



Bundesamt für  
Sicherheit im  
Gesundheitswesen  
**BASG**

Unternehmen/Frau/Herr  
Organisationseinheit (optional)  
(z. H.) Vorname Nachname  
Straße  
PLZ Ort

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**Ihr Zeichen:**

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### **PHV-issue: Ethinylestradiol**

Sehr geehrte Damen und Herren,

Im Rahmen des PSUSA-Verfahrens zu Desogestrel/Ethinylestradiol (PSUSA/00000967/202009) stellte das PRAC fest, dass in den Produktinformationen Ethinylestradiol haltiger Arzneispezialitäten widersprüchliche Informationen zu "Angioödemem" enthalten sind.

Daher empfiehlt das PRAC, in die Produktinformationen aller Ethinylestradiol-haltigen Arzneimittel das Wording gemäß Anhang aufzunehmen.

Bei der Umsetzung in die Produktinformation der betroffenen Arzneispezialitäten beachten Sie auch die CMDh Minutes (Meeting vom 22. bis 23. Juni 2021): <https://www.hma.eu/457.html>



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## **Auszug aus dem Protokoll des CMDh meetings vom 22. bis 23. Juni 2021**

## 6.2.2. Information on PRAC recommendations for PSUSAs for maintenance

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### 6.2.2.1. Desogestrel / ethinylestradiol - PSUSA/00000967/202009

In the framework of the PSUSA on desogestrel / ethinylestradiol, the PRAC noted that inconsistent information related with angioedema is included in section(s) 4.4 and 4.8 of the Summary of Product Characteristics and in sections 2 and 4 of the Package Leaflet of all ethinylestradiol containing medicinal products (single agent and in fixed dose combinations).

Therefore, PRAC recommends that the following is included in the product information of all ethinylestradiol containing medicinal products:

#### **Summary of product characteristics**

A warning should be added/revised as follows:

Section 4.4

**Exogenous estrogens may induce or exacerbate symptoms of hereditary and acquired angioedema.**

Section 4.8

Text in the tabulated list of adverse reactions in the SOC Immune system disorders should be added/revised as follows:

**Exacerbation of symptoms of hereditary and acquired angioedema. (Frequency 'Unknown')**

#### **Package leaflet**

2. What you need to know before you use [brand name]

Tell your doctor if any of the following conditions apply to you.

If the condition develops or gets worse while you use [trade name], you should also tell your doctor.

**- If you experience symptoms of angioedema such as swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing contact a doctor immediately. Products containing estrogens may cause or worsen the symptoms of hereditary and acquired angioedema.**

#### 4. Possible side effects

Serious side effects

**Contact a doctor immediately if you experience any of the following symptoms of angioedema: swollen face, tongue and/or throat and/or difficulty swallowing or hives potentially with difficulty breathing (see also section "Warnings and precautions").**