

Direct Healthcare Professional Communication

June 2020

Brinzolamide 10mg/Timolol Maleate 5mg Eye Drops -Omission of legal category of Prescription only medicine (POM) on packaged cartons in the UK.

Dear Healthcare professional,

Mylan in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA) would like to inform you of packaged cartons that do not indicate the legal category of Prescription only medicine (POM) in the UK:

Summary

- **Brinzolamide 10mg/Timolol Maleate 5mg Eye Drops is indicated for decrease of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension for whom monotherapy provides insufficient IOP reduction.**
- **Pharmacists should be advised that Brinzolamide 10mg/Timolol Maleate 5mg Eye Drops - PL 045609/1807 have been packaged in cartons which do not indicate the legal category of Prescription only medicine (POM).**
- **Impacted batches are 20BQ152 and 20BQ154.**

Background on the safety concern

Brinzolamide 10mg/Timolol Maleate 5mg Eye Drops is indicated for decrease of intraocular pressure (IOP) in adult patients with open-angle glaucoma or ocular hypertension for whom monotherapy provides insufficient IOP reduction.

Patients will require a diagnosis and a prescription from their treating physician and should only obtain the product from a licenced pharmacy. The Patient Information leaflet present in each pack highlights that this medication must be prescribed, "This medicine has been prescribed for you only".

A patient prescribed Brinzolamide 10mg/Timolol Maleate 5mg Eye Drops (as timolol maleate) should have interactions with Healthcare professionals (Pharmacist & Physician) that would highlight appropriate usage, direct the patient to read the leaflet and be available to respond to questions on the product.

Conclusion

Neither Brinzolamide nor Timolol are available as Pharmacy (P) or General Sale List (GSL) products within the pharmacy and hence the pharmacist should recognise that this product is a Prescription only Medicine (POM).

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Pharmacy systems should flag the product as POM, whilst serialisation on the pack may help ensure that stock cannot be sold without a prescription.

Pharmacists should be advised about this labelling discrepancy on the carton before dispensing Brinzolamide 10mg/Timolol Maleate 5mg Eye Drops.

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated across to pharmacists.

A corrective action has been initiated to update the carton labelling for future batches.

Call for reporting

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to Mylan on UKPharmacovigilance@mylan.com

Please continue to report suspected adverse drug reactions to the MHRA via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

Company contact point

For further information please contact:

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Hertfordshire AL10 9UL
Tel: +44 1707 853000 (option 1)

Email: info.uk@mylan.co.uk

Annexes

Not applicable.

Signed:



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