CIOMS FORM

SUSPECT ADVERSE REACTION REPORT	

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION	
		Day	Month	Year			Day	Month	Year		
Masked	Kazakhstan				16 Years	Male	12	Dec	2024	☐	PATIENT DIED
										☐	INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
										☐	INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
										☐	LIFE THREATENING
										☐	CONGENITAL ANOMALY
										☒	OTHER

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)
Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)

Other Seriousness Criteria: Medically Significant
#1| Allergic reaction [Hypersensitivity] |

Other Seriousness Criteria: Medically Significant
#2| convulsions [Seizure] |

Other Seriousness Criteria: Medically Significant
#3| shortness of breath [Dyspnoea] |

Initial spontaneous case received on 10Apr2025 from Acino (MFR CONTROL NO: KZ-FE-25-142), Ferrer's partner, and forwarded to Ferrer on 13Apr2025, originally reported by a Kazakh pharmacist.

/...continued

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1| GAMALATE | Magnesium glutamate hydrobromide + GABA + GABOB + Pyridoxine | Coated tablet | Unknown {Lot#: Unknown}

20 DID REACTION ABATE AFTER STOPPING DRUG?
#1| ☒ YES ☐ NO ☐ NA

15. DAILY DOSE(S)
#1| 2 tablets 1 time

16. ROUTE(S) OF ADMINISTRATION
#1| Unknown

17. INDICATION(S) FOR USE
#1| Unknown

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
#1| ☐ YES ☐ NO ☐ NA

18. THERAPY DATES (from/to)
#1| 12-Dec-2024 to 12-Dec-2024

19. THERAPY DURATION
#1| Unknown

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY (e.g diagnostics, allergics, pregnancy with last month of period, etc.)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
FERRER INTERNACIONAL, S.A.
Diagonal Avenue 549, 08029, Barcelona, Spain
Phone: +34936003700,

26. REMARKS
Company Comments: ID: 20-25-KAZ-FER-0000205
Hypersensitivity and Dyspnoea are expected according to the reference safety document of Magnesium glutamate hydrobromide + GABA + GABOB + Pyridoxine, while Seizure is not. These adverse reactions were involved in a serious case due to other medically important condition. The intensity of the adverse reactions was unknown. The suspected drug was withdrawn and the event outcomes were unknown. From a medical oint of view, Gamalate b6 can cause mild gastrointestinal upset, including symptoms such as stomach pain, nausea or flatulence when used in high doses and any type of allergic reaction like. In this case, the temporal association and the well-known pharmaco-toxicologic profile could enhance the causal relationship. Further information should be needed to make a clear medical asssessment and to investigate other ethiologies. In summary, based on the information provided, the Company considered as possible the causal relationship between the drug and the events according to the Karch Lassagna method.

ID: 20-25-KAZ-FER-0000205 FU1
Hypersensitivity and Dyspnoea are expected according to the reference safety document of Magnesium glutamate hydrobromide + GABA + GABOB + Pyridoxine, while Seizure is not expected. These adverse reactions were involved in a serious case due to other medically important condition. The intensity of the adverse reactions was unknown. The suspected drug was withdrawn and the event outcomes were recovered within one day. In this case, the temporal association and the well-known pharmaco-toxicologic profile could enhance the causal relationship. Further information should be needed to make a clear medical asssessment and to investigate other ethiologies. In summary, based on the information provided, the Company considered as probable the causal relationship between the drug and the events according to the Karch Lassagna method.

24b. MFR CONTROL NO.
20-25-KAZ-FER-0000205

25b. NAME AND ADDRESS OF REPORTER
Kazakhstan
Pharmacist
Pharmacist

24c. DATE RECEIVED BY MANUFACTURER
02-May-2025

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE
☒ HEALTH PROFESSIONAL ☐ OTHER:

DATE OF THIS REPORT
07-May-2025

25a. REPORT TYPE
☐ INITIAL ☒ FOLLOWUP: 1

ADDITIONAL INFORMATION

7+13 DESCRIBE REACTION(S) continued

A 16 year-old male patient (DOB unkown and initials mask) started the treatment with GAMALATE B6 film-coated tablets (Magnesium glutamate hydrobromide + GABA + GABOB + Pyridoxine) on 12Dec2024 and after receiving 2 tablets 1 time, he suffered allergictic reaction (LLT: Allergic reaction), convulsions (LLT: Convulsions) and shortness of breath (LLT: Shortness of breath) on 12Dec2024. The ambulance was called and he received drugs for the allergic reaction.

The action taken with the treatment was reported as withdrawn on 12Dec2024. The reactions abated after stopping the treatment but the outcome of the reactions was not reported, so they were considered as unknown,

He didn't receive any other treatment.

The past medical history and the tests were reported as not appliacable.

Additional information was received by Ferrer on 02May2025 via email from the partner (Acino).

According to this follow-up, the outcomes of the reported adverse reactions (LLT: allergic reaction, convulsions, and shortness of breath) were confirmed as recovered/resolved.

The adverse reactions resolved within one day, with an end date of 13December2024.

No diagnostic tests were performed in relation to the reported reactions.

The batch number of the product was not available.

The case has been considered as serious (other medically important condition for all the reactions).

This case is considered as invalid for KZ HA due to unknown date of birth (unavailability to obtain the patient's date of birth).