

Trial: CHDR1939-B

9.2.1.3 Adverse Events Listing

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**Listing 9.2.1.3.1 System Organ Class Abbreviations**

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## Listing 9.2.1.3.1 System Organ Class Abbreviations

SOC	System Organ Classification
-----	
BALSD	BLOOD AND LYMPHATIC SYSTEM DISORDERS
CARD	CARDIAC DISORDERS
CONG	CONGENITAL, FAMILIAL AND GENETIC DISORDERS
EARLA	EAR AND LABYRINTH DISORDERS
ENDO	ENDOCRINE DISORDERS
EYE	EYE DISORDERS
GASTR	GASTROINTESTINAL DISORDERS
GENRL	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS
HEPAT	HEPATOBIILIARY DISORDERS
IMMUN	IMMUNE SYSTEM DISORDERS
INFCT	INFECTIONS AND INFESTATIONS
INJUR	INJURY, POISONING AND PROCEDURAL COMPLICATIONS
INVST	INVESTIGATIONS
METAB	METABOLISM AND NUTRITION DISORDERS
MUSCL	MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS
NEOPL	NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)
NERV	NERVOUS SYSTEM DISORDERS
PREG	PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS
PSYCH	PSYCHIATRIC DISORDERS
RENAL	RENAL AND URINARY DISORDERS
REPRO	REPRODUCTIVE SYSTEM AND BREAST DISORDERS
RESP	RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS
SKIN	SKIN AND SUBCUTANEOUS TISSUE DISORDERS
SOCIA	SOCIAL CIRCUMSTANCES
SURG	SURGICAL AND MEDICAL PROCEDURES
VASC	VASCULAR DISORDERS
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**Listing 9.2.1.3.2 Serious Adverse Events**

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## Listing 9.2.1.3.2 Serious Adverse Events

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No serious adverse events were registered

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[1]: Refer to System Organ Classification table; M=Missing Value  
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**Listing 9.2.1.3.3 Pre-Dose Adverse Events**

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## Listing 9.2.1.3.3 Pre-Dose Adverse Events

Subject	Visit	Treatment	MedDRA code (v21.1)		Signs and Symptoms	Start Date/Time	Duration	Dosing Date/Time	Time after dosing	Severity	SAE	Related?	Chronicity
			SOC[1]	Preferred Term									
214	SCR	SCR	INFCT	Gastroenteritis	Vomiting and diarrhea. Tested negative for COVID	26JAN22 23:00	09H00M	NA	NA	Mild	No	Unrelated	Single occasion

[1]: Refer to System Organ Classification table; M=Missing Value

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**Listing 9.2.1.3.4 Post-Dose Adverse Events**

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## Listing 9.2.1.3.4 Post-Dose Adverse Events

Subject	Visit	Treatment	MedDRA code (v21.1)		Signs and Symptoms	Start Date/Time	Duration	Dosing Date/Time	Time after dosing	Severity	SAE	Related?	Chronicity
			SOC[1]	Preferred Term									
202	V1	Clonazepam	NERV	Somnolence	Tired, falling asleep during CNS activities.	02OCT21 11:30	04H30M	11SEP21 12:25	20D23H05M	Mild	No	Probable	Single occasion
			GENRL	Fatigue	very tired	15SEP21 M	0D	11SEP21 12:25	M	Mild	No	Possible	Single occasion
			NERV	Somnolence	Tired look (vermoeid blik)	19SEP21 M	0D	11SEP21 12:25	M	Mild	No	Possible	Single occasion
			NERV	Somnolence	Fell asleep early morning in the car ride	22SEP21 08:30	00H30M	11SEP21 12:25	10D20H05M	Mild	No	Probable	Single occasion
203	V1	Placebo	NERV	Headache	Headache	12SEP21 08:00	0D	11SEP21 12:36	19H24M	Mild	No	Unrelated	Single occasion
	V2	Clonazepam	GENRL	Fatigue	Fatigue since Day 5 of the study period. The fatigue is constantly present and seems not to be related to the time of dosing.	27OCT21 08:00	03D00H00M	23OCT21 12:08	03D19H52M	Mild	No	Probable	Single occasion

