

Nemera's preservative-free multidose eye dropper Novelia® approved for Santen's Cosopt®, for Glaucoma treatments in 29 European countries

PRESS RELEASE
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"There is no limit to Nemera's ambition to serve patients. We already market devices in over 40 countries for millions of users. We'll keep investing in new products and in state-of-the-art manufacturing equipment, to help even more patients with high quality devices all over the world."

Marc Haemel, CEO

Nemera in figures:

- 4 plants in Europe and the USA
- Over:
 - 1,900 employees
 - 30,000 sq. meters of manufacturing clean rooms
 - 100 engineers and experts working in our Innovation Center.

Attached documents:

- Santen's Cosopt iMulti® with Novelia® bottle
- Novelia®

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Santen announced that the preservative-free formulation Cosopt iMulti® will launch in 29 European countries in the coming months.

Nemera is pleased to announce that its multidose eye dropper Novelia® has been approved for the preservative-free formulation Cosopt iMulti® (20mg/ml dorzolamide + 5mg/ml timolol eye drops, solution).

The granting of licences by the relevant national European competent authorities represents an innovation in glaucoma management, providing preservative-free medicines in multi-dose bottles to allow for effective and convenient, 24-hour intraocular pressure (IOP) control to glaucoma patients aged 18 or over.¹

The European Medicines Agency (EMA) outlines that preservatives should be avoided in patients who are on long-term treatment, or do not tolerate preserved eye drops.² Switching from preserved to preservative-free topical ocular medications can diminish the harmful effects caused by preservatives.³ For example, switching to Cosopt® preservative-free improved local ocular tolerability for 85% of patients compared with their previous preserved medication.⁴

Cosopt® is indicated in the treatment of elevated IOP in patients with open-angle glaucoma or pseudoexfoliative glaucoma when topical beta-blocker monotherapy is not sufficient.¹ European local market launches of the new preservative-free multi-dose formulations are expected throughout 2019, under the following names:

The new preservative-free multi-dose formulations have already been launched in some European local markets under the following names:

United Kingdom	COSOPT iMulti
Denmark	COSOPT sine ukonserveret
Finland, Germany, Iceland, Norway, Sweden	COSOPT sine

Some more launches are expected throughout 2019 in the following countries:

Austria, Bulgaria, Croatia, Cyprus, Greece, Portugal, Spain	COSOPT iMulti
Belgium, Luxembourg	COSOPT Sine Conservans
Czech Republic	COSOPT Multi Dose bez konzervačních přísad
Estonia, France	COSOPT sine

¹ Cosopt SmPC, available here: <https://www.medicines.org.uk/emc/product/5114/smpc>

² EMA Public Statement. Doc. Ref.: EMEA/622721/2009. Last accessed: December 2018

³ Steven, DW et al. Preservative in glaucoma medication. British Journal of Ophthalmology 2018;102:1497-1503

⁴ Renieri G et al. Efficacy and tolerability of preservative-free eye drops containing a fixed combination of dorzolamide and timolol in glaucoma patients. Journal of Ocular Pharmacology and Therapeutics 2010;26 (6):597-603.

Press contact

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Hungary	COSOPT Multi
Ireland	COSOPT Multi Preservative Free
Italy	COSOPT
Latvia, Lithuania	COSOPT PF
Poland	COSOPT PF Multi
Romania	COSOPT fara conservant
Slovak Republic	COSOPT Multi Dose Free
Slovenia	COSOPT brez konzervansa
The Netherlands	COSOPT Multidose conserveermiddelvrij

The preservative-free multi-dose bottles for Cosopt[®], developed by Nemera, feature a low squeeze force and smooth bottle, to reduce the pressure required to dispense a drop and improve ease-of-use, particularly for the elderly.^{5,6}

"We are delighted to launch preservative-free multi-dose formulations of these glaucoma therapies in Europe," said Luis Iglesias, Corporate Officer and Head of EMEA, Santen. "By providing highly effective and well-tolerated, preservative-free medicines, with the option for multi-dose bottles, we hope to empower patients in their daily lives and improve the management of their condition."

"Patient adherence is the key for success for all treatments, especially silent chronic ophthalmic diseases. This is why, at Nemera, we developed an innovative system combining all patient needs: a safe preservative-free multi-dose bottle with a blue tip that makes consistent drops one by one" commented Fanny Sellier, Global Category Manager for Ophthalmic Products, Nemera.

Novelia[®] is a multidose closing tip system which avoids the need for preservatives in the drug and prevents bacterial contamination over the duration of treatment.

It limits the distribution of liquid to one drop at a time, with a precise and consistent drop size, to improve patients' adherence.

Key benefits of Novelia[®]

- 100% controlled and safe thanks to its patented PureFlow[®] Technology
- Works with high viscosity suspensions, emulsions and solutions up to 1500cps
- User-friendly and intuitive: easy eye targeting thanks to its blue tip feature, as easy to use as any standard eyedropper
- One drop at a time into the patient's eye
- Calibrated drops providing a precise dose for a better treatment adherence

For more information, you can visit the dedicated page:

<https://www.nemera.net/products/ophthalmic-novelias-eyedropper/>

Novelia[®] will also be shown at different events in the next months: Interphex, ARVO, FCE Pharma, CPhI China and CPhI Worldwide.

⁵ Kaarniranta K et al. Preferences and ease of use of preservative-free IOP-lowering eye drop containers: A comparison of two multi-dose bottles. Clinical Investigation 2018; DOI:10.4172.

⁶ Novelia White Paper. Accessible at: <http://www.nemera.net/wp-content/uploads/2014/06/WVP-Novelia-alternativetofilters-June2015.pdf> Last accessed: December 2018

About Nemera

Find Nemera on the web at www.nemera.net

Nemera is a world leader in the design, development and manufacturing of drug delivery solutions. Its expertise covers all five modes of delivery: **ophthalmic (multidose, preservative-free eyedroppers)**, parenteral (auto-injectors, pens, safety devices & implanters), nasal, buccal, auricular (pumps, valves and actuators for sprays), pulmonary (pMDIs, DPIs), dermal and transdermal (airless & atmospheric dispensers).

Nemera provides solutions for the pharmaceutical, biotechnology & generics industries, from full solution development to pure contract manufacturing, through customized solutions.

About Santen

As a specialised company dedicated to ophthalmology, Santen carries out research, development, marketing, and sales of pharmaceuticals, over-the-counter products and devices. Santen has long been the market leader in Japan for prescription ophthalmic pharmaceuticals and is now a leader in the sector in the EMEA (Europe, Middle East and Africa) region. With scientific knowledge and organisational capabilities nurtured over nearly 130 years, Santen provides products and services to contribute to the well-being of patients, their loved ones and consequently to society in more than 60 countries. For more information, please visit Santen websites www.santen.com (Japan headquarters) and www.santen.eu (EMEA).

