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Withdrawal of application for the marketing authorisation of Durysta (bimatoprost intracameral implant)

AbbVie Deutschland GmbH & Co. KG withdrew its application for a marketing authorisation of Durysta for the reduction of intraocular pressure (IOP) in adults with open angle glaucoma or ocular hypertension.

The company withdrew the application on 13 September 2024.

What is Durysta and what was it intended to be used for?

Durysta was developed as a medicine to reduce the pressure inside the eye in adults with open angle glaucoma or ocular hypertension (when the pressure in the eye is higher than normal). In open angle glaucoma the high pressure is caused by fluid being unable to drain out of the eye. Durysta was intended for use in patients who could not use eye drops to lower the eye pressure.

Durysta contains the active substance bimatoprost.

How does Durysta work?

The active substance in Durysta, bimatoprost, is a prostaglandin analogue (a copy of the natural substance prostaglandin) that works on the cells and tissues controlling the drainage of liquid in the eye. By increasing the amount of liquid that is drained out of the eye, bimatoprost reduces the pressure inside the eye in patients with open angle glaucoma or high inner eye pressure.

Eye drops containing bimatoprost are already authorised in the European Union for reducing intraocular pressure. Durysta was to be available as an implant that slowly releases bimatoprost directly into the eye and was to be given via intracameral injection (an injection inside the anterior chamber of the eye, the front part of the eye between the cornea and the iris).

What did the company present to support its application?

The company presented the results of two main studies in patients with high intraocular pressure. One study involving 183 patients compared up to two Durysta implants with laser treatment in patients who had open angle glaucoma or high inner eye pressure in both eyes. The study looked at the change in eye pressure at 4, 12 and 24 weeks after treatment.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Another ongoing study involving 313 patients looked at the safety and the duration of effect of up to 3 Durysta implants.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the European Medicines Agency had evaluated the information from the company and prepared questions for the company. The company had not responded to the last round of questions at the time of the withdrawal.

What did the Agency recommend at that time?

Based on the review of the data and the company's response to the Agency's questions, at the time of the withdrawal the Agency had major concerns and its provisional opinion was that Durysta, given as two implants per affected eye, could not have been authorised for the reduction of intraocular pressure in adults with open angle glaucoma or ocular hypertension. The benefits and risks of giving Durysta as a single implant were not established, based on the available data.

In particular, the Agency considered the safety profile of Durysta to be of concern because of the increased occurrence of irreversible corneal endothelial cell loss (ECL). Corneal ECL can occur naturally with age, but its frequency, extent and severity in patients receiving Durysta were not considered acceptable. There were also concerns about incomplete biodegradation of the implant even after 5 years, potentially leading to implant residues remaining in the patient's eyes for a long time. The risk of multiple implants remaining inside the eye for a long time also made re-treatment with Durysta not acceptable.

There were also several major concerns about the quality of Durysta, including differences in the release of the active substance between the product used during clinical studies and the one intended for the market, the possibility of particulate contamination, and concerns about the sterility of the finished product.

Therefore, at the time of the withdrawal, the Agency's opinion was that the benefits of Durysta given as two implants per eye did not outweigh its risks.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of the application, the company stated that it decided to withdraw because the major objections raised could not be resolved within the available timeframe.

Does this withdrawal affect patients in clinical trials?

The company informed the Agency that there are no consequences for patients in clinical trials using Durysta.

If you are in a clinical trial and need more information about your treatment, speak with your clinical trial doctor.