Genovate Biotechnology Co., Ltd.

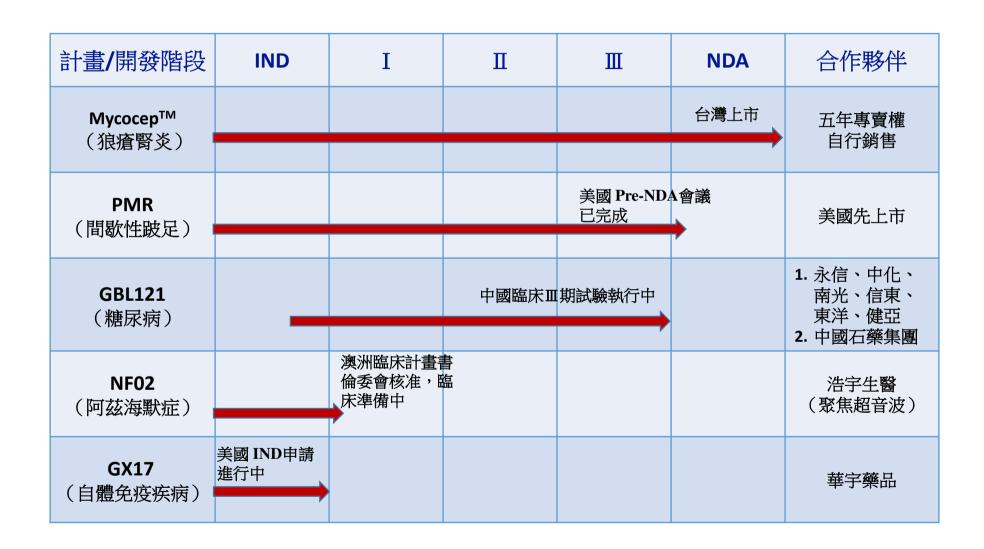
健亞生物科技股份有限公司

19 November 2021

Company Overview

- Genovate is a fully integrated specialty pharmaceutical company focusing on new drug development and equipped with PIC/S GMP manufacturing, marketing and distribution capabilities.
- Major Investor:
 - National Development Fund, Executive Yuan (26.54%)
- Established: 1993
- Number of Employees: 175
- Capital: NT\$1,100M
- Revenue: NT\$472.7M (2020)
- Profit before tax: NT\$38.7M (2020)
- Key Products
 - Genso, Winbest, Rocuron
 - Gendobu, Angidil
 - Mycocep, Geniquin
- Major Partners:
 - NaviFUS, UniPharma, SyneuRx

新藥/新醫材產品進度



Top 11 of 2020's Best Selling Drugs

Drug name	Manufacturer(s)	2020 Sales	Indication(s)
Humira (adalimumab)	AbbVie	\$19,832,000,000	rheumatoid and psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis
Keytruda (pembrolizumab)	Merck	\$14,380,000,000	various cancers
Fliailie (anivahan)	Bristol Myers Squibb and Pfizer	\$14,117,000,000	blood clots
Revlimid (lenalidomide)	Bristol Myers Squibb	\$12,106,000,000	myelodysplastic syndrome, multiple myeloma, and mantle cell lymphoma
EVIPA (ATIINETCENT)	Regeneron Pharmaceuticals, Bayer	\$10,722,220,000	age-related macular degeneration, macular edema and diabetic retinopathy
Imbruvica (ibrutinib)	Pharmacyclics (AbbVie) and Janssen (Johnson & Johnson)	\$9,442,000,000	chronic lymphocytic leukemia/small lymphocytic lymphoma with 17p deletion, Waldenström's macroglobulinemia
Duniyant (duniluman)	Sanofi Genzyme, Regeneron Pharmaceuticals	\$8,073,560,000	atopic dermatitis, asthma, chronic rhinosinitus with nasal polyps.
Stelara (ustekinumab)	Janssen (Johnson & Johnson)	\$7,707,000,000	plaque psoriasis and psoriatic arthritis.
Biktarvy (bictegravir, emtricitabine, and tenofovir alafenamide)	Gilead Sciences	\$7,259,000,000	HIV
Opdivo (nivolumab)	Bristol Myers Squibb	\$6,992,000,000	various forms of cancer
Xarelto (rivarovahan)	Janssen (Johnson & Johnson)/Bayer	\$6,498,020,000	reducing risk of stroke in nonvalvular atrial fibrillation, deep vein thrombosis, pulmonary embolism, DVT prophylaxis following knee or hip replacement surgery

