glad pharm

Address: P.O.Box 22, Kyiv 02092, Ukraine
Tel.: (044)4958287; (067)4340378
E-mail: <pv@kusum.ua>

Report № _____/_____
❑ initial ❑ final
(to be filled in by Pharmacovigilance Department)

REPORT FORM "ADVERSE REACTIONS OF MEDICINES"

ALL THE INFORMATION PROVIDED BY YOU IS CONFIDENTIAL AND IS NOT SUBJECT TO DISCLOSURE EXCEPT AS OTHERWISE PERMITTED BY THE LAW

INFORMATION ABOUT A PATIENT

INITIALS (first letters of patient's surname, name and patronymic):	☐☐☐	**Hepatic disease**	❑ yes ❑ no ❑ no information
		Renal disease	❑ yes ❑ no ❑ no information
Sex:	❑ male ❑ female	**Pregnancy**	❑ yes **Term**_____ weeks
Date of birth (age):		**Allergy** (please, specify):	❑ yes ❑ no
Weight (kg):			
Height (cm):			

SUSPECTED PHARMACEUTICAL PRODUCT(-S) (SPP)

Brand name	International non-proprietary name	Pharmaceutical form	Batch No	Dosage, frequency and method of administration	Prescribed for	Start date	End date

OTHER PHARMACEUTICAL PRODUCTS (administered in the last 3 months)

Brand name	International non-proprietary name	Pharmaceutical form	Batch No	Dosage, frequency and method of administration	Prescribed for	Start date	End date

SUSPECTED ADVERSE REACTION(-S) (AR)

Description of the AR (including any results of relevant supportive laboratory tests and other investigations)	Start date of AR	End date of AR

Did the AR disappear after the drug was discontinued? ❑ yes ❑ no ❑ The drug was not discontinued

Did rechallenge of SPP cause repeated AR? ❑ yes ❑ no ❑ The drug was not rechallenged

Measures taken:
- ❑ none:
- ❑ drug withdrawal
- ❑ dose reducing
- ❑ co-treatment cessation
- ❑ medicinal therapy
- ❑ non-medicinal therapy (including surgical treatment)
- ❑ other (please, specify):

Pharmacological therapy of AR (if any):

Result:
- ❑ recovery without consequences
- ❑ amelioration
- ❑ no changes
- ❑ death caused by AR
- ❑ death not caused by AR
- ❑ recovery with any consequences (please specify):
- ❑ no information

Measures of the seriousness:
- ❑ death of the patient (date ___/___/_____)
- ❑ danger to life
- ❑ hospitalization or its prolongation
- ❑ prolongation of out-patient treatment
- ❑ disability
- ❑ congenital abnormality
- ❑ clinically significant event (please, specify):

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INFORMATION ABOUT A REPORTER (a person that informs about AR)

Full name:			
Occupation:	❑ doctor ❑ pharmacist ❑ medical representative ❑ other (please, specify):		
Health care institution:			
Address:			
Phone:		**E-mail:**	
Date of AR information receiving:		**Filling date:**	

I give my consent to Gladpharm LLC for processing my personal data (PD).
I am notified of:

1) PD owner – Gladpharm LLC;
2) the composition and content of PD – they are specified in this message above;
3) their rights under Art. 8 of the Law of Ukraine "On Protection of Personal Data";
4) the purpose of PD processing – ensuring pharmacovigilance over drug efficacy;
5) persons to whom PD may be transferred – State Enterprise "State Expert Center of the Ministry of Health of Ukraine", the company Kusum Healthcare Pvt Ltd, India and KUSUM PHARM LLC, Ukraine, as well as their legal successors.

❑YES ❑NO

SIGNATURE _____ **SEAL**_____