Medicines & Healthcare products
Regulatory Agency

Public Assessment Report

National Procedure

Tobramycin/Dexamethasone 3mg/ml + 1mg/ml eye drops, suspension

tobramycin and dexamethasone

PL 35533/0240

Aspire Pharma Limited

LAY SUMMARY

Tobramycin/Dexamethasone 3mg/ml + 1mg/ml eye drops, suspension
tobramycin and dexamethasone

This is a summary of the Public Assessment Report (PAR) for Tobramycin/Dexamethasone 3mg/ml + 1mg/ml eye drops, suspension. It explains how this product 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 this product.

This product will be referred to as Tobramycin/Dexamethasone eye drops, suspension in this lay summary for ease of reading.

This product has been authorised by Medicines and Healthcare products Regulatory Agency (MHRA) for the United Kingdom. This procedure takes into account the outcome of a decentralised (DC) procedure in European Union Member States (and/or Iceland, Liechtenstein, Norway) on 4 November 2022 (LV/H/0207/001/DC). This is known as the MR/DC Reliance Procedure.

This application was approved under Regulation 52 of the Human Medicines Regulation 2012, as amended (previously Article 10.3 of Directive 2001/83/EC, as amended).

For practical information about using Tobramycin/Dexamethasone eye drops, suspension, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

What is Tobramycin/Dexamethasone eye drops, suspension and what is it used for?
Tobramycin/Dexamethasone eye drops, suspension is used to prevent and treat inflammation and prevent possible infection of the eye after cataract surgery in adults and children aged 2 years and older.

How does Tobramycin/Dexamethasone eye drops, suspension work?
This medicine contains dexamethasone, a corticosteroid, and tobramycin, an antibiotic which is active against a wide range of bacteria that may infect the eye.

How is Tobramycin/Dexamethasone eye drops, suspension used?
The pharmaceutical form of this medicine is eye drops, suspension and the route of administration is application into the eye(s) (ocular use).

<u>The recommended dose is:</u>
One drop in the affected eye(s) every 4 to 6 hours while the patient is awake. During the initial 48 hours, the patient's doctor may increase the dose to one drop every 2 hours.

The patient should use this medicine for as long as their doctor has told them to.

The patient should not use this medicine for more than 24 days.

<u>Use in children and adolescents</u>
Tobramycin/Dexamethasone eye drops, suspension may be used in children 2 years of age and older at the same dose as in adults.
Before using this medicine for the first time, the patient should make sure the tamper evident ring is unbroken.

Instructions for use

1. Patients should wash their hands before they start.
2. Shake the bottle well.
3. Twist off the bottle cap. Remove the loose collar from the cap when the bottle is first opened.
4. Hold the bottle pointing down, between the thumb and fingers.
5. Tilt the head back.
6. Pull down the lower eyelid with a finger, until there is a 'pocket' between the eyelid and the eye. The drop will go in here.
7. Bring the bottle tip close to the eye.
8. Do not touch the eye or eyelid, surrounding areas or other surfaces with the dropper. It could contaminate the drops.
9. Gently press on the base of the bottle to release one drop at a time.
10. Do not squeeze the bottle, only a gentle press on the bottom is needed.
11. After using Tobramycin/Dexamethasone eye drops, suspension, keep the eyelid closed, while simultaneously applying gentle pressure with a finger to the corner of the eye, by the nose for at least 1 minute. This helps to limit the amount of medicine that will get into the rest of the body.
12. If the drops are to be used in both eyes, the steps should be repeated for the other eye. Put the bottle cap firmly back on immediately after use.
13. If a drop misses the eye, the patient should try again.

The dispenser tip is designed to provide a single drop; patients should NOT enlarge the hole of the dispenser tip.

For further information on how Tobramycin/Dexamethasone eye drops, suspension is used, refer to the PIL and Summary of Product Characteristics (SmPC) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

This medicine can only be obtained with a prescription.

The patient should always take the medicine exactly as their doctor/pharmacist has told them. The patient should check with their doctor or pharmacist if they are not sure.

What benefits of Tobramycin/Dexamethasone eye drops, suspension have been shown in studies?

No additional studies were needed as Tobramycin/Dexamethasone eye drops, suspension contains the same active substance as the reference medicine, and satisfactory data to justify the differences have been provided.

What are the possible side effects of Tobramycin/Dexamethasone eye drops, suspension?

For the full list of all side effects reported with this medicine, see Section 4 of the PIL or the SmPC available on the MHRA website.

If a patient gets any side effects, they should talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in the product information or the PIL that comes with the medicine. Patients can also report suspected side effects themselves, or a report can be made on their behalf by someone else who cares for them, directly via the Yellow Card scheme at https://yellowcard.mhra.gov.uk or search for 'MHRA Yellow Card' online. By

reporting side effects, patients can help provide more information on the safety of this medicine.

As Tobramycin/Dexamethasone eye drops, suspension is a hybrid medicine and considered therapeutically equivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

Why was Tobramycin/Dexamethasone eye drops, suspension approved?
It was concluded that Tobramycin/Dexamethasone eye drops, suspension can be considered to be therapeutically equivalent to the reference medicine. Therefore, the MHRA decided that, as for the reference medicine, the benefits are greater than the risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Tobramycin/Dexamethasone eye drops, suspension?
As for all newly-authorised medicines, an Risk Management Plan (RMP) has been developed for Tobramycin/Dexamethasone eye drops, suspension. The RMP details the important risks of Tobramycin/Dexamethasone eye drops, suspension, how these risks can be minimised, any uncertainties about Tobramycin/Dexamethasone eye drops, suspension (missing information), and how more information will be obtained about the important risks and uncertainties.

