



General Instructions for completing the form
Suspected Adverse Event Report for Sino-implant (II)/Levoplant

Important note: Only adverse events occurring in users of Sino-implant (II)/Levoplant (with brand names including Femplant, Zarin or Trust) should be reported to Shanghai Dahua Pharmaceutical Co., Ltd. Adverse events among women using a different hormonal implant should be reported to the manufacturer and/or distributor of that implant. Adverse events should also be reported to your national drug regulatory authority (NRA).

General Instructions

Please complete all entries in either black or blue ink. Kindly make entries as legible as possible.

Please complete all sections that apply to your report.

Dates should be entered as dd/mm/yyyy (example: 23 March 2011 or 23/03/2011). If exact dates are unknown please provide the best estimate (example: March 2011).

If the fields do not provide adequate space, attach additional pages as needed. Identify all attached pages as Page _of_, indicating the appropriate section (example: "additional clinical information").

User Details

Please provide the user's initials or some other type of identifier that will allow you to readily locate the case file if you are contacted for more information. Please do not record user's name. Please provide the user's age, date of birth, weight in kg, and height in cm.

Batch/Lot number is generally printed on the side of the box. For Sino-implant (II)/Levoplant, it is an 8-digit number.

Suspected Reaction

An adverse reaction is any incident in which the use of a medication at any dose is followed by an adverse clinical event or complication in the user. We are not, however, collecting information on the common, mild side effects of 2-rod contraceptive implants, particularly menstrual changes such as irregular bleeding or amenorrhea. You **should not** submit a Suspected Adverse Event Report for those expected side effects.



See below for the list of common mild side effects that **should not** be reported:

- Changes in bleeding patterns such as no monthly bleeding, infrequent bleeding, lighter bleeding, irregular bleeding, and heavy or prolonged bleeding (unless a serious underlying condition is suspected)
- Headaches
- Abdominal pain
- Acne
- Weight changes
- Breast tenderness
- Dizziness
- Mood changes
- Nausea

However, if any side effect is moderate to life-threatening in severity (see below), or if the side effect results in a Serious Adverse Event (SAE; see definitions below), you **should** report that reaction.

For reporting purposes, it is not necessary to be certain of a cause-and-effect relationship between the adverse reaction and the use of the medical product in question. Suspicion of an association is sufficient reason to report.

Submission of a report does not constitute confirmation that medical personnel or the product caused or contributed to the event.

For the date that the adverse reaction started, please indicate the date when the user first became aware of the event or reaction.

Guide to scale of severity of the reaction

Mild

- The adverse drug reaction (ADR) requires no treatment or change in product use
- No increase in length of stay (if hospitalized)

Moderate

- The ADR requires treatment or management, but does not require that the product be withheld, discontinued or otherwise changed
- The ADR requires that the suspected drug be withheld, discontinued or otherwise changed, and/or an antidote or other treatment is required
- Increases length of stay by at least one day (if hospitalized)
- The ADR is the reason for admission (if hospitalized)



Severe

- The ADR requires intensive medical care
- The ADR causes permanent harm to the patient

Life-threatening

- The patient was at substantial risk of dying at the time of the adverse event
- Use or continued use of the medical product might have resulted in the death of the patient

Guide to seriousness of the reaction

A serious adverse event, or SAE, is a special sub-set of adverse reactions. For an adverse reaction to be considered serious, it must involve one or more of the following:

- Death
- Life-threatening condition
- Hospitalization, or prolongation of hospitalization
- Persistent or significant disability
- Congenital anomaly or birth defect

Pregnancy

Please provide the basic facts about the pregnancy (including whether a pre-insertion pregnancy test was done, what the outcome of the pregnancy was, and how pregnancy was confirmed, etc)

Concomitant Medications

Provide the names, including trade and brand names, of all drugs used at the time of the suspected reaction. If the trade/ brand names are not known, use the generic product name. Also include over-the-counter drugs and traditional drugs used, if known. If more than 3 drugs were used, list additional drugs on a supplemental sheet and attach to the report.

Dosage – provide the dosage being taken for this drug. For example, 500 mg QID/BD.

Route – indicate route of administration of the drug. For example, IV for intravenous, IM for intramuscular, etc.

Indication – write down what the drug was prescribed for. For example, hypertension management, diabetes, etc.



Treatment of Reaction

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

Outcome of Reaction

Indicate the current medical status of the user here.

Additional Clinical Information

In this section, please provide information not otherwise covered on the form. Knowledge of other risk factors can help in the evaluation of a suspected adverse reaction. Please provide information on the user's medical history, for example hypertension, diabetes mellitus, liver or kidney problems. Known allergies should be specified. Laboratory tests performed should be included. Include any other data that might be useful in understanding the sequence of events.

Reporter details

Confidentiality is an important concern in the context of adverse reaction reporting. The user's identity should not be reported on the form.

The reporter's identity is needed to allow for timely follow-up in serious cases. The provider or the physician who is completing the report should provide his/her name, mailing address, phone number, fax number and email address. Also, please include the name of your institution or organization. Finally, please indicate if the suspected adverse event was reported to your national drug regulatory authority (NRA).