**Table 2:** Nimotuzumab toxicity. General profile of toxicity in the clinical study by patients and adverse events.



**Content**

|  |  |
| --- | --- |
| **Adverse Events (AE)** | **Nimo (%)** |
| Patients with any adverse event | 53 (70.7) |
| Patients with any adverse Related to the treatment | 18 (24) |
| Patients with any adverse event grade 3 and 4 | 34 (45.3) |
| Patients with any adverse event grade 3 and 4 Related to the treatment | 4 (5.3) |
| Patients with severe adverse Events | 14 (18.7) |
| Patients with any severe adverse Events Related to the treatment | 3 (4) |
| Adverse Events  | 354 (100) |
| AE Related to the treatment | 83 (23.4) |
| AE grade 3 and 4 | 61 (17.2) |
| AE grade 3 and 4 Related to the treatment | 4 (1.1) |
| ***Severe Adverse Events (SAE)\**** | ***71 (20.1)*** |
| SAE Related to the treatment | 4 (1.1) |

\*71 patients had some SAE related to nimo, considered more frequent when it appeared 3 or more times.

Of the 9 classified as severe, 2 were anemia, 1 asthenia, 5 pains, 1 cystitis and of the very serious 2 were pain.

There were only two reported rash with light intensity and no related deaths were reporte

|  |  |  |
| --- | --- | --- |
|  | **SAE Patients (%)** | **Total** |
|
| **MILD** | **MODERATE** | **SEVERE** | **VERY SEVERE** |
| **PAIN TUMOR RELATED** | 5 (7.0) | 9 (12.7) | 5 (7.0) | 2 (2.8) | 21 (29.5) |
| **COUGH** | 3 (4.2) | 4 (5.6) | 0 (0.0) | 0 (0.0) | 7 (9.9) |
| **ANEMIA** | 0 (0.0) | 3 (4.2) | 2 (2.8) | 0 (0.0) | 5 (7.0) |
| **CYSTITIS** | 3 (4.2) | 1 (1.4) | 1 (1.4) | 0 (0.0) | 5 (7.0) |
| **ASTHENIA** | 3 (4.2) | 0 (0.0) | 1 (1.4) | 0 (0.0) | 4 (5.6) |
| **VOMITING** | 1 (1.4) | 2 (2.8) | 0 (0.0) | 0 (0.0) | 3 (4.2) |
| **OTHERS** | 16 (22.5) | 10 (14.1) | 0 (0.0) | 0 (0.0) | 26 (36.6) |
| **TOTAL** | 31 (47.3) | 29 (40.8) | 9 (12.7) | 2 (2.8) | 71 (100) |