J Headache Pain (2001) 2:191–192


# Glossary

**Good clinical practice (GCP)**
International standards of ethics and scientific quality used in the planning, execution, and recording of clinical studies that involve human subjects. Adhesion to good clinical practice (GCP) not only guarantees that the laws, safety and well-being of the subjects who participate in the study, in conformity with the established principles of the Declaration of Helsinki are respected, but also that the findings of the study are reliable

**Intensity of headache**
The degree of head pain is recorded on a verbal analogical scale of 4 points: 0, no headache; 1, light intensity, when headache does not limit normal daily activities; 2, moderate intensity, when headache partially limits the normal daily activities of the patient; 3, severe intensity, when pain is of such an intensity to completely prevent a social life

**Functional disability**
The functional impairment of the migraine patient is recorded on a verbal analogical scale of 4 points: 0, no disability, the patient has a normal functional ability; 1, the performance of the patient is slightly impaired but he can, however, carry out normal daily activities; 2, the performance of the patient is moderately impaired and he can only carry out some daily routine activities; 3, the performance of the patient is severely impaired, he cannot carry out any routine daily activities and may need to stay in bed

**Efficacy parameters for migraine**
***Symptomatic treatment***
*Headache response*
Reduction of pain intensity from severe or moderate to light or absent. It is measured in the patient at certain time points (e.g. 1 hour, 2 hours, 4 hours) compared with the baseline time (before taking the study drug)

*Headache-free patients*
Percentage of patients without headache at defined time points (e.g. 15 minutes, 30 minutes) after taking the study drug

*Sustained headache response*
Percentage of patients with no headache at two hours, without taking an escape medication and with no headache recurrence within 48 hours

*Effectiveness on accompanying symptoms*
Percentage of patients free of nausea, vomiting, photophobia and phonophobia at defined time points compared with baseline (before the administration of the study drug)

*Effectiveness on functional disability*
Percentage of patients with partial or total recovery of functional disability at defined time points compared with baseline (before the administration of the study drug)

*Need for an escape medication*
Necessity to take a drug different from the one on which the effectiveness is being assessed, due to a recurrence of headache

*Headache recurrence*
Worsening of headache (to moderate or severe pain) within 24 hours of treatment and subsequent to headache response (mild or no pain)

*Headache relapse*
Headache recurrence occurs when the patient is pain-free at two hours and a headache of any intensity reappears within 48 hours

*Consistency*
Maintenance in the effectiveness of the treatment in subsequent attacks

***Prophylactic treatment***
*Efficacy*
A treatment is considered efficacious when it reduces the frequency or intensity of the attacks by at least 50%

**Efficacy parameters for cluster headache**
***Symptomatic treatment***
*Pain-free patients*
Percentage of pain-free headache patients at defined time points (e.g. 1, 2, 4 hours) after taking the study drug

*Effectiveness on functional disability*

Percentage of patients with partial or total recovery of functional disability at defined time points (e.g. 15 minutes, 30 minutes) after taking the study drug

***Prophylactic treatment***

*Efficacy*

A treatment is considered efficacious when it induces a rapid disappearance of the attacks and consequently the end of the cluster phase. Secondary objectives are the reduction in the frequency, intensity and duration of the attack by at least 50%

**Non-responders**

Patients who do not have a significant headache response to a defined symptomatic treatment and no response is confirmed in other attacks (at least 3)

**Serious side effects**

Any unfavorable clinical event that, at any dosage:

- Is fatal
- Puts life in danger
- Requires the hospitalization of the patient or a prolonged recovery
- Results in a persistent or significant invalidity
- Causes a congenital abnormality or a defect at birth

**Side effects**

Any unfavorable clinical event that occurs after the administration of the study drug. Side effects are distinguished on the basis of the frequency in: rare, <1/10,000; occasional, inclusive between 1/10,000 and 1/100; and frequent, >1/100 cases. They may be distinguished on the basis of the severity into severe and not severe side effects