



BHM[®] Anti-Viral Nasal Spray NoriZite[™] Nasal Spray

2022

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BHM® Anti-Viral Nasal Spray

Protect, Capture, Prevent

- ✓ An easy-to-use nasal device
- ✓ Helps to protect against inhalation of infectious virus, transmitted primarily by the airborne route.
- ✓ Contains a novel formula tailored for greater and long-lasting protection
- ✓ Carry out your daily activity with an added layer of protection and peace of mind.



Intended use

Many viruses including SARS-CoV-2 are transmitted person-to-person, primarily via airborne droplets released through breathing, coughing, sneezing or talking. The nasal cavity then represents one of the major routes for viral entry into the body. In addition, during early-onset, viral load is believed to be highest in the nose. ^[1-2]

The **BHM® Anti-Viral Nasal Spray** is designed to work by **encapsulating** and **deactivating** the virus while it is still in the nose, preventing its wider uptake by the body. The spray should help prevent person-to-person transmission, which usually occurs by infected people shedding active viruses

The mechanism of action is purely physical!!



^[1]: Gallo, *et al. Mucosal Immunology* 2021, 14, 305

^[2]: Zho, *et al. New England Journal of Medicine* 2020, 382, 1177

Competitors overview

Product	Active targeting			Passive protection -Carrageenan based nasal sprays	
	VIRALEZE™	TaffiX®	FabiSpray (SaNOtize)	Coldamaris Prophylactic, Nasitrol®, Betadine® Cold Defense, Boots Dual Defence...nasal sprays	BHM® Anti-Viral Nasal Spray
Origin	Australia, Starpharma	Israel, Nasus Pharma	Canada, SaNOtize Research & Development Corp.	Marinomed is the IP holder of Carregelose®	United Kingdom, University of Birmingham
Published data	No human trial results published, efficacy data is for in-vitro experiments	Claimed to have prevented COVID-19 spread at a religious event in Israel but is not a controlled scientific study	Phase III Trials completed with positive results	Several publications and completed/on-going multicentred, randomized clinical trials for common cold and flu-like diseases initially and have expanded to COVID-19. ^[5]	<i>In vitro</i> experiments prove significantly enhanced sprayability compared to other sprays and showed antiviral efficacy against SARS-CoV-2 and some variants. Formulated using compounds widely approved.
Regulatory Approval/Notes	The UK MHRA rebuked the product related to promotional claims with respect to COVID-19. ^[1] Australian TGA has fined Starpharma \$93,000 over ‘illegal advertising’. ^[2]	Spain's medical regulator, the Agency for Medicines and Health Products (AEMPS), has banned its sale on the basis there was 'not enough clinical evidence'. ^[3] The UK MHRA also withheld approvals	Obtain market approval in India through accelerated process. ^[4] Seeking emergency approval in Canada and the UK	Carregelose® products marketed in Europe, parts of Asia, Canada, and Australia. ^[6] Nasitrol is the only nasal spray based on iota carrageenan available in the US.	Registered in the UK, Europe, USA, Singapore, Hong Kong, and Thailand. Registrations in Australia, Malaysia, Ghana, and LATAM are in process.
Viral Prevention Action	The antiviral active, SPL7013, is a microbiocide , meaning the spray breaks down the virus and disables it by chemical action	The main chemical ingredient, Hypromellose, is often used as an antiseptic before surgery. It is a biocide that creates an acidic coating on the inside of the nose	Treatment is based on nitric oxide , a nanomolecule with anti-microbial properties	Uses carrageenan as a main inhibitor	Uses carrageenan as a main inhibitor and added gellan to increase usability. Carrageenan on its own will cause dripping of the nose. The blended spray covers 6 times more area per spray, sticks to the mucosa and enhances activity in vitro, making the effects last longer
Format	Liquid (may drip out of the nasal cavity quickly)	Liquid (may drip out of the nasal cavity quickly)	Liquid (may drip out of the nasal cavity quickly)	Liquid (may drip out of the nasal cavity quickly)	Higher viscosity formulation that would be held in place on the near vertical surfaces inside the nose rather than dripping out.
Other	Pulled from the shelves	Pulled from the shelves			Launch in Singapore and Hong Kong in May 2022

