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| Please return this form to: **HRA Pharma Pharmacovigilance**  **200 Avenue de Paris - 92320 CHATILLON - France**  **fax : +33 (0)1.42.77.03.52, e-mail :** [**pharmacovigilance@hra-pharma.com**](mailto:pharmacovigilance@hra-pharma.com) | | | | | | | | | |
| **For internal use only: Reception date of the information (D0): \_ \_ / \_ \_ / \_ \_ \_ \_** Case n°:\_.\_.\_.\_.\_.\_.\_.\_.\_.\_.\_ | | | | | | | | | |
| **patient identification** | | | **reporter identification** | | | | | | |
| Initials (First name, Last name): \_ \_  Birthdate : \_ \_ / \_ \_ / \_ \_ \_ \_ or group age (foetus, neonate, infantn child, adolescent, adult, elderly):  Sex : □ M □ F  Weight : \_ \_ \_ kg  Height: \_ \_ \_ cm | | | Name :  Adress :  Country:  Tel : Fax :  Health Care Professional: □ Yes / □ No  □ Market research: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | |
| **Past medical history, concomitant diseases**  **(for Cosmetovigilance case, include allergy history and type of skin)** | | | | | | | | | |
|  | | | | | | | | | |
| **Hra suspected Drug or Medical Device** | | | | | | | | | |
| **Drug or Medical Device** | **Batch n° / Expiration date** | **Posology** | | **Dates of administration** | | | **Indication** | | |
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| **Hra suspected Cosmetic Product** | | | | | | | | | |
| **Cosmetic Product**  **(exact name, not only brand)** | **Batch n° / Expiration date** | **Application area(s)** | **Frequency of use** | | **Modalities of use** | **Dates of applications** | | **Reason for use** | |
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| **Other treatments** | | | | | | | | | |
|  | | **Posology** | | **Dates of administration** | | **Indication** | | | |
| Other suspected drugs / cosmetic products | |  | |  | |  | | | |
| Concomitant treatments/cosmetic products | |  | |  | |  | | | |
| **For internal use only:** Case n°:\_.\_.\_.\_.\_.\_.\_.\_.\_.\_.\_ | | | | | | | | | |
| **EVENT(s)** (see definitions on page 4) | | | | | | | | | |
| □ Adverse reaction/Undesirable event □ Misuse □ Overdose □ Abuse □ Medication error □ Off-label use □ Lack of efficacy□ Exposure during breastfeeding □ Pregnancy (LMP \_ \_ / \_ \_ / \_ \_ \_ \_)  □ Suspicion of infectious agent transmission □ Occupational exposure □ Falsified medicinal product  Onset date of event: \_ \_ / \_ \_ / \_ \_ \_ \_ and f*or cosmetic products undesirable events*:   * Number of applications before event:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ * Time after last application:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ * Reaction in/out of application area: □ In □ Out, specify:\_\_\_\_\_\_\_\_   Description: | | | | | | | | | |
| **seriousness Criteria** | | | | | | | | |
| The adverse reaction/undesirable event fulfil a seriousness criteria: □ No / □ Yes, which one:  □ Hospitalisation or prolongation of hospitalisation □ Life threatening if yes, from \_ \_/ \_ \_ / \_ \_ \_ \_ to \_ \_/ \_ \_ / \_ \_ \_ \_  □ Persistent or significant disability/incapacity □ Death, if yes date : \_ \_/ \_ \_ / \_ \_ \_ \_  □ Medically significant\* □ Congenital anomaly or birth defect  □ Temporary or permanent functional incapacity (*specific to cosmetic products*), specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \*e.g.: Important medical event that may not be immediately life-threatening or result in death or hospitalisation but may jeopardise the patient or may require intervention to prevent one of the other seriousness criteria. | | | | | | | | |
| **Action taken** | | | | | | | | |
| HRA Pharma drug/medical device/cosmetic stopped? □ No □ Yes, date: \_ \_/ \_ \_ / \_ \_ \_ \_  & reaction abate? □ No □ Yes, date: \_ \_/ \_ \_ / \_ \_ \_ \_ or Time after last application (for cosmetics):\_\_\_\_\_\_\_\_\_\_\_\_\_  Other measures taken (corrective treatment, modification of daily dose): | | | | | | | | |
| **Outcome** | | | | | | | | |
| □ Recovered □ Resolving □ Continues □ Aggravation □ Recovered with sequelae □ Death  HRA Pharma drug/medical device/cosmetic was reintroduced: □ No □ Yes, date: \_ \_/ \_ \_ / \_ \_ \_ \_  & posology/conditions of use: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Did the reaction reappear after reintroduction? □ No / □ Yes, date: \_ \_/ \_ \_ / \_ \_ \_ \_ | | | | | | | | |

