**Appendix**

**Appendix** Adverse events: all adverse events that occurred during the study, listed by SOC group, treatment group, severity, and relationship to study medication

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| --- | --- | --- | --- | --- | --- |
|  | **SOC Group** | **AE** | **Treatment Group** | **Severity** | **Relationship** |
| 1 | blood and lymphatic system disorders | itching and diarrhea after alcohol | omalizumab | mild | unlikely |
| 2 | stomach cramps in the context of mastocytosis | omalizumab | mild | unlikely |
| 3 | weakness, diarrhea, fatigue in the context of mastocytosis | omalizumab | mild | unlikely |
| 4 | attack with sensation of cold, fatigue, diarrhea, depression, weakness, tremor | placebo | moderate | unlikely |
| 5 | gastrointestinal problems and dizziness after withdrawal of mastocytosis medication | placebo | mild | unlikely |
| 6 | Heartburn, rash on the buttock | placebo | mild | unlikely |
| 7 | increased itch and sweating | placebo | mild | unlikely |
| 8 | malaise, precursors of anaphylaxia after white wine and cheese | placebo | mild | unlikely |
| 9 | nausea, vomiting 10 min after last meal, skin burning (mastocytosis crisis) | placebo | mild | unlikely |
| 10 | short deterioration of mastocytosis | placebo | mild | unlikely |
| 11 | sleep disturbances, increased itch and intermittent diarrhea in context of mastocytosis | placebo | mild | unlikely |
| 12 | slight deterioration of mastocytosis | placebo | mild | unlikely |
| 13 | stomach cramps in the context of mastocytosis | placebo | mild | possible |
| 14 | cardiac disorders | rapid heartbeat, arterial hypertension and malaise | omalizumab | mild | unlikely |
| 15 | palpitations | placebo | moderate | unlikely |
| 16 | tachycardia in context with known accessory bundle | placebo | mild | unlikely |
| 17 | eye disorders | conjunctivitis | placebo | mild | unlikely |
| 18 | conjunctivitis | placebo | mild | unlikely |
| 19 | gastrointestinal disorders | treatment of tooth root | omalizumab | mild | unlikely |
| 20 | abdominal pain | placebo | mild | unlikely |
| 21 | diarrhea and nausea | placebo | mild | unlikely |
| 22 | hemorrhoids | placebo | mild | unlikely |
| 23 | oral aphthous ulcers | placebo | mild | unlikely |
| 24 | general disorders and administration site conditions | flu-like infection | omalizumab | mild | unlikely |
| 25 | flu-like infection | omalizumab | mild | unlikely |
| 26 | headache and local pain after injection of Omalizumab | omalizumab | mild | possible |
| 27 | 20 minutes after Arixta 2.5 sc: faintness, speech difficulties, urticaria, vomit | placebo | moderate | unlikely |
| 28 | 24h later on local injection site shoulder muscle pain, abdominal bloating | placebo | mild | possible |
| 29 | 3 minutes after Clexane 40mg sc injection: itching and erythema of neck | placebo | mild | unlikely |
| 30 | chest tightness and epigastralgia | placebo | mild | unlikely |
| 31 | difficultiy in concentration, fatigue, headache | placebo | mild | unlikely |
| 32 | fatigue after introduction of Bilaxten 20mg/day | placebo | mild | unlikely |
| 33 | fatigue, sleepiness with Bilastine 20 mg/day | placebo | mild | unlikely |
| 34 | flu-like infection | placebo | mild | unlikely |
| 35 | flush and dizziness after injection of study medication | placebo | mild | uossible |
| 36 | immune system disorders | allergic reaction to strawberry (known but patient ate them anyway), larynxedema | placebo | moderate | unlikely |
| 37 | infections and infestations | herpes simplex | omalizumab | mild | unlikely |
| 38 | herpes simplex | omalizumab | mild | unlikely |
| 39 | injury, poisoning and procedural complications | accident with knee injury | omalizumab | mild | unlikely |
| 40 | diving accident | omalizumab | mild | unlikely |
| 41 | headache and cervical and diffuse bone pain after rubbery | omalizumab | mild | unlikely |
| 42 | headache and cervical pain after robbery | omalizumab | mild | unlikely |
| 43 | headache and cervical pain after rubbery | omalizumab | mild | unlikely |
| 44 | headache and cervical pain after rubbery | omalizumab | mild | unlikely |