[1] <https://www.bioworld.com/articles/508600-starpharma-halts-sales-of-covid-19-antiviral-spray-viraleze-in-the-uk-following-mhra-rebuke?v=preview>

[2] <https://www.theaustralian.com.au/breaking-news/starpharma-fined-93000-for-viraleze-nasal-spray-over-illegal-advertising/news-story/90034d642e911f56b180e4847c0eb835>

[3] <https://www.dailymail.co.uk/news/article-9368071/Spanish-regulators-BAN-51-nasal-spray-studies-cut-risk-catching-Covid.html>

[4] <https://www.pharmaceutical-technology.com/news/glenmark-nasal-spray-covid-india/>

[5] <https://www.carragelose.com/en/publications>

[6] <https://www.carragelose.com/en/portfolio/launched-products>

Carrageenan-based nasal sprays for common cold and flu-like diseases

- Carrageenans (kappa-, iota-, and lambda-) have demonstrated efficacy *in vitro* against numerous RNA and DNA viruses causing human respiratory disease including influenza, rhinovirus, and coronavirus and SARS-CoV-2.^[1]
- Marinomed Biotech AG, an Austrian science-based biotech company, is holder of the IP rights of Carragelose® nasal spray containing iota-carrageenan and has licensed Carragelose® for marketing in Europe, parts of Asia, Canada, and Australia.^[2]
- Carrageenan formulated into a nasal spray has already been proven effective (i.e. reduced severity and duration of symptoms and/or reduced viral load) in common cold treatment, shown in 5 clinical trials.^[3]
 - 4 in Austria using Coldamaris Prophylactic® Nasal Spray
 - 1 in the UK using Bisolviral® Nasal Spray licensed to Boehringer Ingelheim which is no longer available in the market)

^[1]: Frediansyah A. *Clin Epidemiol Glob Health*. 2021;2:100826.

^[2]: <https://www.carragelose.com/en/portfolio/launched-products>

^[3]: a) Eccles R. *et al.*, *Respiratory Research* 2010, 11; b) Eccles R. *et al.*, *Respiratory Research* 2015, 16, 121; c) Fazekas T. *et al.*, *BMC Complementary and Alternative Medicine* 2012, 12, 147; d) Koenighofer M. *et al.*, *Multidisciplinary Respiratory Medicine* 2014, 9, 57; e) Ludwig M. *et al.*, *Respiratory Research* 2013, 14.

Carrageenan-based nasal spray exhibits prophylactic efficacy in preventing SARS-CoV-2 infection

- In an interim report of a trial conducted in Argentina, a nasal spray with iota-carrageenan (Nasitrol® nasal spray) showed significant efficacy in the prevention of COVID-19 in hospital staff who manage patients with this disease.^[1] The percentage of participants that developed COVID-19 was significantly lower in the group that received the iota-carrageenan spray compared to placebo (1.0 % vs. 5.1 %, respectively) and reduced COVID transmission among ICU staff by nearly 80%.
- Two more trials are running on COVID-19 cases in the UK ^[2] (Coldamaris Plus, marketed as Boots Dual Defence in the UK) and in Austria ^[3] (Coldamaris Prophylactic), investigating the prophylactic and therapeutic effect of iota-carrageenan containing nasal sprays for health care workers.

^[1]: Figueroa J. M. *et al.*, *Int J Gen Med* 2021, 14, 6277.

^[2]: <https://clinicaltrials.gov/ct2/show/results/NCT04590365>

^[3]: <https://clinicaltrials.gov/ct2/show/NCT04681001>

What is unique about the BHM[®] anti-viral nasal spray?