There are no safety concerns associated with use of Tobramycin/Dexamethasone eye drops, suspension.

The information included in the SmPC and the PIL is compiled based on the available quality, non-clinical and clinical data, and includes appropriate precautions to be followed by healthcare professionals and patients. Side effects of Tobramycin/Dexamethasone eye drops, suspension are continuously monitored and reviewed including all reports of suspected side-effects from patients, their carers, and healthcare professionals.

An RMP and a summary of the pharmacovigilance system have been provided with this application and are satisfactory.

Other information about Tobramycin/Dexamethasone eye drops, suspension
A marketing authorisation was granted in the United Kingdom on 9 January 2024.

The full PAR for Tobramycin/Dexamethasone eye drops, suspension follows this summary.

This summary was last updated in March 2024.

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I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) considered that the application for Tobramycin/Dexamethasone 3mg/ml + 1mg/ml eye drops, suspension (PL 35533/0240) could be approved.

The product is approved for the following indications:

- Prevention and treatment of inflammation and prevention of infection associated with cataract surgery in adults and children aged 2 years and older.

The product contains the active substances tobramycin and dexamethasone.

Dexamethasone

The efficacy of corticosteroids for the treatment of inflammatory conditions of the eye is well established. Corticosteroids achieve their anti-inflammatory effects through suppression of vascular endothelial cell adhesion molecules, cyclooxygenase I or II, and cytokine expression. This action culminates in a reduced expression of pro-inflammatory mediators and the suppression of adhesion of circulating leukocytes to the vascular endothelium, thereby preventing their migration into inflamed ocular tissue. Dexamethasone has marked anti-inflammatory activity with reduced mineralocorticoid activity compared with some other steroids, and is one of the most potent anti-inflammatory agents.

Tobramycin

Tobramycin is a potent, broad-spectrum, rapidly bactericidal aminoglycoside antibiotic. It exerts its primary effect on bacterial cells by inhibiting polypeptide assembly and synthesis on the ribosome. Tobramycin in this combination provides antibacterial protection against susceptible bacteria.

This product has been authorised by MHRA for the United Kingdom. This procedure takes into account the outcome of a decentralised (DC) procedure in European Union Member States (and/or Iceland, Liechtenstein, Norway) on 4 November 2022 (LV/H/0207/001/DC).

For the scientific discussion of the quality, non-clinical and clinical assessment conducted during the DC procedure, please refer to the Reference Member State (RMS) Public Assessment Report, available on the RMS regulatory agency website or on the Heads of Medicines Agencies website.

This application was approved under Regulation 52 of the Human Medicines Regulation 2012, as amended (previously Article 10.3 of Directive 2001/83/EC, as amended).

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for this product at all sites responsible for the manufacture, assembly and batch release of this product.

A Risk Management Plan (RMP) and a summary of the pharmacovigilance system have been provided with this application and are satisfactory.

A marketing authorisation was granted on 9 January 2024.

II. PRODUCT INFORMATION

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The SmPC is in line with current guidelines and was satisfactory.

PATIENT INFORMATION LEAFLET (PIL)

The PIL is in line with current guidelines and is satisfactory.

LABEL

The labelling is in line with current guidelines and is satisfactory.

III. QUALITY ASPECTS

MHRA considered that the quality data submitted for this application is satisfactory.

The grant of a marketing authorisation was recommended.

IV. NON-CLINICAL ASPECTS

MHRA considered that the non-clinical data submitted for this application is satisfactory.

The grant of a marketing authorisation was recommended.

V. CLINICAL ASPECTS

MHRA considered that the clinical data submitted for this application is satisfactory.

The grant of a marketing authorisation was recommended.

VI. RISK MANAGEMENT PLAN (RMP)

The applicant has submitted an RMP, in accordance with the requirements of Regulation 182 of The Human Medicines Regulation 2012, as amended. The applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns. This is acceptable.

VII. USER CONSULTATION

A full colour mock-up of the Patient Information Leaflet (PIL) has been provided with the application, in accordance with legal requirements.

The PIL has been evaluated via a user consultation with target patient groups, in accordance with legal requirements. The report submitted by the MAH is acceptable.

VIII. OVERALL CONCLUSION, BENEFIT/RISK AND RECOMMENDATION

The quality of the product is acceptable, and no new non-clinical or clinical safety concerns have been identified. The benefit/risk balance is, therefore, considered to be positive.

The Summaries of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and labelling are satisfactory.

In accordance with legal requirements, the current approved UK versions of the SmPC and PIL for these products are available on the MHRA website.

IX. TABLE OF CONTENT OF THE PAR UPDATE

Steps taken after the initial procedure with an influence on the Public Assessment Report (non-safety variations of clinical significance).

Please note that only non-safety variations of clinical significance are recorded below and in the annexes to this PAR. The assessment of safety variations, where significant changes are made, are recorded on the MHRA website or European Medicines Agency (EMA) website. Minor changes to the marketing authorisation are recorded in the current SmPCs and/or PIL available on the MHRA website.

Application type	**Scope**	**Product information affected**	**Date of grant**	**Outcome**	**Assessment report attached Y/N**