

Safety of Anthroposophic Medicinal Products: An Analysis of Adverse Drug Reactions from German Pharmacovigilance Databases

Safety analysis of anthroposophic medicinal products

Miek C. Jong (ORCID 0000-0001-8523-9632)¹, Herman van Wietmarschen (ORCID 0000-0003-2225-0337)^{1,2}, Anja Glockmann (ORCID 0000-0003-2257-3507)^{1,3}, Erik W. Baars (ORCID 0000-0003-4428-5135)^{1,2,4}, Harald J. Hamre (ORCID 0000-0003-1098-1079)^{1,3,5}

¹ ESCAMP – European Scientific Cooperative on Anthroposophic Medicinal Products, Zechenweg 6, D-79111 Freiburg, Germany

² Louis Bolk Institute, Hoofdstraat 24, NL-3972 LA Driebergen, The Netherlands

³ Institute for Applied Epistemology and Medical Methodology at the Witten/Herdecke University, Zechenweg 6, D-79111 Freiburg, Germany

⁴ University of Applied Sciences Leiden, Zernikedreef 11, NL-2333 CK Leiden, The Netherlands

⁵ Faculty of Health, Witten/Herdecke University, Gerhard-Kienle-Weg 4, D-58313 Herdecke, Germany

Table S1. Characteristics of labelled versus unlabelled Adverse Drug Reactions

Characteristic	Labelled		Unlabelled		Other	
	N	%	N	%	N	%
Seriousness*						
Serious	41	1.2%	57	3.1%	6	2.5%
Not serious	3300	98.8%	1793	96.9%	235	97.5%
Total	3341	100.0%	1850	100.0%	241	100.0%
Gender						
Male	544	16.4%	285	15.6%	57	19.3%
Female	2782	83.6%	1543	84.4%	239	80.7%
Total	3326	100.0%	1828	100.0%	296	100.0%
Age groups*						
Neonate (0-27 days)	7	0.2%	14	0.9%	11	4.1%
Infant (28 days-23 months)	69	2.4%	79	5.1%	52	19.5%
Child (2-11 years)	143	5.0%	74	4.8%	17	6.4%
Adolescent (12-18 years)	22	0.8%	30	2.0%	5	1.9%
Adult (19-64 years)	1984	69.2%	954	62.1%	121	45.5%
Elderly (65 years and older)	641	22.4%	385	25.1%	60	22.6%
Total	2866	100.0%	1536	100.0%	266	100.0%
Outcome*						
Recovered/resolved	2282	85.5%	1291	87.7%	159	59.6%
Recovering/resolving	224	8.4%	72	4.9%	21	7.9%
Not recovered/not resolved	159	6.0%	99	6.7%	8	3.0%
Not applicable ^a	0	0.0%	6	0.4%	71	26.6%
Recovered/resolved with sequelae	3	0.1%	4	0.3%	6	2.2%
Sequelae	1	0.0%	0	0.0%	0	0.0%
Not assessable	0	0.0%	0	0.0%	2	0.7%
Total	2669	100.0%	1472	100.0%	267	100.0%
Route of administration*						
Injections	1095	32.8%	374	20.2%	67	22.1%
Oral	291	8.7%	714	38.5%	55	18.2%
Topical	1956	58.5%	766	41.3%	181	59.7%
Total	3342	100.0%	1854	100.0%	303	100.0%
Concentrations AMPs						
Non-diluted	2665	79.8%	923	49.8%	204	67.3%
D1-D3 dilution	531	15.9%	526	28.4%	40	13.2%
≥ D4 dilution	77	2.3%	326	17.6%	28	9.2%
Mixture of dilutions	68	2.0%	77	4.2%	31	10.2%
Total	3341	100.0%	1852	100.0%	303	100.0%

^aNot applicable: incorrect use of the AMP, the ADR was reported in terms of lack of effect or similar, or the ADR was evaluated to be causally linked to another AMP that was concomitantly administered in that patient.

* distributions labelled versus unlabelled are significantly different (p<0.0001. Chi-square test)

Characteristic	Labelled		Unlabelled		Other	
	N	%	N	%	N	%
Starting material						
Botanical	1776	53.2%	750	40.5%	154	50.2%
Zoological	2	0.1%	84	4.5%	6	2.0%
Chemical	13	0.4%	33	1.8%	5	1.6%
Mineral	3	0.1%	6	0.3%	3	1.0%
Vegitabilized metal	0	0.0%	18	1.0%	0	0.0%
More than one starting material	938	28.1%	603	32.6%	105	34.2%
Compositions	609	18.2%	358	19.3%	34	11.1%
Totals	3341	100.0%	1852	100.0%	307	100.0%
System Organ Class*						
1. Blood and lymphatic system disorders	2	0.1%	9	0.5%	0	0.0%
2. Cardiac disorders	2	0.1%	67	3.6%	1	0.3%
3. Ear and labyrinth disorders	2	0.1%	27	1.5%	1	0.3%
4. Endocrine disorders	0	0.0%	2	0.1%	0	0.0%
5. Eye disorders	696	20.8%	325	17.5%	9	2.9%
6. Gastrointestinal disorders	123	3.7%	302	16.3%	23	7.4%
7. General disorders and administration site conditions	1515	45.4%	304	16.4%	75	24.2%
8. Hepatobiliary disorders	2	0.1%	6	0.3%	0	0.0%
9. Immune system disorders	58	1.7%	29	1.6%	8	2.6%
10. Infections and infestations	15	0.4%	25	1.3%	6	1.9%
11. Injury, poisoning and procedural complications	2	0.1%	22	1.2%	92	29.7%
12. Investigations	10	0.3%	33	1.8%	6	1.9%
13. Metabolism and nutrition disorders	0	0.0%	8	0.4%	0	0.0%
14. Musculoskeletal and connective tissue disorders	8	0.2%	33	1.8%	4	1.3%
15. Nervous system disorders	95	2.8%	115	6.2%	7	2.3%
16. Pregnancy, puerperium and perinatal conditions	0	0.0%	1	0.1%	1	0.3%
17. Psychiatric disorders	3	0.1%	113	6.1%	6	1.9%
18. Renal and urinary disorders	0	0.0%	13	0.7%	0	0.0%
19. Reproductive system and breast disorders	16	0.5%	19	1.0%	2	0.6%
20. Respiratory, thoracic and mediastinal disorders	96	2.9%	108	5.8%	17	5.5%
21. Skin and subcutaneous tissue disorders	684	20.5%	252	13.6%	45	14.5%
22. Surgical and medical procedures	0	0.0%	3	0.2%	2	0.6%
23. Vascular disorders	11	0.3%	36	1.9%	4	1.3%
24. Product issues	0	0.0%	0	0.0%	1	0.3%
Totals	3340	100.0%	1852	100.0%	310	100.0%

* distributions labelled versus unlabelled are significantly different (p<0.0001. Chi-square test)