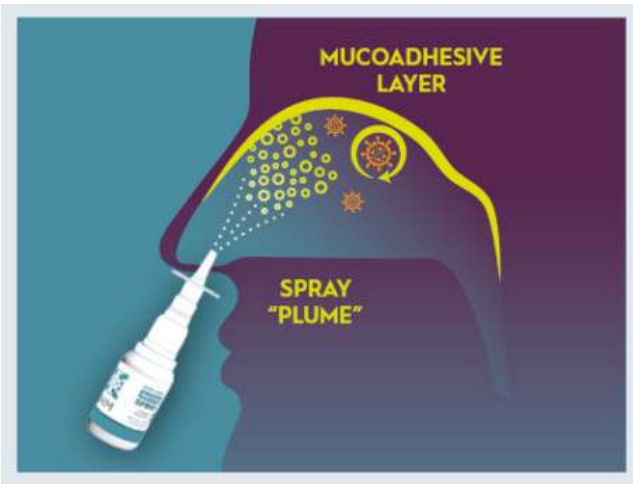
Patented novel formulation tailored to achieve well-distributed yet greater coverage

The BHM[®] anti-viral nasal spray contains **NoriZite™**, consisting of two naturally occurring polysaccharides: **Carrageenan** and **Gellan gum**.

Carrageenan has a broad spectrum of anti-viral properties. **Gellan gum** has never been used in nasal sprays and is initially approved as food additive, and has subsequently been approved for wide non-food, cosmetic and pharmaceutical uses by many countries including the USA and EU.

Gellan gum can '**plume**' rather than 'jet' when applied with a typical nasal spray applicator and is retained on the mucous-coated epithelia in the nose where it coats and retains the virus, so it does not travel further down the respiratory tract.

The blended combination has enhanced spray characteristics to **improve both surface coverage and muco-adhesion, prolonging residence time in the nasal cavity for longer lasting protection.**^[1] Research published by the University of Birmingham has confirmed that the formulation containing the gellan system covers a surface area that is **six times greater** than without the gellan.

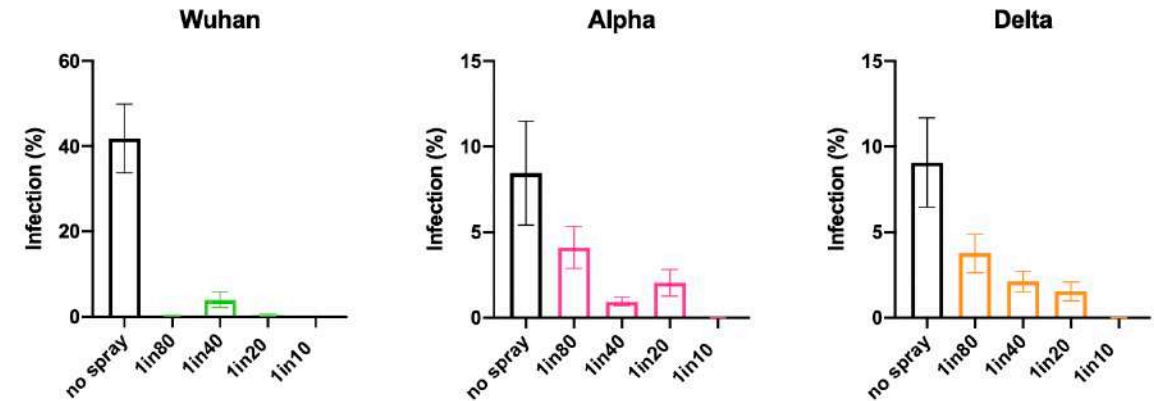


- ✓ Yielding and augmented viscosity (not possible with carrageenan alone)
- ✓ Enhanced sprayability while maintaining the advantage of carrageenan's intrinsic anti-viral capacity

^[1]: Moakes R., et al. *Adv Mater.* 2021;33(26):2008304.

