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| **MedDRA System Organ Class** | **SAF (N=338)** |
| **AEs [n (%)]a** | **ADRs [n (%)]a** |
| Skin and subcutaneous tissue disorders |  190 (56.2) |  176 (52.1) |
| General disorders and administration site conditions |  166 (49.1) |  43 (12.7) |
| Gastrointestinal disorders |  152 (45.0) |  75 (22.2) |
| Investigations |  109 (32.2) |  24 ( 7.1) |
| Neoplasms benign, malignant and unspecified (incl. cysts and polyps) |  65 (19.2) |  1 ( 0.3) |
| Infections and infestations |  62 (18.3) |  5 ( 1.5) |
| Respiratory, thoracic and mediastinal disorders |  43 (12.7) |  5 ( 1.5) |
| Metabolism and nutrition disorders |  38 (11.2) |  14 ( 4.1) |
| Nervous system disorders |  35 (10.4) |  12 ( 3.6) |
| Vascular disorders |  30 ( 8.9) |  9 ( 2.7) |
| Hepatobiliary disorders |  26 ( 7.7) |  0 ( 0.0) |
| Psychiatric disorders |  17 ( 5.0) |  3 ( 0.9) |
| Blood and lymphatic system disorders |  16 ( 4.7) |  3 ( 0.9) |
| Eye disorders |  10 ( 3.0) |  4 ( 1.2) |
| Cardiac disorders |  8 ( 2.4) |  2 ( 0.6) |
| Renal und urinary disorders |  8 ( 2.4) |  0 ( 0.0) |
| Injury, poisoning and procedural complications |  6 ( 1.8) |  2 ( 0.6) |
| Musculoskeletal and connective tissue disorders |  4 ( 1.2) |  0 ( 0.0) |
| Congenital, familial and genetic disorders |  1 ( 0.3) |  0 ( 0.0) |
| Reproductive system and breast disorders |  1 ( 0.3) |  0 ( 0.0) |
| Surgical and medical procedures |  1 ( 0.3) |  0 ( 0.0) |

a Percentages are based on the total number of patients (SAF).

ADR = Adverse drug reaction (AE with causal relationship to erlotinib); AE = Adverse event; MedDRA = Medical Dictionary for Regulatory Activities; SAF = Safety analysis set.