[1]: Refer to System Organ Classification table; M=Missing Value

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## Listing 9.2.1.3.4 Post-Dose Adverse Events

Subject	Visit	Treatment	MedDRA code (v21.1)		Signs and Symptoms	Start Date/Time	Duration	Dosing Date/Time	Time after dosing	Severity	SAE	Related?	Chronicity
			SOC[1]	Preferred Term									
203	V2	Clonazepam	NERV	Somnolence	Somnolence. Subject fell asleep on a chair while at the farm. His attendant has not seen this behavior before.	28OCT21 14:00	01H00M	23OCT21 12:08	05D01H52M	Mild	No	Probable	Single occasion
			NERV	Dysarthria	Slurred speech	27OCT21 08:00	03D00H00M	23OCT21 12:08	03D19H52M	Mild	No	Probable	Single occasion

[1]: Refer to System Organ Classification table; M=Missing Value

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## Listing 9.2.1.3.4 Post-Dose Adverse Events

Subject	Visit	Treatment	MedDRA code (v21.1) SOC[1] Preferred Term	Signs and Symptoms	Start Date/Time	Duration	Dosing Date/Time	Time after dosing	Seve- rity	SAE Related?	Chronicity
204	V1	Clonazepam	GASTR Abdominal pain upper	Lower stomach ache, with a slight elevation in body temp for a couple of hours. The body temp was normal two hours later. No other symptoms besides the lower stomach ache. Due to the complaints, the supervisor advised the patient to go back home and take a rest.	27SEP21 12:00	20H00M	25SEP21 12:15	01D23H45M	Mod	No	Unrelated Single occasion
			INFCT Nasopharyngitis	Subject had a cold.	23OCT21 08:00	03D00H00M	25SEP21 12:15	27D19H45M	Mild	No	Unrelated Single occasion

[1]: Refer to System Organ Classification table; M=Missing Value



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## Listing 9.2.1.3.4 Post-Dose Adverse Events

Subject	Visit	Treatment	MedDRA code (v21.1)		Signs and Symptoms	Start Date/Time	Duration	Dosing Date/Time	Time after dosing	Severity	SAE	Related?	Chronicity
			SOC[1]	Preferred Term									
204	V1	Clonazepam	MUSCL	Bursitis	Subject has bursitis-like complaints in the right shoulder	02NOV21 18:00	02D14H00M	25SEP21 12:15	38D05H45M	Mild	No	Unrelated	Single occasion
205	V2	Clonazepam	GASTR	Nausea	Feeling nauseous during cns tests.	27NOV21 12:30	00H15M	06NOV21 11:07	21D01H23M	Mild	No	Possible	Single occasion
206	V1	Clonazepam	GENRL	Fatigue	Fatigue. Once the patient had to sit down somewhere, the mother noticed that she was getting tired. She wasnt sleepy. On Day 4 this was more pronounced than on Day 5.	28SEP21 12:00	01D03H00M	25SEP21 12:45	02D23H15M	Mild	No	Probable	Intermittent

[1]: Refer to System Organ Classification table; M=Missing Value

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## Listing 9.2.1.3.4 Post-Dose Adverse Events

Subject	Visit	Treatment	MedDRA code (v21.1)		Signs and Symptoms	Start Date/Time	Duration	Dosing Date/Time	Time after dosing	Severity	SAE	Related?	Chronicity
			SOC[1]	Preferred Term									
206	V1	Clonazepam	RESP	Oropharyngeal pain	Sore throat and raspy voice. Parents have not heard about this complaint before, so the duration of the vomplaints are unknown.	16OCT21 10:20	04H01M	25SEP21 12:45	20D21H35M	Mild	No	Unrelated	Single occasion
	V2	Placebo	GENRL	Fatigue	Fatigue	21NOV21 12:30	07H30M	21NOV21 10:05	02H25M	Mild	No	Probable	Single occasion
			GASTR	Nausea	Nausea	21NOV21 12:30	07H30M	21NOV21 10:05	02H25M	Mild	No	Probable	Single occasion