NoriZite™ formulation showed completed inhibition of SARS-CoV-2 infection *in vitro* – not only prophylactic capacity, but the ability to prevent viral transmission

Laboratory data have confirmed the NoriZite™ formulation can prevent infection of cells in culture with SARS-CoV-2.^[1] Gellan gum enhances the efficacy of the carrageenan at high levels of dilution, which should mean that it is effective for longer. **The composite demonstrated synergistic behaviours in which the blend has a more potent anti-viral effect.**



In a follow up *in vitro* study, Vero cells were treated with BHM® anti-viral nasal spray in a range of dilutions prior to virus infection. The nasal spray is effective against **SARS-CoV-2** and its two **infectious variants of SARS-CoV-2** (namely the Alpha (B.1.1.7) and the Delta (B.1.617.2)) in cell culture.^[2] Research is also underway to demonstrate the efficacy of the spray in other SARS-CoV-2 variants and other airborne viruses.

^[1]: Moakes R., *et al. Adv Mater.* 2021;33(26):2008304.

^[2]: On-going studies; data not published.

Product approval and registration status

UK MHRA



Medicines & Healthcare products
Regulatory Agency

Application reference: 2022041102256557

Manufacturer organisation: **Birmingham Biotech LTD**

Address:
29-31 Castle Street
High Wycombe
HP13 6RU
England, United Kingdom

Manufacturer registration status: **Registered**

US FDA

U.S. Department of Health & Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary

Establishment Registration & Device Listing

FDA Home Medical Devices Databases

New Search		Back To Search Results
Proprietary Name:	Nasal Spray	
Classification Name:	NASAL SPRAY, ENT DELIVERY	
Product Code:	KCO	
Device Class:	1	
Regulation Number:	874.5220	
Medical Specialty:	Ear Nose & Throat	
Registered Establishment Name:	BIRMINGHAM BIOTECH LTD	
Owner/Operator:	Birmingham Biotech LTD	
Owner/Operator Number:	10083995	
Establishment Operations:	Manufacturer	

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แบบ จ.จ.น. ๑

ใบรับจดแจ้งนำเข้าเครื่องมือแพทย์

ใบรับจดแจ้งที่ 65-2-3-2-0003523

ใบรับจดแจ้งฉบับนี้ให้ไว้แก่

บริษัท จำกัด เมดิคัล ส์ ซีเครท (ไทยแลนด์) จำกัด

ผู้จดทะเบียนสถานประกอบการนำเข้าเครื่องมือแพทย์ ใบจดทะเบียนที่ กท. สน. 668/2563
เพื่อแสดงว่าเป็นผู้จดทะเบียนนำเข้าเครื่องมือแพทย์ตามมาตรา ๑๙ แห่งพระราชบัญญัติเครื่องมือแพทย์ พ.ศ. ๒๕๕๑
และที่แก้ไขเพิ่มเติม สำหรับเครื่องมือแพทย์

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BHM@Anti-Viral Nasal Spray

EU



La notificación se ha realizado correctamente.

Datos de registro	
Código de Expediente:	RPS/9/2022
Fecha Registro:	05/01/2022 03:27:06
Nº registro General:	RPS/9/2022
Oficina:	ETEL
Nº registro Oficina:	RPS/9/2022



