

March XXX, 2019

URGENT INFORMATION ON POTENTIAL MISUSE

Medical device [CHOOSE THE PRODUCT NAME IN YOUR COUNTRY: Objectif ZeroVerrue® /Endwarts®/Vartfri®/Vortefri®/Syylend®] solution in bottle of [CHOOSE THE PRODUCT FORMAT IN YOUR COUNTRY: 5/3] ml

Commercial code: [if such a code/bar code/registration number exists and is available for order the product]

For the attention of dispensing Pharmacists

[CHOOSE THE PRODUCT NAME IN YOUR COUNTRY: Objectif ZeroVerrue /Endwarts/Vartfri/Vortefri/Syylend], solution in bottle is a medical device intended for the topic treatment of warts and **containing a corrosive solution** (formic acid), as indicated on the labelling.

Pictograms and bold text are presents on the packages, including the bottle label, to warn about corrosive risk and how to avoid it.

The device is presented as a brown glass bottle with a white cap, similar to other medicinal products, in particular for oral use, also having white cap **which could lead to a product confusion with severe outcome if mixed up and applied erroneously orally.**



Mylan Medical has already implemented a corrective action by changing the color of the cap of [CHOOSE THE PRODUCT NAME IN YOUR COUNTRY: Objectif ZeroVerrue /Endwarts/Vartfri/Vortefri/Syylend original/bottle] from white to orange: product with an orange cap will be soon marketed (next weeks).

To avoid as much as possible this risk of mix-up, bottles of [CHOOSE THE PRODUCT NAME IN YOUR COUNTRY: Objectif ZeroVerrue /Endwarts/Vartfri/Vortefri/Syylend] **must be always stored with its external carton and it is important to remind the users, during the dispensing of this product, that it is a corrosive solution. Users should always remember to read the label before use and keep the internal leaflet in case of future needs.**

We thank you for sharing this security information with your team.
The Agence nationale de sécurité du médicament et des produits de santé (ANSM) has been informed of this security note.

Best regards.

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Location gérant du fonds de commerce de la société Meda Pharma – RCS 456 204 569]

Mylan [Site, authorized personnel for signature if different from Managing Director]