[1]: Refer to System Organ Classification table; M=Missing Value

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## Listing 9.2.1.3.4 Post-Dose Adverse Events

Subject	Visit	Treatment	MedDRA code (v21.1)		Signs and Symptoms	Start Date/Time	Duration	Dosing Date/Time	Time after dosing	Severity	SAE Related?	Chronicity
			SOC[1]	Preferred Term								
207	V1	Clonazepam	GENRL	Paradoxical drug reaction	On Day 4 of the study period 1 (study medication dose: 3 drops BID: each dose 0.25mg clonazepam or placebo) the subject showed aggressive behavior at home and at school. Next to this, she was also agitated and restless. Lastly her mother noted that the subject was more sleepy in the hours after dosing. The teachers at school also noted the	13OCT21 07:00	02D00H00M	09OCT21 11:02	03D19H58M	Mod	No	Probable Intermittent

[1]: Refer to System Organ Classification table; M=Missing Value

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## Listing 9.2.1.3.4 Post-Dose Adverse Events

Subject	Visit	Treatment	MedDRA code (v21.1) SOC[1] Preferred Term	Signs and Symptoms	Start Date/Time	Duration	Dosing Date/Time	Time after dosing	Seve- rity	SAE Related?	Chronicity
				same behavior as the mother							

[1]: Refer to System Organ Classification table; M=Missing Value

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## Listing 9.2.1.3.4 Post-Dose Adverse Events

Subject	Visit	Treatment	MedDRA code (v21.1) SOC[1] Preferred Term		Signs and Symptoms	Start Date/Time	Duration	Dosing Date/Time	Time after dosing	Seve- rity	SAE	Related?	Chronicity
208	V1	Placebo	NERV	Headache	Subject had headache and temp 37,8. Subject was tested for corona and tested negative.	11NOV21 08:00	01D00H00M	10OCT21 11:31	31D20H29M	Mild	No	Unrelated	Single occasion
209	V2	Placebo	INFCT	Nasopharyngitis	Flu like symptoms (incl. cough and rinorro). Family member tested positive on SARS-CoV-2, PCR of subject is pending	11DEC21 09:00	04D23H00M	21NOV21 11:08	19D21H52M	Mild	No	Unrelated	Single occasion
210	V2	Clonazepam	GENRL	Fatigue	Feeling a bit more tired (mother notices because of red cheeks).	21NOV21 11:10	01H45M	21NOV21 10:37	00H33M	Mild	No	Probable	Single occasion

[1]: Refer to System Organ Classification table; M=Missing Value

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## Listing 9.2.1.3.4 Post-Dose Adverse Events

Subject	Visit	Treatment	MedDRA code (v21.1)		Signs and Symptoms	Start Date/Time	Duration	Dosing Date/Time	Time after dosing	Severity	SAE	Related?	Chronicity
			SOC[1]	Preferred Term									
210	V2	Clonazepam	INFCT	Nasopharyngitis	Subject had a cold from 29 nov till 5 dec. Selftest for COVID-19 was negative	29NOV21 08:00	06D00H00M	21NOV21 10:37	07D21H23M	Mild	No	Unrelated	Single occasion
			PSYCH	Disinhibition	More disinhibited than usual. He usually needs a lot of guidance, but this has markedly increased in he has been on 4 drops BID	24NOV21 11:00	04D21H00M	21NOV21 10:37	03D00H23M	Mild	No	Probable	Single occasion
			GENRL	Feeling drunk	Behaving as if he is drunk. Having a distinct laugh that reminds the other of someone who is drunk	24NOV21 11:00	04D21H00M	21NOV21 10:37	03D00H23M	Mild	No	Probable	Single occasion

[1]: Refer to System Organ Classification table; M=Missing Value

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## Listing 9.2.1.3.4 Post-Dose Adverse Events