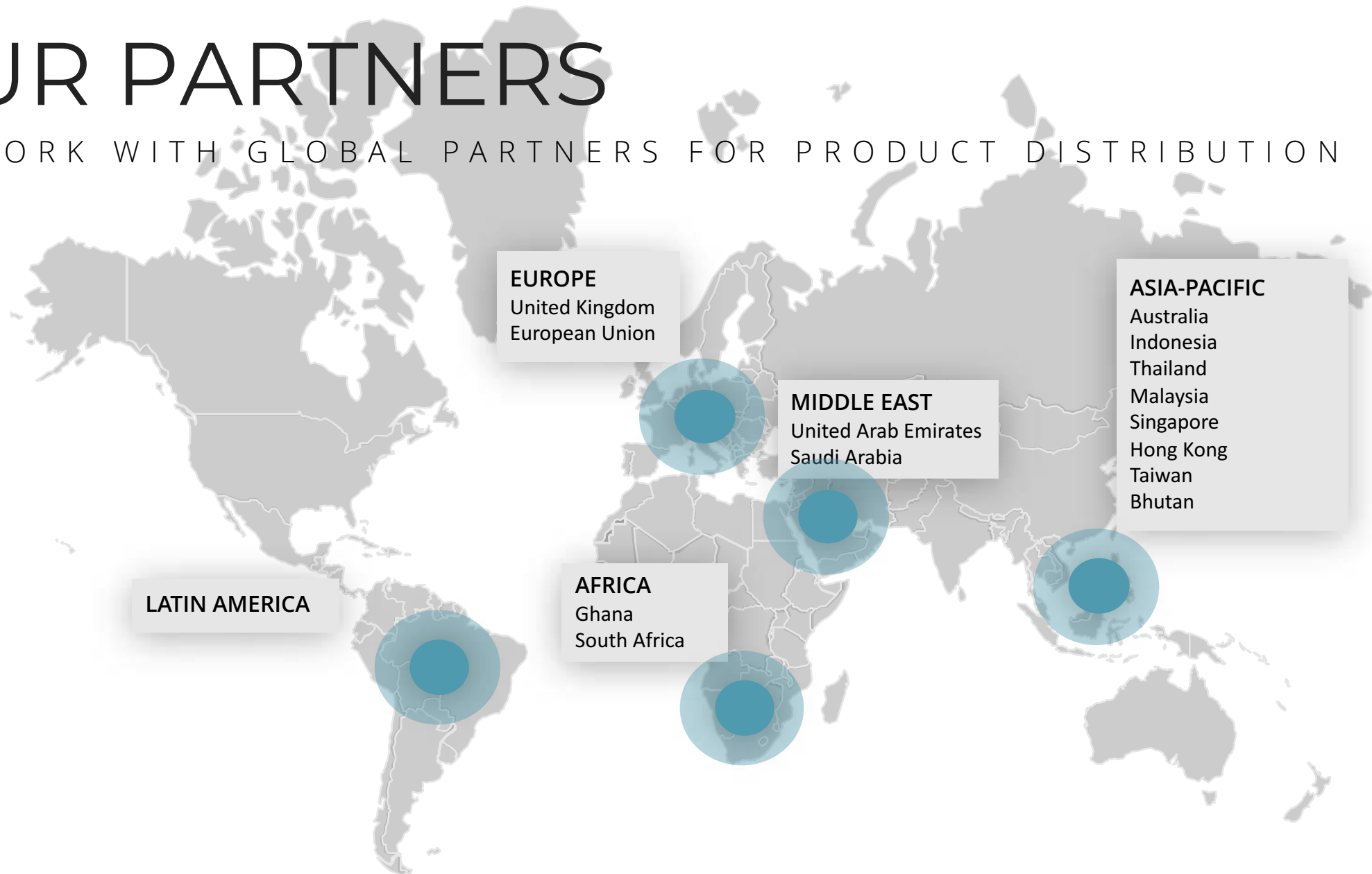
Singapore HSA

Dealer's Licence No	Dealer's Name	Dealer's Type	Product Owner Name	Name as per Device Label	Intended Purpose	Device Identifier	UDI-DI	DM-DI	Country of Sterile/No Manufacture	Non-sterile
1. ES0501638	PURE PHARM PTE LTD	Importer	Birmingham Biotech LTD	Anti-Viral Nasal Spray	Nasal spray 20ml capable of slowing or preventing viral infection through the nasal cavity.	20ml	5070000532707		United Kingdom	Non-sterile

Registrations in other countries/regions are in process (e.g. Australia, Taiwan, Malaysia, Vietnam, Philippines, South Africa, Ghana, Middle East and LatAm).