| 45 | headache and cervical, diffuse bone pain pain after robbery | omalizumab | mild | unlikely |
| 46 | headache and cervicale pain after robbery | omalizumab | mild | unlikely |
| 47 | fracture of metatarsale bone and ligament tear right foot after fall on slippery | placebo | mild | unlikely |
| 48 | local infiltration of right foot after metatarsal fracture and ligament tearment | placebo | mild | unlikely |
| 49 | residual oedema of right fracture of metatarsale bone | placebo | mild | unlikely |
| 50 | investigations | ambulant drug provocation Sintrom and observation intensive unit: urticaria neck | placebo | mild | unlikely |
| 51 | ambulant drug provocation Xarelto and observation intensive unit: urticaria neck | placebo | mild | unlikely |
| 52 | elevated liver enzymes | placebo | mild | possible |
| 53 | elevated liver enzymes | placebo | mild | possible |
| 54 | hypercholesterolemia | omalizumab | mild | possible |
| 55 | loss of weight from 85 kg to 72.7 kg and diarrhea after Duphalac use | placebo | mild | unlikely |
| 56 | weight increase | placebo | mild | unlikely |
| 57 | metabolism and nutrition disorders | flush and palpitation after alcohol | placebo | mild | unlikely |
| 58 | musculoskeletal and connective tissue disorders | back pain | placebo | mild | unlikely |
| 59 | back pain | placebo | mild | unlikely |
| 60 | myalgia after back muscle training | placebo | mild | unlikely |
| 61 | myalgia and neck pain | placebo | mild | unlikely |
| 62 | neoplasms benign, malignant and unspecified | lipoma in the back | omalizumab | mild | unlikely |
| 63 | lipoma in the back | omalizumab | mild | unlikely |
| 64 | lipoma of the back | omalizumab | mild | unlikely |
| 65 | lipoma on both ankle and elbow | omalizumab | mild | unlikely |
| 66 | nervous system disorders | headache | omalizumab | mild | unlikely |
| 67 | headache in the morning (sometimes) | placebo | mild | unlikely |
| 68 | psychiatric disorders | post-traumatic stress disorder after rubbery | omalizumab | moderate | unlikely |
| 69 | respiratory, thoracic and mediastinal disorders | bronchitis | omalizumab | mild | unlikely |
| 70 | cold | omalizumab | mild | unlikely |
| 71 | common cold without fever | omalizumab | mild | unlikely |
| 72 | cough, asthma, viral infection | omalizumab | mild | unlikely |
| 73 | febrile upper respiratory infection | omalizumab | mild | unlikely |
| 74 | rhinitis, no fever | omalizumab | mild | unlikely |
| 75 | sore throat and irritating cough | omalizumab | mild | unlikely |
| 76 | throat infection with fever | omalizumab | mild | unlikely |
| 77 | viral flu with rhinitis, asthenia, muscle pain, psychic irritability | omalizumab | mild | unlikely |
| 78 | acute dyspnea | placebo | moderate | unlikely |
| 79 | common cold | placebo | mild | unlikely |
| 80 | common cold | placebo | mild | unlikely |
| 81 | common cold | placebo | mild | unlikely |
| 82 | common cold | placebo | mild | unlikely |
| 83 | cough | placebo | mild | unlikely |
| 84 | dyspnea, difficulties with expiration | placebo | moderate | unlikely |
| 85 | rhinitis | placebo | mild | unlikely |
| 86 | rhinoconjunctivitis | placebo | mild | unlikely |
| 87 | sensation of tightening of the throat | placebo | mild | unlikely |
| 88 | skin and subcutaneous tissue disorders | rash | omalizumab | mild | unlikely |
| 89 | stasis dermatitis | omalizumab | mild | unlikely |
| 90 | contact sensitation to suncreen | placebo | moderate | unlikely |
| 91 | itchy skin lesion on the scalp | placebo | mild | unlikely |
| 92 | skin rash on shoulders and abdomen | placebo | mild | unlikely |
| 93 | surgical and medical procedures | excision of atypical nevi | omalizumab | mild | unlikely |
| 94 | vascular disorders | anaphylactic reaction to after wasp sting | omalizumab | moderate | unlikely |
| 95 | hypertension | omalizumab | mild | possible |
| 96 | hypertension | omalizumab | mild | possible |
| 97 | hypertension | omalizumab | mild | unlikely |
| 98 | dizziness | placebo | mild | unlikely |
| 99 | sudden feeling of faintness after mosquito bite | placebo | mild | unlikely |