

**NOTIFICATION FOR PRODUCT INFORMATION AMENDMENT UNDER ARTICLE 61(3)  
(NOT ACCOMPANYING A VARIATION CHANGE)**

**NATIONAL AUTHORISATION IN DC or MR Procedure**

**Product Information amendment number<sup>1</sup>:** \_\_\_\_/\_\_\_\_/\_\_\_\_/\_\_\_\_/\_\_\_\_/\_\_\_\_

**Reference Member State**

AT BE BG CY CZ DE DK EE EL ES FI FR HU IE IS  
IT LI LT LU LV MT NL NO PL PT RO SE SI SK UK

**Concerned Member State(s)**

AT BE BG CY CZ DE DK EE EL ES FI FR HU IE IS  
IT LI LT LU LV MT NL NO PL PT RO SE SI SK UK  
NONE

<sup>1</sup> Number to be completed by the Marketing Authorisation Holder, reflecting the correct consequential Mutual Recognition or Decentralised Procedure Number according to the CMD(h) Standard Operating Procedure for Article 61(3) Changes to Patient Information.' (<http://www.hma.eu/>).

(Invented)Name:

Name and address of MA holder:

Active substance(s):

Name and address of Contact:

Pharmaceutical form(s) and strength(s):

Telephone number:

MA number(s)<sup>3</sup>:

Fax number:

E-mail:

Pharmacotherapeutic Classification

Applicant's reference:

(Group & ATC Code):

**BACKGROUND:**

*Please give brief background explanation for the proposed changes to your label and/or package leaflet (PL). Provide the following: one full colour mock-up of the current approved label/PL, two full colour mock-ups of the proposed label/PL (one copy to be annotated with the proposed changes and one clean copy).*

**Declaration of the Applicant:**

I hereby submit an application for the labels and/or package leaflet of the above Marketing Authorisation to be amended in accordance with the proposals given above. I declare that (*Please tick*):

- The required amended actual size colour mock-ups have been supplied;
- There are no other changes than those identified in this application;
- The change(s) do not affect the Summary of Product Characteristics;
- The change(s) will not affect the safe use of the product or require user Acceptance testing to be undertaken;

Change will be implemented from:

- Next production run/next printing (*indicate approximate date*) \_\_\_\_\_
- Date: \_\_\_\_\_

Fees paid (*if applicable*) amount/currency: \_\_\_\_\_

*Please specify fee category under National rules* \_\_\_\_\_

**Main Signatory**<sup>2</sup> \_\_\_\_\_ Status (Job title) \_\_\_\_\_

Print name \_\_\_\_\_ Date \_\_\_\_\_

**Second Signatory** \_\_\_\_\_ Status (Job title) \_\_\_\_\_

Print name \_\_\_\_\_ Date \_\_\_\_\_

<sup>2</sup>The main signatory is mandatory

Please quote the MR or DC product information amendment number, the name of the medicinal product and the MA number in any future correspondence.