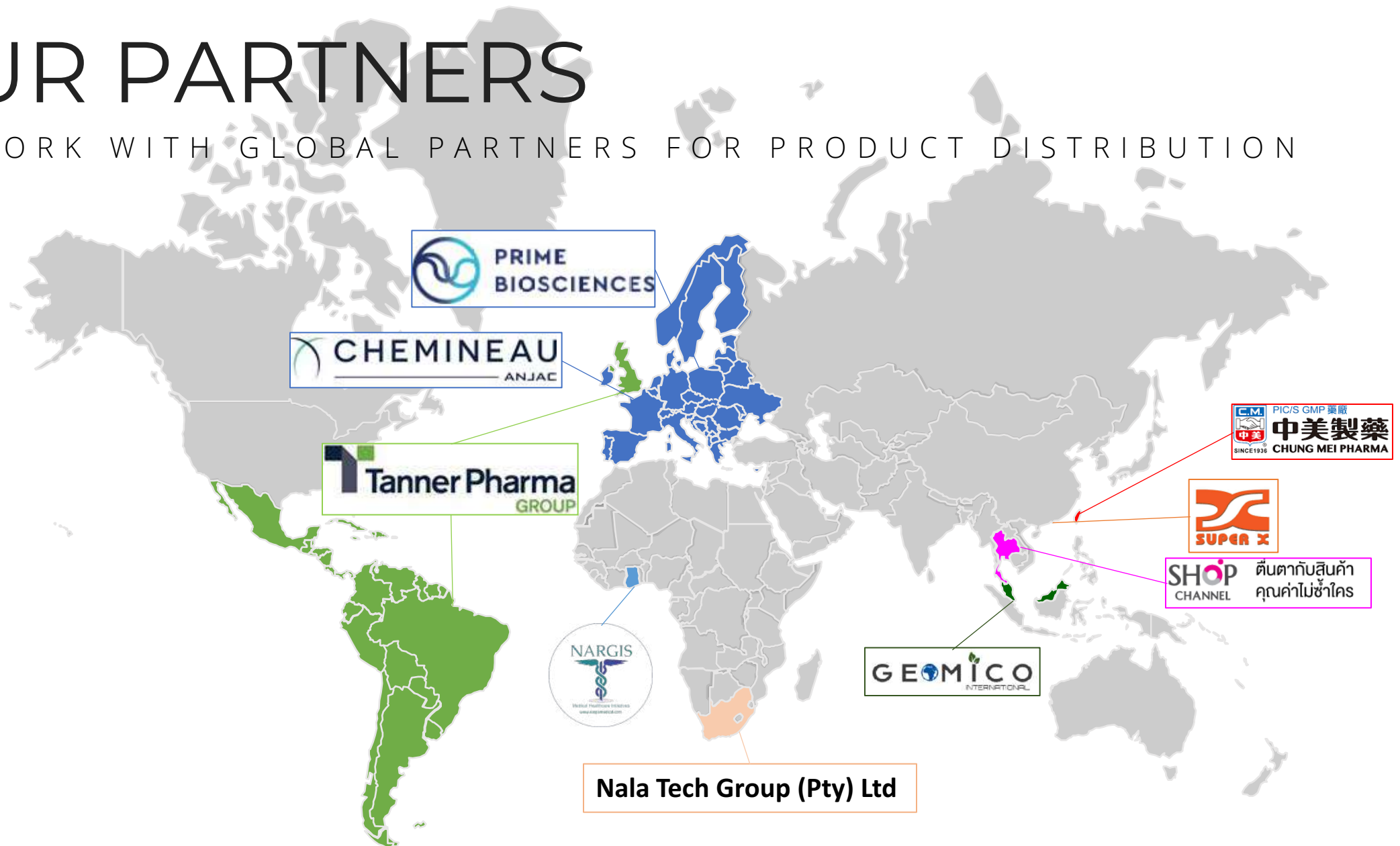
OUR PARTNERS

WE WORK WITH GLOBAL PARTNERS FOR PRODUCT DISTRIBUTION



OUR PARTNERS

WE WORK WITH GLOBAL PARTNERS FOR PRODUCT DISTRIBUTION



Our partner in Taiwan – Chung Mei Pharmaceutical



Founded in 1936, Chung Mei's business scope ranges from manufacturing to end-user sales, and the integration of biotechnology medical research and development to sales channel management. Chung Mei has a stronghold in the Taiwan market, with thousands of distribution channels domestically.

