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Federal Commission for the Protection against Sanitary Risks

Notice of Suspected Adverse Drug Reactions

Homoclave of the format
FF-COFEPRIS-11
RUPA number

Exclusive use of COFEPRIS

Admission number

Before filling out this form, carefully read the instructions, the guide and the list of attached documents.
Fill out with legible print or typewriter or computer.
The format will not be valid if it contains any deletions or corrections to the information.

1. Homoclave and name of the procedure

Homoclave: COFEPRIS-04-017	Name: Notice of suspected adverse drug reactions

Notification No. (according to origin)	Notification No. (general)	Notification No (Laboratory)

2. Patient data

Patient's initials	Birthdate	Age	Sex	Height (cm)	Weight (kg)
	DD / MM / AAAA	Years Months	○ Man ○ Women		

3. Data on suspected adverse reaction

Date of start of reaction	DD / MM / AAAA

Description of suspected adverse reaction (including examination and laboratory data)

Consequences of the event

- ○ Recovered without sequelae
- ○ Recovered with sequel
- ○ Not recovered
- ○ Death-due to adverse reaction
- ○ Death - the drug may have contributed
- ○ Death - not related to medication
- ○ It is not known

"In accordance with articles 4 and 69-M, section V of the Federal Law of Administrative Procedure, the forms to request procedures and services must be published in the Official Gazette of the Federation (DOF)"

Contact:
Oklahoma Street No. 14, Naples
neighborhood; Benito Juarez Delegation, Mexico City, C.P. 03810.
Telephone 01-800-033-5050
contacto@cofepris.gob.mx

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4. Information about the suspected drug

Generic name	
Lot number:	
Route of administration:	
Distinctive name:	
Producing laboratory:	
Dose:	
Reason for prescription:	

Expiration date:	/ / DD MM AAAA
Date of initial administration:	/ / DD MM AAAA
Date of final administration:	/ / DD MM AAAA

Has the suspect drug been recalled?	And	No	He doesn't know
Did the reaction disappear when the medication was stopped?	And	No	He doesn't know
Was the dose reduced? How much? _____	And	No	
Has the drug therapy changed? Which? _____	And	No	
Did the reaction recur when the medication was readministered?	And	No	He doesn't know
If the medication was not withdrawn, did the reaction persist?	And	No	He doesn't know

5. Concomitant pharmacotherapy

Medication	Dose	Routes of administration	Dates		Reason for prescription
			Start	Term	
			/ / DD MM AAAA	/ / DD MM AAAA	
			/ / DD MM AAAA	/ / DD MM AAAA	
			/ / DD MM AAAA	/ / DD MM AAAA	
			/ / DD MM AAAA	/ / DD MM AAAA	
			/ / DD MM AAAA	/ / DD MM AAAA	

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6. Important data from the medical history

Diagnoses, allergies, pregnancy, previous surgery, laboratory data.

7. Origin of the information

Origin and type of report

Producing laboratory	Professional
Report Type: ○ Home ○ Follow-up ○ Study	Report Type: ○ Home ○ Follow-up
Origin: ○ Health professional ○ Patient ○ Out-of-hospital care ○ Hospital	Origin: ○ Hospital ○ Out-of-hospital care

Date received at the laboratory: ( )	Informed within the stipulated period? : ( )	Did you report this reaction to the producing laboratory? : ( )
/ / DD MM AAAA	○ And ○ No	○ And ○ No

(a) In the event that the informant is the producing laboratory.
(b) In case the informant is a professional.

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Informant's data (producing laboratory or professional)

Natural person
RFC:
CURP (optional):
Name(s):
First surname:
Second surname:
Pepper:
Telephone:
Extension:
Email:

Legal entity
RFC:
Name or corporate name:

Address of the informant (producing laboratory or professional)

Postal code:	Locality:
Type and name of road: (For example: Avenue, boulevard, street, highway, road, private, dirt road, among others.)	Municipality or mayor's office: Federative Entity: Between which streets (type and name):
Exterior number: / Inner number:	Back street (type and name):
Type and name of human settlement: (Type of human settlement for example: Colony, private, condominium, hacienda, among others)	Pepper: Telephone: Extension:

Note: Submission of this report does not necessarily constitute an admission that the drug caused the adverse reaction.

If the informant is the producing laboratory, indicate its data. These data are required by the National Pharmacovigilance Centre when the laboratory notifies directly and must be provided within a period of no more than 15 days after receipt of the notification. Indicate the data of the notifying professional, address and telephone number in order to channel a response if necessary. If the informant is a professional, indicate their data, address and telephone number in order to channel a response if necessary.

I declare under protest that I comply with the applicable requirements and regulations, without exempting me from having to verify compliance by the health authority, this without prejudice to the sanctions that I may incur for false statements given to an authority. And I accept that the notification of this procedure be carried out through the Comprehensive Service Center or offices in the states corresponding to the Federal Health System. (Article 35, section II of the Federal Law of Administrative Procedure)

The data or attachments may contain confidential information, do you agree to make them public? ○ Yeah ○ **No**

For any clarification, doubt and/or comment regarding this procedure, please call the COFEPRIS Telephone Service Center in Mexico City or anywhere in the country, dial toll-free **01-800-033-5050 ,** and if you require the entry number and/or tracking of your procedure sent to the Foreign Processing area, dial toll-free **01-800-420-4224.**

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