



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

## General Instructions for completing the form

### *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 or the letter YZ/ZZ+an 8-digit number.

#### Adverse 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. Users should report any adverse reactions during use according to the principle of suspicious reporting.



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

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:



上海达华药业有限公司

SHANGHAI DAHUA PHARMACEUTICAL CO., LTD

Death

Life-threatening condition

Hospitalization, or prolongation of hospitalization

Persistent or significant disability

Congenital anomaly or birth defect

Causing permanent or significant disability

Leading to other important medical events, these conditions may occur if no treatment is given.

### **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 adverse 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 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 adverse event was reported to your national drug regulatory authority (NRA).