DAFRA Pharma (Pharmacovigilance)
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SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

Patient identifier (initials)	birthdate (or age) (dd/mm/yyyy)	Sex M : ☐ F : ☐	height (cm)	weight (kg)	Ethnicity	pregnant: Yes: ☐ No : ☐

Importance ranking	***Suspected adverse event(s)*** *Please describe the observed adverse event in detail and specify the intensity*	***Start*** (dd/mm/yyyy)	***End*** (dd/mm/yyyy)
1.			
2.			
3			

Seriousness of the event

☐ death date : dd/mm/yyyy Autopsy : Y ☐ N ☐
☐ life threatening
☐ hospitalization (initial or prolonged)
☐ disability
☐ Required intervention to prevent permanent impairment / damage
☐ Congenital anomaly
☐ other (specify)

Outcome

☐ full recovery ☐ recovery but rest lesions ☐ improvement ☐ no improvement ☐ Fatal ☐unknown

Suspected medication's (batch n°)	***Unit dose***	***Posology***	***Total daily dosage***	***Route used***	***Therapy dates*** dd/mm/yyyy ***start***	***end***	***Reason for use / Prescribed for (indication)***
1.							
2.							
3.							
4.							
5.							

What decision was made related to the Dafra medication ?	Reaction abated after drug stopped or dose reduced*?*	***Reaction reappeared after reintroduction Dafra drug?***
None ☐ Stopped ☐ Temporary stop ☐ Decrease of dose ☐	Yes ☐ No ☐ Unknown ☐	Yes ☐ No ☐ Unknown ☐

SIGNIFICANT ANTECEDENTS

Alcohol use ☐ smoking ☐ illegal Drugs ☐ medication ☐ diet ☐ Pacemaker ☐ Allergies ☐

Congenital /genetic condition ☐ disturbed metabolism ☐ if yes, specify?

Others (specify) :

OTHER RELEVANT INFORMATION

NARRATIVE DESCRIPTION OF THE ADVERSE EVENT AND COMMENTS

RELEVANT TESTS / LABORATORY DATA WITH DATES

Submitted to national autorities ? Y ☐ N ☐ by: **Date :** (dd/mm/yyyy)

Name and address of the reporter (confidential)

Telephone :
Profession :
E-mail:

Signature :

DATE of arrival report at Dafra :

((dd/mm/yyyy))

Initial Report ☐

Follow up report ☐ **(num :)**

Local number :

Reported by HCP ☐
Reported by patient ☐