上 海 达 华 药 业 有 限 公 司

SHANGHAI DAHUA PHARMACEUTICAL CO., LTD

Suspected 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) suspected adverse event reporting. If unsure whether an event constitutes an adverse event, file a report. For additional information, see the *General Instructions for Completing the Suspected 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: _____ Batch/Lot Number: _____

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 REACTION

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

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: _____

TREATMENT OF REACTION

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

_____

_____

_____

_____

_____

_____

上 海 达 华 药 业 有 限 公 司
SHANGHAI DAHUA PHARMACEUTICAL CO., LTD

Suspected 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) suspected adverse event reporting. If unsure whether an event constitutes an adverse event, file a report. For additional information, see the *General Instructions for Completing the Suspected Adverse Event Report*. If further information needs to be provided, please attach as necessary.

OUTCOME OF REACTION

Recovered ☐ 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.						

ADDITIONAL CLINICAL INFORMATION

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

_____

_____

_____

_____

上 海 达 华 药 业 有 限 公 司

SHANGHAI DAHUA PHARMACEUTICAL CO., LTD

Suspected 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) suspected adverse event reporting. If unsure whether an event constitutes an adverse event, file a report. For additional information, see the *General Instructions for Completing the Suspected Adverse Event Report*. If further information needs to be provided, please attach as necessary.

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 ☐

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