Public Reporting Form for Side Effects on LEO Pharma Products

Instructions

- Please print this form and fill it out.
- Please use the date format DD-MMM-YYYY (Example 25-FEB-2014). If you do not know the exact date, please state as close as possible (Example NOV-2013).
- Please fill in the form as accurate as possible. If there are fields you cannot fill in, please write "unknown".
- If you have further relevant information or should more space be needed than available in the different fields, please use the field "Additional information" on page 2.

- Send the completed form to: **LEO Pharma A/S**
  Att.: Global Pharmacovigilance
  Industriparken 55
  DK – 2750 Ballerup
  Denmark

- Or scan and send it to **drug.safety@leo-pharma.com**

Patient information

Patient's initials:	Gender: Male ☐ Female ☐		Pregnant? Yes ☐ No ☐
Age at time of the side effect:	Weight:	Are you the patient? ☐ Yes - I am the patient ☐ No- I am reporting on behalf of someone else	

Drug information

Name of LEO Pharma drug used	
Lot no./Batch no. (if available)	
Name of the disease for which this LEO Pharma drug was used	
First date of treatment with the LEO Pharma drug	Date:
Daily dose of the LEO Pharma drug	
Has treatment with the LEO Pharma drug been stopped?	☐ Yes - Date: ☐ No

Side effect information

Which side effect(s) did the patient experience?	
At what date was the side effect(s) first noticed?	Date:

Describe what happened (how did the side effect(s) start, how did it develop, did the patient seek advice or treatment from a healthcare professional, and how was the side effect treated. Also, please state if the patient has suffered from the same side effect previously and specify which drug(s) was taken at the time):

_____

_____

_____

_____

_____

_____

How is the side effect(s) right now?
Recovered ☐ Recovering ☐ It is still on-going ☐ I do not know ☐

Did the side effect(s) following use of the LEO Pharma drug lead to any of the following? (Please tick one or more boxes of the below and provide a date where relevant):

☐ Admittance to hospital
☐ Prolongation of an existing hospitalisation
☐ Permanent disability or incapacity that effects daily life and that is not going to improve further
☐ Birth defect
☐ Life threatening situation
☐ Death of the patient. Please specify the date the patient died: _____

Other drug information

Were other drugs taken at the same time as the side effect(s) occurred? Yes ☐ No ☐

Other drugs taken at the time of the side effect(s) should be listed below, including the disease(s) for which the drug(s) was taken and the start date.
If the date when started is difficult to state, please state if the drug was started before or after treatment with LEO Pharma drug.

Name of drug: _____ Disease: _____ Date when started: _____
Name of drug: _____ Disease: _____ Date when started: _____
Name of drug: _____ Disease: _____ Date when started: _____

Disease information

At the time of the side effect to the LEO drug, was the patient suffering from any other diseases, including allergies?

☐ No
☐ Yes – Please fill in below:

Disease: _____ Date started: _____ Treatment prescribed? _____
Disease: _____ Date started: _____ Treatment prescribed? _____

Additional information

_____
_____
_____
_____
_____
_____

Reporter information

Your name	
Country	
E-mail address	
Are you a Health Care Professional? ☐ No ☐ Yes – Type:	
May LEO Pharma contact you via e-mail if clarification or additional information should be needed in the medical assessment of this side effect report? Yes ☐ No ☐	