Through the international standard cGMP, PIC/S GMP and ISO 22000 certifications, Chung Mei is able to expand sales to international markets into China, ASEAN countries, Macau, Hong Kong and other regions, as well as distributing Japanese branded products. In 2011, Chung Mei received highest national award in the western medicine biotech category from the Institute for Biotechnology and Medicine Industry (IBMI) and strives to produce excellent quality control.



SELECTED MEDIA COVERAGE

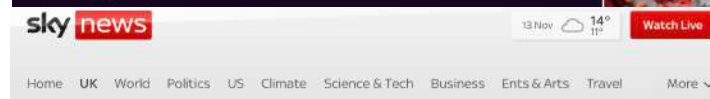
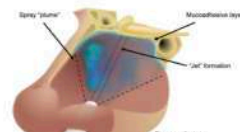


Birmingham Biotech and the University of Birmingham sign licensing agreement for anti-viral nasal spray against COVID-19

Posted on 09 Nov 2021



Birmingham Biotech Ltd, an innovator in diagnostic tests, protective nasal sprays and mobile medical facilities, and the University of Birmingham have signed a licensing agreement to commercialise a novel anti-viral nasal spray that protects against COVID-19.



COVID-19: University of Birmingham develops nasal spray that 'protects against coronavirus and prevents transmission'

Researchers say the spray protects against COVID-19 and can also prevent the virus being passed from person to person.

Sources

<https://www.birmingham.ac.uk/news/latest/2021/11/birmingham-biotech-and-university-of-birmingham-sign-licensing-agreement-for-anti-viral-nasal-spray.aspx>

<https://www.ncub.co.uk/insight/birmingham-biotech-and-the-university-of-birmingham-sign-licensing-agreement-for-anti-viral-nasal-spray-against-covid-19/>

<https://news.sky.com/story/covid-19-university-of-birmingham-develops-nasal-spray-that-protects-against-coronavirus-and-prevents-transmission-12136189>

<https://www.europeanpharmaceuticalreview.com/news/165186/anti-viral-covid-19-nasal-spray-to-be-commercialised-in-birmingham/>

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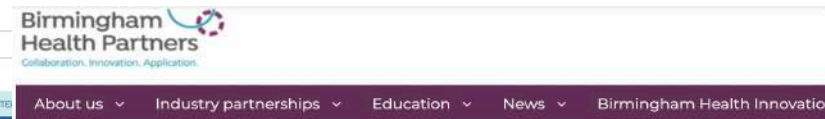


Anti-viral COVID-19 nasal spray to be commercialised

Birmingham Biotech and the University of Birmingham, UK, have signed a licensing agreement for an anti-viral nasal spray against COVID-19.



Licensing agreed by University of Birmingham for COVID nasal spray



Birmingham Health Partners > News > COVID-19 news > Birmingham to commercialise anti-viral nasal spray against COVID-19

Birmingham to commercialise anti-viral nasal spray against COVID-19



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Birmingham Biotech and the University of Birmingham sign licensing agreement for anti-viral nasal spray against COVID-19

09 Nov 2021 | Network Updates | Update from UoB
These updates are republished press releases and communications from the University of Birmingham

Birmingham Biotech Ltd, an innovator in diagnostic tests, protective nasal sprays and mobile medical facilities, and the University of Birmingham have signed a licensing agreement for an anti-viral nasal spray against COVID-19.

COVID-19 is both contracted and transmitted by the nose is the major viral entry point into the body to person-to-person transmission.

The formulation was engineered by Professor Lia team of researchers who also collaborated on its the world are gradually lifting, there is a real need wearing masks and handwashing remain essential potential to reduce transmission. We are thrilled spray to individuals around the world.