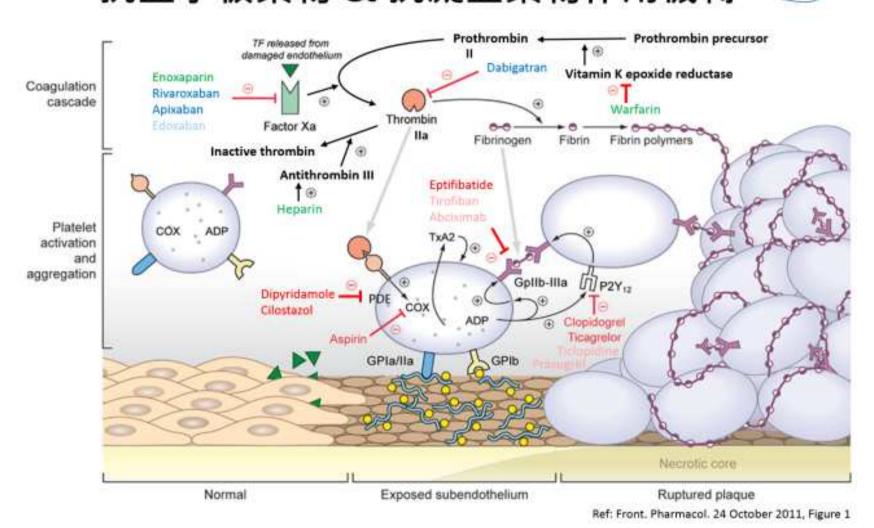
Source: Drug Discovery & Development, 14 May 2021 **Genovate**

2019年健保給付藥品申報金額前十名

	中文名稱	藥品名稱	適應症(簡述)	申請醫令總額 (約新台幣億元)
1	夏奉寧	Harvoni	c肝	39.57
2	艾百樂	Maviret	C肝	28.63
3	保栓通	Plavix	防中風、心肌梗塞	25.79
4	冠脂妥	Crestor	高膽固醇	23.88
5	貝樂克	Baraclude	B肝	18.37
6	立普妥	Lipitor	高膽固醇	17.97
7	基利克錠	Glivec	骨髓性白血病	17.26
8	賀癌平	Herceptin	乳癌	16.57
9	脈優	Norvasc	高血壓	16.05
10	艾非特基因工程第八凝 血因子製劑	Advate	A型血友病	15.89

抗血小板藥物&抗凝血藥物作用機轉

抗血小板藥物 & 抗凝血藥物作用機轉



Stroke Management Market Overview

The Global Stroke Management Market accounted for \$22,581 million in 2016, and is estimated to reach \$36,756 million by 2023, growing at a CAGR of 7.1% during the analysis period (2017-2023). Stroke is a medical emergency that occurs when the blood flow to the brain is interrupted and brain cells start to die.

Rise in incidence and prevalence of chronic diseases drives the market. In addition, growth to geriatric population that is susceptible to stroke, and patient increase incidences of diabetes and tobacco usage are driving the market during the analysis period. However, high cost of treatment and stringent government regulations for the approval of new and advances and drugs is anticipated to restrict the market growth.

Source: Sumant, O. and Thakur, A., 2017. Stroke Management Market by Type (Diagnostics, and Therapeutics) and by Application (Ischemic Stroke, and Haemorrhagic Stroke) - Global Opportunity Analysis and Industry Forecast, 2017-2023. [online] Allied Market Research. Available at: https://www.alliedmarketresearch.com/stroke-diagnostics-and-therapeutics-market

GLOBAL STROKE MANAGEMENT MARKET BY GEOGRAPHY



Asia-Pacific region would exhibit the highest CAGR of 8.4% during 2017-2023.

Source: Sumant, O. and Thakur, A., 2017. Stroke Management Market by Type (Diagnostics, and Therapeutics) and by Application (Ischemic Stroke, and Haemorrhagic Stroke) - Global Opportunity Analysis and Industry Forecast, 2017-2023. [online] Allied Market Research. Available at: https://www.alliedmarketresearch.com/stroke-diagnostics-and-therapeutics-market

Cilostazol for prevention of secondary stroke (CSPS 2): an aspirincontrolled, double-blind, randomised non-inferiority trial

Lancet Neurol. 2010 Oct;9(10):959-68.

Abstract

Background: The antiplatelet drug cilostazol is efficacious for prevention of stroke recurrence compared with placebo. We designed the second Cilostazol Stroke Prevention Study (CSPS 2) to establish non-inferiority of cilostazol versus aspirin for prevention of stroke, and to compare the efficacy and safety of cilostazol and aspirin in patients with non-cardioembolic ischaemic stroke.

Methods: Patients aged 20-79 years who had had a cerebral infarction within the previous 26 weeks were enrolled at 278 sites in Japan and allocated to receive 100 mg cilostazol twice daily or 81 mg aspirin once daily for 1-5 years. Patients were allocated according to a computer-generated randomisation sequence by means of a dynamic balancing method using patient information obtained at registration. All patients, study personnel, investigators, and the sponsor were masked to treatment allocation. The primary endpoint was the first occurrence of stroke (cerebral infarction, cerebral haemorrhage, or subarachnoid haemorrhage). The predefined margin of non-inferiority was an upper 95% CI limit for the hazard ratio of 1·33. Analyses were by full-analysis set. This trial is registered with ClinicalTrials.gov, number NCT00234065.

