**Appendix 1: Adverse drug reaction criteria definitions**

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| **ADR Criterion** | **Definition** | **Example Use** |
| **Quantitative frequency** | Frequencies provided in numeric format | Gastrointestinal upset (14%) |
| **Qualitative frequency** | Frequencies provided in word-based format | Common ADRsGastrointestinal upset |
| **Comparative placebo frequency** | Frequencies provided for both patients who received medication and those who received placebo | Gastrointestinal upset (14% in medication group; 7% in placebo group) |
| **Severity information** | Monograph stratifies ADRs by level of potential harm | Non-severe reactions:Gastrointestinal upset |
| **Onset information** | Monograph details when ADR presents following initiation of medication | Gastrointestinal upset (most common within 6 months of initiation) |
| **Grouping by organ system** | Monograph separates ADR information based on affected organ system | Gastrointestinal system:Gastrointestinal upset, diarrhea |
| **References** | Monograph cites ADR information using references to specific sources | Gastrointestinal upset1References:1. Medication package insert (2020). |