Subject	Visit	Treatment	MedDRA code (v21.1)		Signs and Symptoms	Start Date/Time	Duration	Dosing Date/Time	Time after dosing	Severity	SAE Related?	Chronicity
			SOC[1]	Preferred Term								
210	V2	Clonazepam	INJUR	Head injury	Bumped his head twice in one day. The first time, the subject hit his brow at the school desk, which needed medical assistants in the form of a bandage. The second time was at home, when the subject hit his head reasonably hard against a closet. Mother does not recognize this behavior.	24NOV21 11:00	01D00H00M	21NOV21 10:37	03D00H23M	Mild	No	Probable
												Single occasion

[1]: Refer to System Organ Classification table; M=Missing Value

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## Listing 9.2.1.3.4 Post-Dose Adverse Events

Subject	Visit	Treatment	MedDRA code (v21.1) SOC[1] Preferred Term	Signs and Symptoms	Start Date/Time	Duration	Dosing Date/Time	Time after dosing	Seve- rity	SAE Related?	Chronicity
			PSYCH Impulse-control disorder	Subject is more demanding in his request than usual. For example, when he used to want a cookie, he would quickly give up when he is denied the cookie. However, the subject now is way more demanding and keeps persisting the things he wants. After lowering the drug dose, this AE is still present, but less than what	24NOV21 11:00	04D21H00M	21NOV21 10:37	03D00H23M	Mild	No Probable	Single occasion

[1]: Refer to System Organ Classification table; M=Missing Value



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## Listing 9.2.1.3.4 Post-Dose Adverse Events

Subject	Visit	Treatment	MedDRA code (v21.1) SOC[1] Preferred Term	Signs and Symptoms	Start Date/Time	Duration	Dosing Date/Time	Time after dosing	Seve- rity	SAE Related?	Chronicity
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it was on  
the higher  
dose

[1]: Refer to System Organ Classification table; M=Missing Value

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## Listing 9.2.1.3.4 Post-Dose Adverse Events

Subject	Visit	Treatment	MedDRA code (v21.1)		Signs and Symptoms	Start Date/Time	Duration	Dosing Date/Time	Time after dosing	Severity	SAE	Related?	Chronicity
			SOC[1]	Preferred Term									
210	V2	Clonazepam	NERV	Balance disorder	Balance disorder. Falling more often than usual.	24NOV21 11:00	05D00H00M	21NOV21 10:37	03D00H23M	Mild	No	Probable	Single occasion
211	V1	Placebo	PSYCH	Inappropriate affect	Burst of suddenly crying really long and loud. Subject never did this before. The cause was unprovoked. No explanation as to why this happened.	14MAR22 11:00	01D09H00M	12MAR22 12:40	01D22H20M	Mild	No	Unlikely	Intermittent

[1]: Refer to System Organ Classification table; M=Missing Value

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## Listing 9.2.1.3.4 Post-Dose Adverse Events

Subject	Visit	Treatment	MedDRA code (v21.1) SOC[1] Preferred Term		Signs and Symptoms	Start Date/Time	Duration	Dosing Date/Time	Time after dosing	Seve- rity	SAE	Related?	Chronicity
211	V2	Clonazepam	GENRL	Fatigue	Subject is fatigued. Due to the fatigue she isnt reading that well. The symptoms come up around an hour after dosing and is significantl y less at the end of the day.	14MAY22 11:30	20D05H30M	14MAY22 10:31	00H59M	Mild	No	Probable	Single occasion
			RESP	Rhinorrhoea	Runny nose.	16MAY22 12:00	02D20H00M	14MAY22 10:31	02D01H29M	Mild	No	Unrelated	Single occasion
212	V1	Clonazepam	GENRL	Fatigue	Fatigue	01FEB22 10:00	03D22H00M	29JAN22 10:35	02D23H25M	Mild	No	Probable	Single occasion
			NERV	Slow response to stimuli	Slow in movement and talking when spoken to. Subject is slow to react to stimulu	01FEB22 10:00	03D22H00M	29JAN22 10:35	02D23H25M	Mild	No	Probable	Single occasion
			NERV	Balance disorder	Balance disorder	01FEB22 10:00	03D22H00M	29JAN22 10:35	02D23H25M	Mild	No	Probable	Single occasion
			GASTR	Abdominal pain upper	Stomach ache.	30JAN22 08:00	05D09H00M	29JAN22 10:35	21H25M	Mild	No	Possible	Intermittent

