

Adliswil, 6 March 2018

## **Approval for the use of 1 PRIMARY WOUND DRESSING for children below 12 years of age**

To whom it may concern,

Herewith we inform you that as of 6 March 2018 the wound healing product 1 PRIMARY WOUND DRESSING can officially be used for children below 12 years of age.

The Notified Body approved the change after evaluating a clinical review submitted by Phytoceuticals, in which the risk-benefit profile of 1 PRIMARY WOUND DRESSING for the treatment of children wounds was extensively analyzed.

As a consequence, following precaution in the instruction for use is replaced:

*“Since no data on the safe use in children below 12 years of age and (...) is available, the use of 1 PRIMARY WOUND DRESSING in these patient groups is not recommended.”*

Following two remarks will be made in the precaution section of the new instruction for use:

- For children from 1 month to 2 years of age, the maximum number of spray puffs per day is limited to 50% of the maximal allowed number of spray puffs.
- The use of 1 PRIMARY WOUND DRESSING in neonates (newborns up to 1 month) is not recommended due to lack of clinical data.

The changes will be reflected in the instructions for use in all batches that are produced after 6 March 2018. The changes, however, are already valid for previous batches.

Yours sincerely,



Eduardo Theiler  
CEO



Alina Frei  
Head Quality Management



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COO