Version:26.03.2009 Supersedes: 15.08.2007

MATERNAL DATA

PREGNANCY OUTCOME REPORT FORM PART 1 – INITIAL REPORT

RS-F-11A.2E/RS-F-6GA.1E Page: 1/3

Please return this form to Lipomed AG, Fabrikmattenweg 4, CH-4144 Arlesheim, Switzerland by mail (save@lipomed.com) or fax (Fax No. +41 61 702 02 20)

Initials:			Birth o		month year		
Body surface area	a:		Weigh	nt: kg		Height:	cm
Week of gestation	:		Estima	ated date of de	1		year
Previous pregn	ancies ar	nd their ou	ıtcome				
no	andies ai	ia tileli ot	ulcome				
yes							
if yes, number	l l, outo	come					
Medical History	(list pre-e	xisting med	ical conditior	ns and other re	levant history)	
				•••••			
Risk factors:							
Nicotine	Alcoh	ol	☐ Drug al	ouse [Other		
Additional infor	rmation						
Family history (e	n risk fac	tors under	lving disease	oe)			
	. g	1010, 4114	iyirig alooass	,0)			
•••••							
Medication prior		•			<u>1</u>		Г
Trade name/ Drug name	Lot. No.	Expiry date	Route of adminis-tration	Daily dose	Therapy from	y dates to	Indication(s) for use

Date: 26.03.2009 Issued: Dr. S. Claassen

Reviewed: Dr. M. Bernstein

Date:

QA-approved: D. Foechterlen

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PREGNANCY OUTCOME REPORT FORM PART 1 – INITIAL REPORT

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Complications / Adverse events occurred during pregnancy?				
☐ no ☐ yes				
if yes, please fill in the separate Adverse Event Report Form which will be send to you				
RELEVANT TESTS / LABORATORY DATA (e. g. prenatal diagnostics, serology tests, other)				
PRESENT COURSE OF PREGNANCY				
without complications				
planned induced abortion				
other				
PATERNAL DATA; IF APPROPRIATE				
day month year				
Initials: Birth date:				
m ² kg cm				
Body surface area: Weight: Height: Height:				
Medical History (list pre-existing medical conditions and other relevant history)				
Risk factors:				
☐ Nicotine ☐ Alcohol ☐ Drug abuse ☐ Other				
Additional information				
Family history (e. g. risk factors, underlying diseases)				

Date: 26.03.2009 Issued: Dr. S. Claassen

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PREGNANCY OUTCOME REPORT FORM PART 1 – INITIAL REPORT

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Medication prior to conception (if relevant)							
Trade name/ Drug name	Lot. No.	Expiry date	Route of adminis-tration	Daily dose	Therap from	y dates to	Indication(s) for use

QUALIFIED REPORTING PERSO	N						
Name:							
Address:							
Postal code:							
State:		Country:					
Telephone:	Profession:	Profession:					
OK to report your name to local Health	Authority?						
Was report submitted to local Health Authority?							
Signature: Date: Date:							
SUBMISSION OF A REPORT DOES NOT NECESSARILY CONSTITUTE A JUDGEMENT THAT THE DRUG CAUSED THE ADVERSE EVENT.							
Will be completed by Lipomed	d AG or local monitor only:						
Company data:	Report source:	Status:	Reported to health authorities:				
National organization:	☐ Market	☐ Initial	Yes				
Contact person:	Health Professional	Follow-up	☐ No				
Signature:	Consumer						
day month year Date:	Other:						
	☐ Health Authority						
	Literature	Date report was received by company:					
	Study						
	Study number:	Date:					
	Patient number:						

Date: 26.03.2009 Date: Issued: Dr. S. Claassen Reviewed: D

Reviewed: Dr. M. Bernstein

Date:

QA-approved: D. Foechterlen