[1]: Refer to System Organ Classification table; M=Missing Value

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## Listing 9.2.1.3.4 Post-Dose Adverse Events

Subject	Visit	Treatment	MedDRA code (v21.1) SOC[1] Preferred Term	Signs and Symptoms	Start Date/Time	Duration	Dosing Date/Time	Time after dosing	Seve- rity	SAE	Related?	Chronicity
212	V1	Clonazepam	NERV Headache	Headache	30JAN22 08:00	05D09H00M	29JAN22 10:35	21H25M	Mild	No	Probable	Intermittent
			NERV Disturbance in attention	Mothers observation was that subject was very absent. She was staring often into the distance	30JAN22 08:00	05D09H00M	29JAN22 10:35	21H25M	Mild	No	Possible	Single occasion
	V2	Placebo	GENRL Fatigue	fatigue	13MAR22 11:00	01D21H00M	12MAR22 09:55	01D01H05M	Mild	No	Probable	Single occasion
			PSYCH Bradyphrenia	Slow in thought	13MAR22 11:00	01D21H00M	12MAR22 09:55	01D01H05M	Mild	No	Probable	Single occasion
			NERV Headache	Headache	13MAR22 11:00	01D21H00M	12MAR22 09:55	01D01H05M	Mild	No	Probable	Single occasion
			RESP Nasal congestion	Stuffed nose.	26MAR22 10:00	02D05H00M	12MAR22 09:55	14D00H05M	Mild	No	Unrelated	Single occasion
			GENRL Fatigue	Feeling tired.	28MAR22 16:00	03D23H00M	12MAR22 09:55	16D06H05M	Mild	No	Possible	Single occasion
214	V1	Placebo	NERV Headache	Headache.	19FEB22 16:00	06H00M	29JAN22 11:21	21D04H39M	Mild	No	Possible	Single occasion
	V2	Clonazepam	INFCT Corona virus infection	COVID-19 positive with some minor complaints such as runny nose and coughing	14MAR22 08:00	02D00H00M	12MAR22 11:17	01D20H43M	Mild	No	Unrelated	Single occasion
215	V1	Clonazepam	GENRL Fatigue	fatigue	15MAR22 12:00	01D20H00M	12MAR22 13:05	02D22H55M	Mild	No	Probable	Single occasion

[1]: Refer to System Organ Classification table; M=Missing Value

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## Listing 9.2.1.3.4 Post-Dose Adverse Events

Subject	Visit	Treatment	MedDRA code (v21.1)		Signs and Symptoms	Start Date/Time	Duration	Dosing Date/Time	Time after dosing	Severity	SAE	Related?	Chronicity
			SOC[1]	Preferred Term									
216	V1	Placebo	INFCT	Nasopharyngitis	Coughing, fever. Parents did not do a covid test	13APR22 08:00	03D00H00M	12MAR22 12:12	31D19H48M	Mild	No	Unrelated	Single occasion
	V2	Clonazepam	GENRL	Fatigue	Subject is reacting more slow than usual and also more tired.	23APR22 17:00	20D15H00M	23APR22 09:43	07H17M	Mild	No	Probable	Single occasion
			GASTR	Salivary hypersecretion	2 times more saliva production than normal coming from mouth. This was on 09-MAY-2022 and on 12-MAY-2022. Subject was most likely drooling, because he was too sedated to realize he was drooling	09MAY22 16:00	02D16H00M	23APR22 09:43	16D06H17M	Mild	No	Possible	Single occasion

[1]: Refer to System Organ Classification table; M=Missing Value

