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 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.						

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: safety.dahua@ddreg.in.

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