SUSPECT ADVERSE REACTION REPORT

Creation Date: 2025-05-19 21:35:41

GT-Inmunotek-GT-2025-000773

I. REACTION INFORMATION

1.PATIENT INITIALS	1a. COUNTRY	2. DATE OF BIRTH	2a. AGE	3. SEX	4-6 REACTION ONSET	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
	Guatemala	28.08.2018	6 year(s)	Male	2025-03-03	

7. + 13. DESCRIBE REACTION(S) (including relevant test/tab data)

MedDra 28.0 LLT(10048961) Localised oedema

MedDra 28.0 LLT(10064351) Localised erythema

MedDra 28.0 LLT(10048961) Localised oedema

MedDra 28.0 LLT(10064351) Localised erythema

MedDra 28.0 LLT(10048961) Localised oedema...(described on Continue)

Case Narrative: ...(continue on next page)

Sender's Diagnosis :

Reporter's Comment:...(continue on next page)

Sender's Comment:...(continue on next page)

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING
- ☐ CONGENITAL ANOMALY/BIRTH DEFECT
- ☐ OTHER MEDICALLY IMPORTANT CONDITION

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
ALXOID 2,000 TU/mL (vial A), 10,000 TU/mL (vial B), suspension for injection., MM09 (Dermatophagoides Mites Mix: D. pteronyssinus and D. Farinae)

15. DAILY DOSE(S)
0.4 mL 1/

16. ROUTE(S) OF ADMINISTRATION
Subcutaneous use (Subcutaneous)

17. INDICATIONS(S) FOR USE
10082852 Bronchial asthma

18. THERAPY DATES (from to)
-

19. THERAPY DURATION

20. DID REACTION ABATE AFTER STOPPING DRUG?
☐ YES ☐ NO ☐ NA

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

III. CONCOMITANT DRUG(S) AND HISTORY

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

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

IV. SENDER INFORMATION

24. NAME AND ADRESS OF SENDER
Inmunotek S.L.
C/ Punto Mobi 5. Parque Científico Tecnológico 28805 Alcalá de Henares

LITERATURE

24b. MFR CONTROL NO.
GT-Inmunotek-GT-2025-000773

24c. DATE RECEIVED BY MANUFACTURER
2025-05-13

24d. REPORT SOURCE
- ✓ HEALTH PROFESSIONAL
- ☐ STUDY
- ☐ LITERATURE
- ☐ OTHER

DATE OF THIS REPORT
2025-05-14

25a. REPORT TYPE
- ✓ INITIAL
- ☐ FOLLOW UP

7 + 13. DESCRIBE REACTION(S) (including relevant test/tab data) (continuation)

Reaction text as reported

MedDRA coding	Duration	Outcome*	Term highlighted	Time interval 1** Time interval 2***	Start date	End date
MedDRA 28.0 LLT (10048961) Localised oedema	-- --	recovered/resolved	Yes - highlighted by the reporter; NOT serious	-- -- -- --	2025-03-03	--
MedDRA 28.0 LLT (10064351) Localised erythema	-- --	recovered/resolved	Yes - highlighted by the reporter; NOT serious	-- -- -- --	2025-03-03	--
MedDRA 28.0 LLT (10048961) Localised oedema	-- --	recovered/resolved	Yes - highlighted by the reporter; NOT serious	-- -- -- --	2025-04-05	--
MedDRA 28.0 LLT (10064351) Localised erythema	-- --	recovered/resolved	Yes - highlighted by the reporter; NOT serious	-- -- -- --	2025-04-05	--
MedDRA 28.0 LLT (10048961) Localised oedema	-- --	recovered/resolved	Yes - highlighted by the reporter; NOT serious	-- -- -- --	2025-05-05	--
MedDRA 28.0 LLT (10064351) Localised erythema	-- --	recovered/resolved	Yes - highlighted by the reporter; NOT serious	-- -- -- --	2025-05-05	--

