

Hikma launches NPH Otic Solution, USP Sterile in the US, in partnership with Orbicular

London, UK, 29 October 2026 – Hikma Pharmaceuticals PLC (Hikma, Group), a multinational pharmaceutical company, today announced the US launch of Neomycin and Polymyxin B Sulfates and Hydrocortisone (NPH) Otic Solution, USP Sterile, developed by its partner Orbicular Pharmaceutical Technologies Pct. Ltd. (Orbicular). The product was approved by the US Food and Drug Administration (FDA) as a Competitive Generic Therapy (CGT), a designation reserved for generic medicines in therapeutic areas with limited competition.

Hafrun Fridriksdottir, Hikma's President, US and Chief R&D Officer said "We are pleased to bring this medicine to US patients, and its approval as a Competitive Generic Therapy reflects a real need for additional, reliable supply in this category. Strong partnerships are important to our strategy, and we have a growing collaboration with Orbicular and look forward to bringing further products from that partnership to market in the future."

"Neomycin and Polymyxin B Sulfates and Hydrocortisone Otic Solution is a technically demanding product, and securing approval as a Competitive Generic Therapy validates both the development model we have built and the depth of our formulation and regulatory capability," said Dr. Hiren Patel, Chief Executive Officer of Orbicular. "Hikma's commercial reach in the US make them an ideal partner to bring it to market, and we look forward to building on this collaboration across our wider pipeline."

NPH Otic Solution, USP Sterile (3.5 mg/mL, 10,000 units/mL, and 10 mg/mL) is indicated for the treatment of superficial bacterial infections of the external auditory canal caused by organisms susceptible to the action of antibiotics. Please see the [Full Prescribing Information](#) for more details.

The abbreviated new drug application (ANDA 220938) for the product is owned by Orbicular. Hikma will commercialise and distribute the product in the US.

According to IQVIA, US sales for NPH Otic Solution were approximately \$30 million for the 12 months ended August 2026.

The reference listed drug for NPH Otic Solution, USP Sterile is CORTISPORIN® of Monarch Pharmaceuticals LLC.

– ENDS –

This product has been approved for marketing in the United States by the US FDA. This product approval does not confer the right on Hikma, or any other party, to market this product outside the United States.

CORTISPORIN® is a registered trademark of Monarch Pharmaceuticals LLC.

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About Hikma

Hikma helps put better health within reach every day for millions of people around the world. For more than 45 years, we've been creating high-quality medicines and making them accessible to the people who need them. Headquartered in the UK, we are a global company with a local presence across North America, the Middle East and North Africa (MENA) and Europe, and we use our unique insight and expertise to transform cutting-edge science into innovative solutions that transform people's lives. We're committed to our customers, and the people they care for, and by thinking creatively and acting practically, we provide them with a broad range of branded and non-branded generic medicines, and, increasingly, animal health products. Together, our 9,400 colleagues are helping to shape a healthier world that enriches all our communities. We are a leading licensing partner, and through our venture capital arm, are helping bring innovative health technologies to people around the world. For more information, please visit: www.hikma.com

Hikma Pharmaceuticals PLC (LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (LEI:549300BNS685UXH4JI75) (rated BBB/stable S&P and BBB/stable Fitch)

About Orbicular Pharmaceutical Technologies Pvt. Ltd.

Orbicular is a partnership driven, B2B specialty pharmaceutical company focused on designing, developing, and delivering complex generics and specialty pharmaceutical products. With integrated capabilities spanning development, advanced analytical characterization, regulatory strategy, and technology transfer, Orbicular enables partners to bring high value, technically complex products to global markets.

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IMPORTANT SAFETY INFORMATION FOR NEOMYCIN AND POLYMYXIN B SULFATES AND HYDROCORTISONE OTIC SOLUTION, USP STERILE

INDICATIONS AND USAGE

For the treatment of superficial bacterial infections of the external auditory canal caused by organisms susceptible to the action of the antibiotics.

CONTRAINDICATIONS

This product is contraindicated in individuals who have shown hypersensitivity to any of its components.

This product should not be used if the external auditory canal disorder is suspected or known to be due to cutaneous viral infection (e.g., herpes simplex virus or varicella zoster virus).

WARNINGS

Neomycin can induce permanent sensorineural hearing loss due to cochlear damage, mainly destruction of hair cells in the organ of Corti. The risk of ototoxicity is greater with prolonged use; therefore, duration of therapy should be limited to 10 consecutive days.

Patients should remain under close clinical observation during treatment with this product. Do not use this product in any patient with a perforated tympanic membrane.

Neomycin sulfate may cause cutaneous sensitization. Discontinue this product promptly if sensitization or irritation occurs.

Bear in mind that skin affected by conditions like chronic otitis externa or stasis dermatitis is more liable than normal skin to become sensitized to many substances, including neomycin. The manifestation of sensitization to neomycin is usually a low-grade reddening with swelling, dry scaling and itching; it may be manifest simply as a failure to heal. Periodic examination for such signs is advisable, and the patient should be told to discontinue the product if they are observed. Neomycin-containing applications should be avoided for the patient thereafter.

This product contains potassium metabisulfite, which may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people.

PRECAUTIONS

As with other antibiotic preparations, prolonged use may result in overgrowth of nonsusceptible organisms, including fungi.

If the infection is not improved after 1 week, cultures and susceptibility tests should be repeated to verify the identity of the organism and to determine whether therapy should be changed.

Treatment should not be continued for longer than 10 days.

Allergic cross-reactions may occur which could prevent the use of any or all of the following antibiotics for the treatment of future infections: kanamycin; paromomycin; streptomycin; and possibly, gentamicin.

Laboratory Tests

Systemic effects of excessive levels of hydrocortisone may include a reduction in the number of circulating eosinophils and a decrease in urinary excretion of 17-hydroxycorticosteroids.

Pregnancy

There are no adequate and well-controlled studies in pregnant women. Corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

Since systemic absorption of hydrocortisone may occur when applied topically, caution should be exercised when this product is used by a nursing woman.

Pediatric Use

There is inadequate data to establish safety and effectiveness in otitis externa for pediatric patients under 2 years of age.

Geriatric Use

Clinical studies of neomycin and polymyxin B sulfates and hydrocortisone otic solution did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects.

ADVERSE REACTIONS

Neomycin occasionally causes skin sensitization. Ototoxicity and nephrotoxicity have also been reported. Adverse reactions have occurred with topical use of antibiotic combinations including neomycin and polymyxin B; the reaction occurring most often is allergic sensitization.

Skin hyperpigmentation has been reported with polymyxin B-containing products.

The following local adverse reactions have been reported with topical corticosteroids, especially under occlusive dressings: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae and miliaria. Stinging and burning have been reported when this product has gained access to the middle ear.

For more information, please see the [Full Prescribing Information](#) for Neomycin and Polymyxin B Sulfates and Hydrocortisone Otic Solution, USP Sterile.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit <https://www.fda.gov/medwatch> or call 1-800-FDA-1088.

For more information about Neomycin and Polymyxin B Sulfates and Hydrocortisone Otic Solution, USP Sterile or to report suspected adverse reactions, please contact Hikma Pharmaceuticals USA Inc. 1-800-962-8364.

Distributed by: Hikma Pharmaceuticals USA Inc.; Berkeley Heights, NJ 07922

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