



## **Trifarotene**

Resolution of: 4 February 2021  
Entry into force on: 4 February 2021  
Federal Gazette, BAnz AT 02.03.2021 B4

valid until: unlimited

### **Therapeutic indication (according to the marketing authorisation of 15 April 2020)**

Trifarotene is indicated for the topical treatment of acne vulgaris on the face and/or trunk in patients 12 years of age and older if many comedones, papules, and pustules are present.

### **Therapeutic indication of the resolution (resolution of 4 February 2021)**

See therapeutic indication according to marketing authorisation

<b>1. Additional benefit of the medicinal product in relation to the appropriate comparator therapy</b>
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Patients 12 years of age and older with acne vulgaris on the face and/or trunk if many comedones, papules, and pustules are present

#### **Appropriate comparator therapy:**

- A topical combination therapy of adapalene + benzoyl peroxide
- or
- A topical combination therapy of clindamycin + benzoyl peroxide

#### **Extent and probability of the additional benefit of trifarotene compared with the appropriate comparator therapy:**

An additional benefit is not proven.

#### **Study results according to endpoints:**

Patients 12 years of age and older with acne vulgaris on the face and/or trunk if many comedones, papules, and pustules are present

There are no relevant data compared with the appropriate comparator therapy.

## Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ Risk of bias	Summary
Mortality	n.a.	No relevant data are available.
Morbidity	n.a.	No relevant data are available.
Health-related quality of life	n.a.	No relevant data are available.
Side effects	n.a.	No relevant data are available.
<p>Explanations:</p> <p>↑: statistically significant and relevant positive effect with low/unclear reliability of data</p> <p>↓: statistically significant and relevant negative effect with low/unclear reliability of data</p> <p>↑↑: statistically significant and relevant positive effect with high reliability of data</p> <p>↓↓: statistically significant and relevant negative effect with high reliability of data</p> <p>↔: no statistically significant or relevant difference</p> <p>∅: There are no usable data for the benefit assessment.</p> <p>n.a.: not assessable</p>		

## 2. Number of patients or demarcation of patient groups eligible for treatment

Patients 12 years of age and older with acne vulgaris on the face and/or trunk if many comedones, papules, and pustules are present

approx. 887,500 to 1,950,700 patients

## 3. Requirements for a quality-assured application

The requirements in the product information are to be taken into account.

## 4. Treatment costs

### Annual treatment costs:

Patients 12 years of age and older with acne vulgaris on the face and/or trunk if many comedones, papules, and pustules are present

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Trifarotene	different for each individual patient
Appropriate comparator therapy:	
Topical combination therapy of adapalene + benzoyl peroxide	different for each individual patient

Designation of the therapy	Annual treatment costs/patient
Topical combination therapy of clindamycin + benzoyl peroxide	different for each individual patient

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 January 2021

Costs for additionally required SHI services: not applicable