

**PV\_SCH\_N\_\_HQ\_Public Reporting Form for Side Effects on LEO Pharma Products****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 Safety**  
**Industriparken 55**  
**DK - 2750 Ballerup**  
**Denmark**
- Or scan and send it to **drug.safety@leo-pharma.com**

**Patient information**

Patient's initials:	Gender: Male <input type="checkbox"/> Female <input type="checkbox"/>	Pregnant? Yes <input type="checkbox"/> No <input type="checkbox"/>
Age at time of the side effect:	Weight:	Are you the patient? <input type="checkbox"/> Yes - I am the patient <input type="checkbox"/> 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?	<input type="checkbox"/> Yes - Date: <input type="checkbox"/> 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):	
<hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/> <hr/>	
How is the side effect(s) right now? Recovered <input type="checkbox"/> Recovering <input type="checkbox"/> It is still on-going <input type="checkbox"/> I do not know <input type="checkbox"/>	



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Products**

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? <input type="checkbox"/> No <input type="checkbox"/> 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 <input type="checkbox"/> No <input type="checkbox"/>	