ADR REPORTING FORM

WWID (I/FU)**:
AUTHOR**:
DATE**:

1. PATIENT

AGE (years/months)*:
DATE OF BIRTH (day/month/year):

SEX*: ☐ Male ☐ Female

WEIGHT (kg) if pediatric patient:

2. REPORTER / PRIMARY SOURCE*

☐ **PHYSICIAN** ☐ **ANOTHER HEALTHCARE PROFESSIONAL** ☐ **CONSUMER** (PATIENT, FAMILY MEMBER, ETC.)

Authorization to contact the Doctor/Patient and/or Family, etc. (see Conditions of Use and Privacy Statement below):

☐ Yes. Contact details (email/phone): ☐ No

3. SUSPECTED MEDICINE

NAME AND COMPOSITION*:

BATCH/LOT AND EXPIRY DATE:

TYPE OF TREATMENT: ☐ Initiation. Specify: ☐ Clúster/Rush ☐ Conventional ☐ Maintenance ☐ N/A (Diagnostic treatment)

INDICATION*:

☐ ALLERGY. Specify:
- ☐ Rhinitis/RC
- ☐ Asthma
- ☐ Other. Specify:

☐ RECURRENT INFECTION. Specify:
- ☐ Respiratory tract
- ☐ Urinary tract

☐ DIAGNOSIS. Specify:
- ☐ Allergy
- ☐ Bronchial hyperactivity
- ☐ Hypersensitive to antibiotics

START DATE (day/month/year):

DATE OF LAST DOSE BEFORE ADR * (day/month/year):

VOLUME* (ml/pulsation) **and VIAL*** associated with ADR:

4. SUSPECTED ADVERSE DRUG REACTION (ADR)

TERM OF THE ADR(S) (Diagnosis according to signs and symptoms):

START DATE (day/month/year): ☐ **IMMEDIATE** (<30min) ☐ **DELAYED** (≥ 30 min)

DESCRIPTION*: Detailed description of the ADR, clinical evolution, presented signs and symptoms, therapeutic measures and relevant laboratory procedures/tests (incl. units and normal values). Indicate hospitalizations.

Mandatory information.** * To be filled in by Pharmacovigilance Dept., Diater.**

The personal identification, contact and health data, provided by the interested party, as well as those other provided by third party reporters, will be processed by Diater Laboratorio de Diagnóstico y Aplicaciones Terapéuticas, S.A. (hereinafter DIATER), in order to manage the communications of adverse reactions, their follow-up and submission, and in order to manage and investigate the communications of quality and efficacy complaints regarding DIATER medicines or medical devices. You can exercise your rights by contacting dpogrupo@grupodiater.com. If you wish to obtain more information about the processing of your data, you can consult our Privacy Policy at www.diater.com.

4. SUSPECTED ADVERSE DRUG REACTION (ADR)

RELATEDNESS OF DRUG TO REACTION(S)/EVENT(S)*

☐ Related ☐ Not Related ☐ Unknown

SERIOUSNESS CRITERION *:

☐ Non serious
☐ Death
☐ Life-threatening
☐ Hospitalisation (>24h) / Prolongation of Hospitalisation (day/month/year):
☐ Results in persistent or significant disability/incapacity
☐ Congenital anomaly/birth defect
☐ Medically important (patient's life jeopardised or required intervention to prevent any of the above outcomes)
☐ Suspected transmission of an infectious agent
☐ Lack of efficacy (only in case of responding patients after recommended immunotherapy period according to WHO)

OUTCOME*:

☐ Recovery (day/month/year): ☐ Recovery with sequelae (day/month/year):
☐ Not recovered (persistence, improvement, etc.) ☐ Unknown
☐ Fatal. Specify:
- Cause of death:
- DIATER treatment causal relationship:
- Autopsy/post-mortem report:

ACTION TAKEN WITH THE MEDICATION IN RESPONSE TO THE ADR:

☐ No change ☐ Unknown
☐ Dose change. Specify:
- Next doce date (day/month/year):
- Next volume (ml/application) and vial:

☐ Temporary withdrawn (day/month/year): ☐ Definite (day/month/year):

TO BE COMPLETED ONLY BY DIATER PHARMACOVIGILANCE DEPT.

Date of report: (Initial (Day 0) / FU) (day/month/year)
Date of receipt: (Initial / FU) (day/month/year)

Information from:

☐ Authority ☐ Internet/digital media ☐ Literature
☐ Studies ☐ Other:

Internal information:

☐ Hospital/Health centre ☐ CCAA: ☐ City/Postal Code:
☐ INE Code: ☐ INE Code:
☐ Special situation. Specify: ☐ Other. Specify:

☐ I agree with the Conditions of Use and Privacy Statement (See Page. 1 of 2)

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