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Report # _____/_____
❑Initial ❑Final
(It is filled by the Department of Pharmacovigilance)

ADVERSE DRUG REACTION REPORT

ALL PROVIDED INFORMATION IS CONFIDENTIAL AND NON-DISCLOSURE WITH THE EXCEPTION OF THE CASES STIPULATED BY LAW

INFORMATION ABOUT PATIENT

Initials:		**Liver disease**	❑ Yes ❑ No ❑ Unknown
№ of ambulatory card/medical patient's history:		**Kidney disease**	❑ Yes ❑ No ❑ Unknown
Sex:	❑ Male ❑ Female	**Pregnancy**	❑ Yes **Term** _____ weeks
Age (at time of reaction):		**Allergy** (specify the allergen):	❑ Yes ❑ No
Weight (kg):			

SUSPECTED DRUG (-S)

Brand Name	International Non-Patented Name	Medicine Form	Batch No.	Dosage, frequency, method of administration	Prescribed for	Date of start	Date of stop

OTHER DRUGS (taken within the last 3 last months)

Brand Name	International Non-Patented Name	Medicine Form	Batch No.	Dosage, frequency, method of administration	Prescribed for	Date of start	Date of stop

SUSPECTED ADVERSE DRUG REACTION (-S) (ADR)

Description of the ADR (including any results of relevant supportive laboratory testes and other investigations)	Date of start	Date of stop

Did the ADR disappear after the drug was stopped? ❑ Yes ❑ No ❑ Drug was not stopped

Did the ADR reappear after the drug was reintroduced? ❑ Yes ❑ No ❑ Drug was not reintroduced

Action taken to treat the ADR:
- ❑ None
- ❑ Drug withdrawal
- ❑ Dose reducing
- ❑ Co-treatment cessation
- ❑ Medicinal therapy
- ❑ Non-medicinal therapy (including surgical intervention)
- ❑ Other (indicate):

Treatment of ADR: ❑ No ❑ Yes. Details:

Outcome:
- ❑ Recovering without consequences
- ❑ Improvement of state
- ❑ State without changes
- ❑ Death related to the ADR
- ❑ Death not related to the ADR
- ❑ Recovering with the consequences (indicate):
- ❑ Unknown

Criteria of Seriousness:
- ❑ Death (dd/mm/yy) ___/___/_____
- ❑ Life threatening
- ❑ Hospitalization – Initial or prolonged
- ❑ Prolongation of outpatient therapy
- ❑ Disability
- ❑ Congenital malformation
- ❑ Clinically significant condition (indicate):

INFORMATION ABOUT REPORTER (person who informed about the ADR)

Name:			
Professional belonging:	❑Doctor ❑Pharmaceutical ❑Medical Representative ❑Other (indicate):		
Address:			
Telephone/Mobile:		**E-mail:**	
Date of receipt of information about ADR:		**Date of report:**	