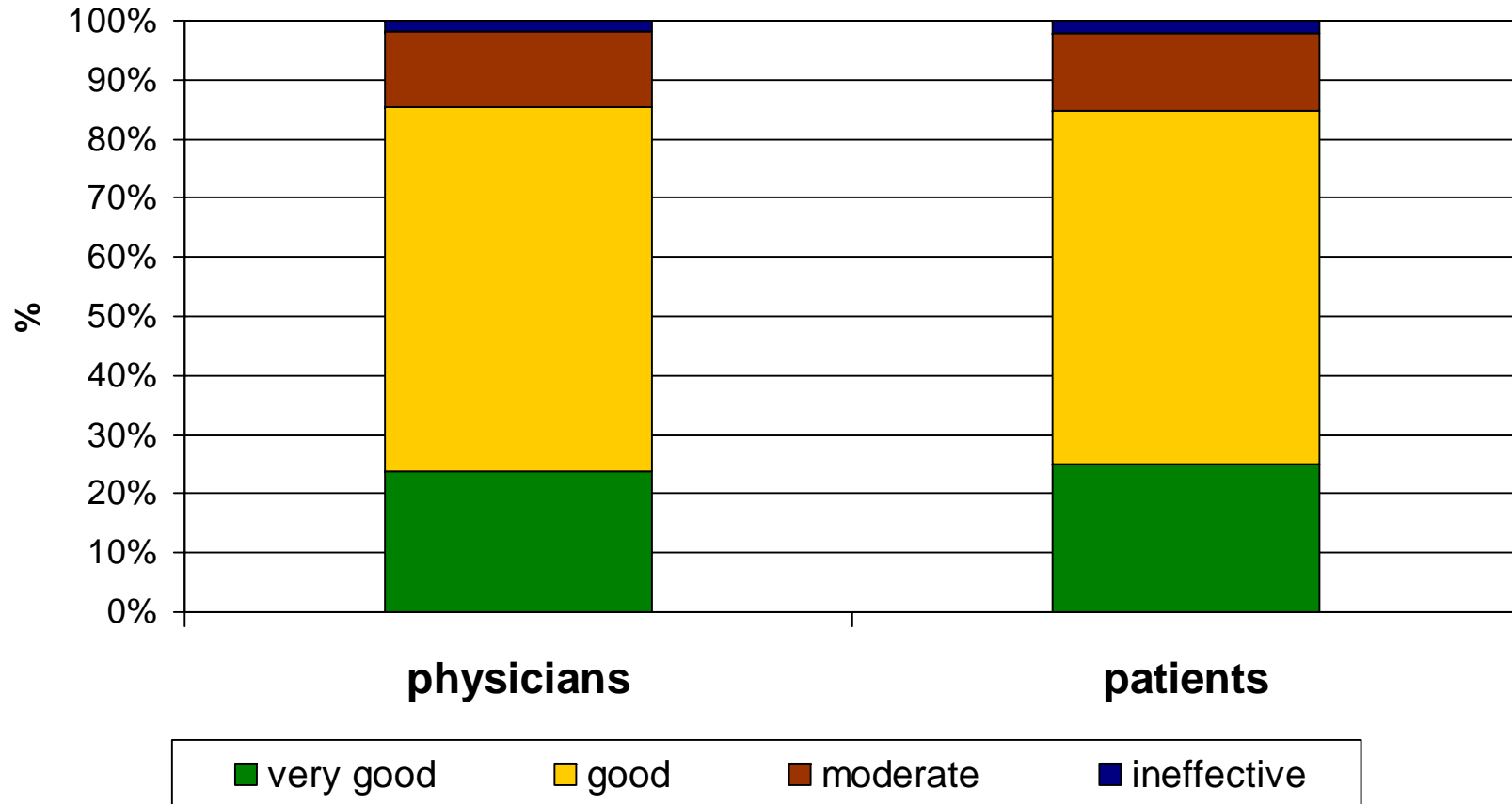


Rating effectiveness





Rating tolerance





Adverse Events

Sum 11 Events:

3 AEs Week6

8 AEs Week12

- **2x Headache**
- **2x Diarrhoea**
- **1x Heartburn and feeling of full stomach and eructation**