* Outcome of reaction/event at the time last observation

** Time interval between beginning of suspect drug administration and start of reaction / event

*** Time interval between last dose and start of reaction / event

Case narrative: IInitial information was received on 09-May-2025.
A non-serious ICSR received from a physician through our contractual partner Grupo Fidaf (local partner ID: R-2025-01) in Guatemala.
A 6-years-old male patient , height 148 cm and weight 60 lbs, with a medical history of Bronchial asthma treated with Budesonida, initiated ALXOID® 10,000 TU/mL, suspension of several polymerized allergen extracts composed by 100% MM09 (Dermatophagoides Mites Mix: 50% D. pteronyssinus and 50% D. Farinae) for subcutaneous injection. Prescribed as a named patient product for allergen immunotherapy. Suspected product batch number: A23G049AX, and expiry date: 02/2026.
Budesonide 200mg (oral inhalation, bid) was reported as concomitant medication indicated for the bronchial asthma.
On 03-Mar-2025 the patient experienced local oedema and erythema.
On 05-Apr-2025 the patient experienced local oedema and erythema.
On 05-May-2025 the patient experienced local oedema and erythema.
On 03-Mar-2025, as a corrective treatment, the patient received Rupatadine (5 mL, bid, orally) and Prednisolone (9 mL, bid, orally). The patient did recover from the event.
On 05-Apr-2025, Rupatadine (5 mL, bid, orally), was administered as corrective treatment. The patient did recover from the event.
On 05-May-2025 Rupatadine in a dose of 5 ml was administered as corrective treatment. The patient did recover from the event.
At the time of this report, the action taken with the medication was unknown.

Reporter's comment: The reporting physician assessed the adverse events described as PTs: local oedema and erythema as non-serious and the causal relationship between the events and the suspect drug as probable.

Sender's comment: With the information received on 09-May-2025, the safety report, the company assessed the adverse reaction described as PT Localised oedema and Erythema as non-serious and expected according to the product safety information that is available.
The causal relationship between the events and the suspect drug was assessed as Probable due to the reasonable time relationship between these adverse events and the drug intake and unlikely to be attributed to disease or other drugs.

14. Suspect drug(s) (include generic name)

Suspect drug and batch number: ALXOID 2,000 TU/mL (vial A), 10,000 TU/mL (vial B), suspension for injection.: MM09 (Dermatophagoides Mites Mix: D. pteronyssinus and D. Farinae), (Suspect) A23G049AX

Medicinal Product Name: ALXOID 2,000 TU/mL (vial A), 10,000 TU/mL (vial B), suspension for injection.

Start date -- End date -- Duration --

Dose*		Route(s) of Administration	Subcutaneous use (Subcutaneous)	Indication(s)	MedDRA 28.0 (10082852) Bronchial asthma
A:	--				
B:	--				
C:	0.4 mL				
D:	1				
E:	--				
Identification of the country where the drug was obtained		--	Name of holder applicant		Inmunotek S.L.
Authorization Applicant Number		--	Country of authorization/application		--
Pharmaceutical form (Dosage form)		--	Parent route of administration (in case of a parent child/fetus report)		--
Gestation period at time of exposure		--	Action(s) taken with drug		Unknown
Time interval between beginning of drug administration and start of reaction / event		--	Time interval between last dose of drug and start of reaction / event		--
Did reaction reappear after reintroduction?		--	Active drug substance name		MM09 (Dermatophagoides Mites Mix: D. pteronyssinus and D. Farinae),

* A: Dosage Text
B: Cumulative dose number (to first reaction)
C: Structure dosages number
D: Number of separate dosages
E: Number of units in the interval

22. Concomitant drug(s) and dates of administration (continuing)

Concomitant drug and batch number: Budesonida: BUDESONIDE, (Concomitant)

Medicinal Product Name:		Budesonida			
Start date	--	End date	--	Duration	--
Dose*		Route(s) of Administration	--	Indication(s)	
A:	--				
B:	--				
C:	--				
D:					
E:	--				
Identification of the country where the drug was obtained		--	Name of holder applicant		--
Authorization Applicant Number		--	Country of authorization/application		--
Pharmaceutical form (Dosage form)		--	Parent route of administration (in case of a parent child/fetus report)		--
Gestation period at time of exposure		--	Action(s) taken with drug		--
Time interval between beginning of drug administration and start of reaction / event		--	Time interval between last dose of drug and start of reaction / event		--
Did reaction reappear after reintroduction?		--	Active drug substance name		BUDESONIDE,

* A: Dosage Text
B: Cumulative dose number (to first reaction)
C: Structure dosages number
D: Number of separate dosages
E: Number of units in the interval

Causality assessment

Active Substance	Substance / Reaction	Source	Method	Result

MM09 (Dermatophagoides Mites Mix: D. pteronyssinus and D. Farinae),	MedDRA 28.0 (10048961) Localised oedema	Physician	Medical judgment	Probable
	MedDRA 28.0 (10048961) Localised oedema	Company	WHO-UMC	Probable
	MedDRA 28.0 (10064351) Localised erythema	Physician	Medical judgment	Probable
	MedDRA 28.0 (10064351) Localised erythema	Company	WHO-UMC	Probable

Patient information (continuation)

Weight (kg)	27.22
Height (cm)	148