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| **For internal use only:** Case n°:\_.\_.\_.\_.\_.\_.\_.\_.\_.\_.\_ |
| **Result of additional examination** |
| Relevant clinical, laboratory, X-ray, and autopsy findings etc. (please give normal laboratory value and dates)  Attached anonymous photocopies if more convenient.  For cosmetics products: skin tests (patch test, prick test, please give results…): |
| **Relationship between adverse reaction and HRA Pharma Product** |
| □ Not related □ Unlikely □ Possible □ Probable □ Certain □ Not assessable due to insufficient data  Could other factors also have contributed to the adverse reaction? Which ones? |
| **Comments** |
|  |
| Date of completion: \_ \_/ \_ \_ / \_ \_ \_ \_ Signature and stamp:  **Thank you for completing this form.** |

**Definitions:**

Healthcare professional: Medically qualified person such as a physician, dentist, pharmacist, nurse, coroner or as otherwise specified by local regulations (Good Pharmacovigilance Practices-Module VI).

Adverse reaction: A response to a medicinal product which is noxious and unintended.

Response in this context means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility.

Adverse reactions may arise from use of the product within or outside the terms of the marketing authorization or from occupational exposure. Use outside the marketing authorization include off-label use, overdose, misuse, abuse and medication errors (Good Pharmacovigilance Practices-Annex I).

Misuse: Situations where a medicinal product is intentionally and inappropriately used not in accordance with the terms of marketing authorization (Good Pharmacovigilance Practices-Annex I).

Overdose: Administration of a quantity of a medicinal product given per administration or cumulatively which is above the maximum recommended dose according to the authorized product information. Clinical judgment should always be applied (Good Pharmacovigilance Practices-Annex I).

Abuse: Persistent or sporadic, intentional excessive use of medicinal products which is accompanied by harmful physical or psychological effects (Good Pharmacovigilance Practices-Annex I).

Off-label use: Situations where a medicinal product is intentionally used for a medical purpose not in accordance with the terms of marketing authorization (Good Pharmacovigilance Practices-Annex I).

Medication error: Refers to any unintended failure in the drug treatment process that leads to, or has the potential to lead to, harm to the patient.

* Intercepted medication error: indicates that an intervention caused a break in the chain of events in the treatment process before reaching the patient which would have resulted in a ‘potential’ ADR. The intervention has prevented actual harm being caused to the patient.
* Potential medication error: all possible mistakes in the prescribing, storing, dispensing, preparation for administration or administration of a medicinal product by all persons who are involved in the medication process. (Good Pharmacovigilance Practices-Module VI).

LMP (Last Menstrual Period): refers to the first day of the woman's last menstrual period.

Occupational exposure: Exposure to a medicinal product for human use as a result of one’s occupation (Good Pharmacovigilance Practices- Module VI).

Falsified medicinal product: Any medicinal product with a false representation of (a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients; (b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or (c) its history, including the records and documents relating to the distribution channels used.

*Data Privacy policy:*

*HRA Pharma is the controller of the processing of personal data implemented for the transmission and the management of potential adverse events regarding its medicinal products. The legal basis of such processing of personal data are the obligation of pharmacovigilance for a pharmaceutical company and the public interest of ensuring high standards of quality and safety for medicinal products.*

*Recipients of your personal data within such processing are:*

*- Pharmacovigilance Department of HRA Pharma,*

*- AB Cube, provider of the software for the management of pharmacovigilance data, located 21 bis rue P. Vaillant Couturier, at Montreuil in France, and its sub-contractor hosting the database Claranet Santé, located 18-20 rue du  Faubourg du Temple, Paris 11e, in France,*

*- Health Authorities in compliance with legal requirements.*

*Your personal data will be stored during ten (10) years starting from the end of the marketing authorization of the concerned pharmaceutical product. Your personal data will be deleted afterwards.*

*In compliance with the regulation in force, notably the General Data Protection Regulation 2016/679, you are entitled to exercise the following rights:*

*- to access to your personal data,*

*- of rectification and erasure of data,*

*- of restriction of processing,*

*- to object,*

*- of data portability.*

*In order to exercise these rights, please contact the Data Protection Officer of HRA Pharma at:*

*-* [*dataprivacy@hra-pharma.com*](mailto:dataprivacy@hra-pharma.com)*, or*

*- Laboratoire HRA Pharma, 200 avenue de Paris, 92320 Châtillon, France*

*In case of dispute, a claim can be submitted to the Data Protection Authority of your country.*