Notification of side effect(s) suspected to be associated with one or more medicinal product(s) or vaccine(s) for human use - **patient form**

The information leaflet on data protection, which explains how personal data is processed for pharmacovigilance declarations, can be referred to online at www.guichet.lu/pharmacovigilance

<table>
<tr>
<td>Patient
Initial letter of the patient's first name __ __ __

Initial letter of the patient's surname __

Gender ☐ F ☐ M

Weight ____ (kg)

Height ____ (m)</td>
<td>Date of birth
(dd/mm/yyyy)
___/___/_______

Or

Age

____ (years)

____ (months)</td>
<td>Is the patient pregnant?
☐ yes ☐ no

Expected delivery date (dd/mm/yyyy)

___/___/_______

Is the patient nursing?
☐ yes ☐ no</td>
<td>Known allergies

Addictions (e.g. tobacco, medication, alcohol, drugs, etc)</td>
</tr>
<tr>
<td colspan="4">Current illnesses, medical or surgical history</td>
</tr>
<tr>
<td colspan="4">Side effect
General description of the side effects
Please describe the observed effect in detail. Specify whether the observed effect is the worsening of an existing disease. If additional tests were carried out, specify which ones and give the results. You can also include, if possible, a report of hospitalization or additional tests (anonymized).</td>
</tr>
</table>

☐ caused or sustained hospitalisation

Details of the adverse effect(s) experienced: *(add lines if necessary)*

Effect	Start and end date (dd/mm/yyy)	Evolution	Treatment of the adverse effect	If yes, specify
1.	From __/__/____ To __/__/____	☐ No improvement ☐ Recovering ☐ Recovery without sequelae ☐ Recovery with sequelae ☐ Death ☐ Unknown	☐ No ☐ Yes ☐ Unknown	
2.	From __/__/____ To __/__/____	☐ No improvement ☐ Recovering ☐ Recovery without sequelae ☐ Recovery with sequelae ☐ Death ☐ Unknown	☐ No ☐ Yes ☐ Unknown	
3.	From __/__/____ To __/__/____	☐ No improvement ☐ Recovering ☐ Recovery without sequelae ☐ Recovery with sequelae ☐ Death ☐ Unknown	☐ No ☐ Yes ☐ Unknown	

Medication(s)

Please list below (in CAPITALS) if possible, all the medicines or vaccines you have taken at the time of the side effect or some time before its onset (including medicines used for chronic diseases and over-the-counter medicines).
Also specify if you are taking hormonal contraceptives (the pill).
IMPORTANT! Please tick the medicine(s) or vaccine(s) that you suspect may have caused the effect.

Commercial name of the medication and batch number	At least one medication must be suspected	Dosage and method of administration	Start date of the treatment (dd/mm/yyyy)	End date of the treatment (dd/mm/yyyy)	Reason of treatment
1.	☐ Yes ☐ No ☐ Don't know		___/____/______	___/____/______ ☐ Still ongoing	
2.	☐ Yes ☐ No ☐ Don't know		___/____/______	___/____/______ ☐ Still ongoing	
3.	☐ Yes ☐ No ☐ Don't know		___/____/______	___/____/______ ☐ Still ongoing	
4.	☐ Yes ☐ No ☐ Don't know		___/____/______	___/____/______ ☐ Still ongoing	

Details of the declarant

Your contact information will potentially enable us to contact you for further details regarding the event(s) you are declaring and to send you an acknowledgment of receipt for your declaration.

Surname : ________________________________ First name : _____________________________

Qualification : ______________________________

I prefer to be contacted by

☐ e-mail____

☐ Phone *(also specify the country code)* ___________________________________

☐ Postal Street, number : ____

City, postal code : ______________________________________

Country : ______________________________

☐ I give my consent for my attending physician to be contacted for further information regarding my case

Contact the attending physician:

Name : ________________________________

Contact (e-mail or phone, *also specify the country code*) :

____

Contact details for the declaration:

Please send the completed form:

- preferably by e-mail to the CRPV (Regional Pharmacovigilance Centres) and the DPM (Pharmacy and Medicines Division);
- or by post to one of the following 2 addresses.

Feel free to attach any other relevant medical document related to your declaration to the PDF form (photos, report, analysis results).

Centre Régional de Pharmacovigilance de Nancy **ou**

E-mail : crpv@chru-nancy.fr

Tél : +33 3.83.65.60.85

Fax : +33 3.83.65.61.33

Adresse physique:

Centre Régional de Pharmacovigilance de Nancy

Bâtiment de Biologie Moléculaire et de Biopathologie (BBB)

CHRU de Nancy - Hôpitaux de Brabois

Rue du Morvan

54 511 VANDOEUVRE LES NANCY CEDEX, France

Division de la Pharmacie et des Médicaments

E-mail : pharmacovigilance@ms.etat.lu

Tél : +352 247 85592

Adresse physique:

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