

# **Summary Public Assessment Report**

## **Fixopost (latanoprost, timolol maleate)**

**SE/H/1602/001-002/DC**

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Fixopost

(latanoprost, timolol maleate)

50 micrograms/ml + 5mg/ml eye drops, solution in single dose container

50 micrograms/ml + 5 mg/ml eye drops, solution

This is a summary of the public assessment report (PAR) for Fixopost. It explains how Fixopost was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Fixopost.

For practical information about using Fixopost, patients should read the package leaflet or contact their doctor or pharmacist.

### **What is Fixopost and what is it used for?**

Fixopost is a 'hybrid medicine'. This means that it is similar to a reference medicine containing the same active substances, but it is free from preservative.

The company has provided additional own data to demonstrate the safety and efficacy of Fixopost regarding this difference from the reference medicine.

The reference medicine for Fixopost is Xalacom. Fixopost is used to reduce the pressure in the eye for conditions known as open angle glaucoma or ocular hypertension. Both these conditions are linked to an increase in the pressure within the eye, eventually affecting the eyesight.

### **How does Fixopost work?**

Fixopost contains two medicines: latanoprost and timolol. Latanoprost belongs to a group of medicines known as prostaglandin analogues. Timolol belongs to a group of medicines known as beta-blockers. Latanoprost works by increasing the natural outflow of fluid from the eye into the bloodstream. Timolol works by slowing the formation of fluid in the eye.

### **How is Fixopost used?**

The pharmaceutical form of Fixopost is eyedrops in single or multiple dose container for ocular use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

### **What benefits of Fixopost have been shown in studies?**

Because Fixopost is a hybrid application of Xalacom, clinical studies have been provided for Fixopost to show efficacy for the difference of Fixopost from the reference product Xalacom.

### **What are the possible side effects of Fixopost?**

For the full list of all side effects reported with Fixopost see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

### **Why is Fixopost approved?**

This medicine is similar to a reference medicine containing the same active substances but is free from preservative. The company has provided additional own data to demonstrate the safety and efficacy of Fixopost regarding this difference from the reference medicine.

No new or unexpected safety concerns arose from the application. Therefore, the Medical Products Agency in Sweden decided that Fixopost's benefits are greater than its risks and recommended that it be approved for use.

### **What measures are being taken to ensure the safe and effective use of Fixopost?**

A risk management plan has been developed to ensure that Fixopost is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Fixopost, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

### **Other information about Fixopost**

The marketing authorisation for Fixopost single dose container was granted on 2018-09-24 in Sweden.

The marketing authorisation for Fixopost multi dose container was granted on 2020-12-21 in Sweden.

The full PARs for Fixopost can be found on the following website:

<http://mri.medagencies.org/Human/>. For more information about treatment with Fixopost, please read the [package leaflet \(single dose\)](#) / [package leaflet \(multi dose\)](#) or contact your doctor or pharmacist.

This summary was last updated in 2021-02.