Michael Hsu, Managing Director at Birmingham B the University of Birmingham and to be able to w medical innovations. We have a shared commitment people as possible at an affordable price, focusing



Birmingham Biotech: Innovating COVID-19 testing and technologies



INTERNATIONAL MEDIA COVERAGE

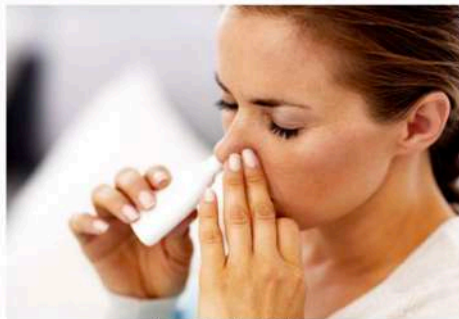
Birmingham Biotech firma un acuerdo de licencia para comercializar su aerosol nasal antiviral Covid

La Covid-19 se contrae y se transmite por inhalación de gotitas o aerosoles que contienen el virus SARS-CoV-2, y la nariz es el principal punto de entrada viral al cuerpo.



英研究新鼻喷剂可遏制病毒 药效长达2天避免感染

2021年01月26日 00:58 稿件来源: 欧联网 【字体: 大 小】



英研究新鼻喷剂可遏制病毒。

Actualité internationale

World news – GB – COVID-19: University of Birmingham develops a nasal spray that 'protects against corona virus and prevents its transmission'

By CAMEROON MAGAZINE - GM - 19/11/2020

HOME OPINION VIDEO WORLD CHINA TECHNOLOGY BUSINESS CULTURE TRA

• Europe

COVID-19 nasal spray nears commercial release

By ANGUS McNEICE in London | China Daily Global | Updated: 2021-01-27 09:14

自由時報
Liberty Times Net

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武漢肺炎》英研究新鼻噴劑可包覆病毒 藥效長達2天避免感染



「病毒病，COVID-19」疫情持續肆虐英國，本月初英國科學家於上週公布新研究成果，一種「鼻噴劑」可以預防感染，無法進入校園的學童是更加合適。

伯明翰（Birmingham）的研究員理查德（Richard Moakes）表示，角菜膠（carrageenan）的抗病毒劑及結蘭膠（gellan）可以包覆病毒，並能緊黏在細胞上，以此使病毒失去活性，避免

Sources

https://www.consalud.es/ecsaud/internacional/birmingham-biotech-firma-acuerdo-licencia-comercializar-aerosol-nasal-antiviral-covid_105071_102.html

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LAUNCH IN SINGAPORE



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BHM Anti-Viral Nasal Spray launches in Singapore

9 MAY 2022 08:50

Birmingham Biotech Ltd, an innovator in diagnostic tests, protective nasal sprays and mobile medical facilities, announces the Singapore launch of its latest technology, BHM Anti-Viral Nasal Spray.



英研發新冠鼻噴劑新加坡上市 48小時抑制感染

撰文 | 記者 李林瑗

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@Guardian in Singapore

Sources


<https://pharmaceuticalmanufacturer.media/pharma-manufacturing-news/latest-pharmaceutical-manufacturing-news/bhm-anti-viral-nasal-spray-launches-in-singapore/>

<https://news.gbimonthly.com/tw/article/show.php?num=48885&range=hot>

'BHM® Anti-Viral Nasal Spray' has been voted as a finalist for the Materials Innovation Award for the Med-Tech Innovation Awards 2022.



Materials Innovation Award★ 5



Entrants should explain why a new or repurposed material has been pivotal to the creation of a medical device.

- Is your material new? How was it developed and how crucial is it in the make up of the device?
- Has your material been used elsewhere? If so, where? How have you used it differently?

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BHM® Anti-Viral Nasal Spray

Description

Entrant: Birmingham Biotech

This easy-to-use nasal device contains Norizite(TM), a patented blend of natural ingredients to help slow or prevent viral infection. The gel-like protection coats the nasal cavity, creating a strong, protective barrier to physically trap viruses, such as SARS-CoV-2, and remove them from the body.

