



上海达华药业有限公司
SHANGHAI DAHUA PHARMACEUTICAL CO., LTD

Adverse Event Reporting form for Sino-implant (II)/Levoplant Users

Instructions: This form, or the equivalent national reporting form, should be used for all Sino-implant (II)/Levoplant (also known as Trust, Zarin or Femplant) adverse event reporting. For additional information, see the *General Instructions for Completing the Adverse Event Report*. If further information needs to be provided, please attach as necessary.

USER DETAILS

Initials: _____ Weight (kg): _____ Height (cm): _____ Age: _____

D.O.B: _____

Breastfeeding at time of incident: (Y/N)

At what clinic was the implant inserted (include town/city and country)? _____

Duration of use of this implant: _____ Was implant removed? Yes No

If yes, date and reason for removal: _____

If yes, where it was removed: _____

Suspected product information

Batch/Lot Number: _____ Manufacturer: _____

Product description(specify brand name; generic name or product type; other relevant product details):

SUSPECTED REACTION

Date reaction started: _____ Date stopped: _____ Duration of reaction: _____
dd/mm/yyyy (if applicable) dd/mm/yyyy

Describe the reaction: _____

What was the severity of the adverse reaction?

Mild Moderate Severe Life-threatening

Was the adverse reaction serious (an SAE)?

No Yes, user died Yes, hospitalization Yes, significant disability

Yes, other please specify: _____



上海达华药业有限公司

SHANGHAI DAHUA PHARMACEUTICAL CO., LTD

Adverse Event Reporting form for Sino-implant (II)/Levoplant Users

Instructions: This form, or the equivalent national reporting form, should be used for all Sino-implant (II)/Levoplant (also known as Trust, Zarin or Femplant) adverse event reporting. For additional information, see the *General Instructions for Completing the Adverse Event Report*. If further information needs to be provided, please attach as necessary.

TREATMENT OF REACTION

Describe the treatment(s) provided in as much detail as is available.

OUTCOME OF REACTIONRecovered Recovering Continuing Not known **PREGNANCY**Was a pre-insertion pregnancy test done? Yes No Don't know Is user pregnant now? Yes No

How was pregnancy confirmed? (if ultrasound report available, please attach)

What was the pregnancy outcome?

Live birth Stillbirth Termination Continuing pregnancy

If continuing pregnancy, what is gestational age of fetus? _____ weeks Expected Date of Delivery: _____ dd/mm/yyyy

CONCOMITANT MEDICATIONS

Was the woman taking any medications at the time of the suspected adverse reaction? Yes No

If yes, list drugs below. If more than 3 drugs were taken, complete supplemental sheet.

Drug	Dosage	Route	Date started dd/mm/yyyy	Date stopped dd/mm/yyyy	Indication
1. _____	_____	_____	_____	_____	_____
2. _____	_____	_____	_____	_____	_____
3. _____	_____	_____	_____	_____	_____



上海达华药业有限公司

SHANGHAI DAHUA PHARMACEUTICAL CO., LTD

Adverse Event Reporting form for Sino-implant (II)/Levoplant Users

Instructions: This form, or the equivalent national reporting form, should be used for all Sino-implant (II)/Levoplant (also known as Trust, Zarin or Femplant) adverse event reporting. For additional information, see the *General Instructions for Completing the Adverse Event Report*. If further information needs to be provided, please attach as necessary.

ADDITIONAL CLINICAL INFORMATION

Include additional relevant medical information here. Examples: medical history, known allergies, lab tests performed and results.

REPORTER DETAILS

Name: _____

Title: _____

Institution: _____

Address: _____

Email: _____

Tel Number(s): _____

Has the distributor been notified? Yes No Unknown Not Applicable

Has the distributor notified the National Drug Regulatory Authority? Yes No Unknown

Detailed instructions for operation are as follows: General Instructions for completing the form Adverse Event Report for Sino-implant (II)/Levoplant

Please send email completed form to: form@dahua-sh.com

Alternatively send completed form to: Shanghai Dahua Pharmaceutical Co. Ltd. Building 2, Room 301,
Lane 425, Baotong Road, Shanghai, China, 200071