



Bundesamt für  
Sicherheit im  
Gesundheitswesen  
**BASG**

EVER Valinject GmbH  
Oberburgau 3  
4866 Unterach am Attersee  
Austria

### **Authorization of the medicinal product**

#### **Testosterone EVER Pharma 1000 mg/4 ml solution for injection**

Basic number: 101529825

Procedure: 101529824

## **B E C A U S E**

### **S p r u c h**

At the request of the company EVER Valinject GmbH, 4866 Unterach am Attersee, the Federal Office for Safety in Health Care, in accordance with § 10 para. 1 and 12 in conjunction with § 20 of the Medicinal Products Act (AMG), Federal Law Gazette No. 185/1983 as amended, is authorizing the proprietary medicinal product

Testosterone EVER Pharma 1000 mg/4 ml solution for injection  
Approval No.: 142130

in the form described in the annexes for distribution in Germany for a period of five years from the date on which the approval notice becomes legally effective.

#### **Attachments:**

Labeling Information  
for healthcare  
professionals  
Instructions for use  
Composition

The annexes are an integral part of the decision.

In accordance with the Prescription Obligations Act BGBl. I No. 413/1972 as amended in conjunction with the Medicinal Products Act BGBl. I No. 185/1983 as amended, the following dispensing restrictions are stipulated:

"Pharmacy-only" and "Prescription-only"

According to Section 75k AMG, marketing authorization holders are obliged to submit regular safety update reports (PSUR).



The frequency and deadlines for the submission of PSUR reports for the medicinal product in question must comply with the applicable legal provisions and, where applicable, the list published by the European Medicines Agency via the European medicines internet portal ([www.ema.europa.eu](http://www.ema.europa.eu)).

### **Objection**

As the application was granted in full, there is no need to state reasons pursuant to § 58 AVG, Federal Law Gazette No. 51/1991 as amended.

### **Temporal validity of the authorization**

The validity of this approval certificate ends after five years.

The marketing authorization holder can apply to the Federal Office for Safety in Health Care for an extension of the marketing authorization if the legal requirements of § 20 AMG are met.

### **Receivment of receipt**

An appeal against this decision may be lodged with the Federal Administrative Court within **four weeks** of notification.

The appeal must contain the name of the contested decision, the name of the authority against which the appeal is lodged, the grounds on which the allegation of illegality is based, the request and the information required to assess whether the appeal has been lodged in good time.

The complaint must be made in writing and must be submitted to the address of the Federal Office for Safety in Health Care, Traisengasse 5 in 1200 Vienna, or by email to [recht@basg.gv.at](mailto:recht@basg.gv.at).

The Federal Office

Beck Gerhard, Reich Katharina, Waxenecker Günter  
on 29.4.2024

	<p>This document has been officially signed.</p> <p>Information on checking the electronic signature and printout can be found at <a href="http://www.basg.gv.at/amtssignatur">http://www.basg.gv.at/amtssignatur</a>.</p> <p>Federal Office for Safety in Health Care Traisengasse 5, 1200 Vienna</p>
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