

Send the form to: Läkemedelsverket
Box 26
S-751 03 Uppsala
Sweden
RIC@mpa.se

Notification of change in labelling and/or package leaflet - national change

| Information about the medicinal product: | |
|--|----------------------------------|
| Name of the medicinal product | Strength and pharmaceutical form |
| Asp No. and Marketing Authorisation No. Asp No: MA No: | ATC-code |
| Approved pack size(s) | |

| Marketing Authorisation Holder: | Local representative: |
|---------------------------------|-----------------------|
| Name | Name |
| Address | Address |

| Manufacturer responsible for batch release: |
|---|
| Name |
| Address |

| Background and scope of the change |
|------------------------------------|
| |

| |
|---|
| <input type="checkbox"/> Proposed mock-up of the labelling is enclosed. <input type="checkbox"/> Currently approved mock-up of the labelling is enclosed. <input type="checkbox"/> Package leaflet with marked change(s) is enclosed. <input type="checkbox"/> The proposed change(s) will not affect the SmPC. <input type="checkbox"/> We certify that no other change(s) has been made. <input type="checkbox"/> Change(s) will be implemented from, date |
|---|

| Contact person: | | |
|-----------------|---------|-----|
| Name | Company | |
| Address | Phone | Fax |
| | e-mail | |

| Signature | | |
|-----------|----------------------------|------|
| Signature | Clarification of signature | Date |