

**Björn Isaksson**

Informationsgranskningsnämnden, IGF, LIF

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Stockholm October 29<sup>th</sup> 2019

Regarding IGN159

We thank you for your letter and for making us aware of this issue.

The original short text for Zomig Nasal (Zolmitriptan) was developed independently of this specific promotional material and thus this particular picture. The entire campaign has several pictures of women in different situations to show women with busy lives and not specifically pregnant or breastfeeding women. The wording for the section on warnings and precautions in the short text was based on a medical evaluation of the SPC as a whole and not based on which individual pictures we would use in the promotional material on a case by case basis.

In addition, as you may see from below, the original picture shows a woman feeding the baby with solid food, hence we did not connect the picture to the issues around breastfeeding and pregnancy, however we fully understand your point of view. With your comments in mind, we fully agree that the SPC should reflect all possible interpretations of the material in its entirety and therefore include the specific limitation regarding pregnancy and breastfeeding, especially since the picture has been cut and therefore does not show the solid food. Due to the higher prevalence of migraine among young women compared to other age groups or men, we will include these precautions in the short text for all promotional material regarding Zomig (zolmitriptan).

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**Grünenthal Sweden AB**

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**General Manager:**

Mrs. Gülizar Aybasti Skjoldager

**Location of headquarter:**

Grünenthal Pharma GmbH & Co. KG  
Aachen, Germany

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The material related to the above IGN has not been distributed and will be revised before use to reflect the extra warnings as discussed during our call.

This is our final answer.

Kind Regards  
**Grunenthal Sweden AB**

*Marc Land, MD MBA*

Marc Land, MD  
Head of Medical Affairs, Nordic

Original picture:



GRÜNENTHAL SWEDEN AB



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