Findings: Between December, 2003, and October, 2006, 2757 patients were enrolled and randomly allocated to receive cilostazol (n=1379) or aspirin (n=1378), of whom 1337 on cilostazol and 1335 on aspirin were included in analyses; mean follow-up was 29 months (SD 16). The primary endpoint occurred at yearly rates of 2·76% (n=82) in the cilostazol group and 3·71% (n=119) in the aspirin group (hazard ratio 0·743, 95% CI 0·564-0·981; p=0·0357). Haemorrhagic events (cerebral haemorrhage, subarachnoid haemorrhage, or haemorrhage requiring hospital admission) occurred in fewer patients on cilostazol (0·77%, n=23) than on aspirin (1·78%, n=57; 0·458, 0·296-0·711; p=0·0004), but headache, diarrhoea, palpitation, dizziness, and tachycardia were more frequent in the cilostazol group than in the aspirin group.

Cilostazol for Secondary Stroke Prevention: History, Evidence, Limitations, and Possibilities

Stroke. 2021 Oct; 52(10):e635-e645.

Adam de Havenon ¹, Kevin N Sheth ², Tracy E Madsen ³, Karen C Johnston ⁴, Tanya N Turan ⁵, Kazunori Toyoda ⁶, Jordan J Elm ⁵, Joanna M Wardlaw ⁷, S Claiborne Johnston ⁸, Olajide A Williams ⁹, Ashkan Shoamanesh ¹⁰, Maarten G Lansberg ¹¹

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Cilostazol for Secondary Stroke Prevention: History, Evidence, Limitations, and Possibilities

Abstract

Cilostazol is a PDE3 (phosphodiesterase III) inhibitor with a long track record of safety that is Food and Drug Administration and European Medicines Agency approved for the treatment of claudication in patients with peripheral arterial disease. In addition, cilostazol has been approved for secondary stroke prevention in several Asian countries based on trials that have demonstrated a reduction in stroke recurrence among patients with noncardioembolic stroke. The onset of benefit appears after 60 to 90 days of treatment, which is consistent with cilostazol's pleiotropic effects on platelet aggregation, vascular remodeling, blood flow, and plasma lipids. Cilostazol appears safe and does not increase the risk of major bleeding when given alone or in combination with aspirin or clopidogrel. Adverse effects such as headache, gastrointestinal symptoms, and palpitations, however, contributed to a 6% increase in drug discontinuation among patients randomized to cilostazol in a large secondary stroke prevention trial (CSPS.com [Cilostazol Stroke Prevention Study for Antiplatelet Combination]). Due to limitations of prior trials, such as openlabel design, premature trial termination, large loss to follow-up, lack of functional or cognitive outcome data, and exclusive enrollment in Asia, the existing trials have not led to a change in clinical practice or guidelines in Western countries. These limitations could be addressed by a double-blind placebo-controlled randomized trial conducted in a broader population. If positive, it would increase the evidence in support of long-term treatment with cilostazol for secondary prevention in the millions of patients worldwide who have experienced a noncardioembolic ischemic stroke.

Cilostazol在中、日、韓批准的適應症

China

- 改善由於慢性動脈閉塞症引起的潰瘍、肢痛、冷感及間歇性跛行等缺血性症狀。
- 預防腦梗死復發(心源性腦梗死除外)。

Japan

- 慢性動脈閉塞引起的潰瘍,疼痛和冷感等缺血症狀的改善。
- 抑制腦梗塞發作後的複發(心源性腦栓塞除外)。

Korea

- 改善由於慢性動脈阻塞(伯格氏病,阻塞性動脈硬化,糖尿病性周圍血管病等)引起的缺血性症狀,例如潰瘍,疼痛和冷感。
- 抑制腦梗塞發作後的複發(不包括心源性腦栓塞)。

Cilostazol在美國、台灣批准的Indications

Taiwan

使用於無休息時疼痛及周邊組織壞死之間歇性跛行病人(周邊動脈疾病 Fontaine stage II),用於增加最大及無痛行走距離及經生活模式改變(包含 戒菸及運動計畫)及其他治療後,仍無法充分改善間歇性跛行症狀病人之二 線治療。無法耐受aspirin且屬非心因性栓塞之腦梗塞患者,以預防腦梗塞之 再復發。

USA

indicated for the reduction of symptoms of intermittent claudication, as demonstrated by an increased walking distance.

適用於減輕間歇性跛行症狀,由步行距離增加所證明。

Pharmacokinetic study of two extended-release formulations of cilostazol in healthy Korean subjects: A randomized, open-label, multiple-dose, two-period crossover study

Wonsuk Shin, Min-Kyoung Kim, Doo-Yeoun Cho Int J Clin Pharmacol Ther. 2019 Aug;57(8):408-415.

Materials and methods: A randomized, open-label, multiple-dose, two-period, crossover study was conducted in 30 healthy male subjects. In each treatment period, subjects received oral doses of 200 mg cilostazol SR (Pletaal SR Cap.) or cilostazol CR (Cilostan CR Tab.) once daily for 5 consecutive days, with a washout period of 9 days. Plasma concentrations of cilostazol and its metabolites were determined using a validated liquid chromatography-tandem mass spectrometry method.

Results: 24 subjects completed the study. The maximum plasma concentrations ($C_{max,ss}$, geometric mean (geometric coefficient of variation, CV%)) of cilostazol after cilostazol SR and cilostazol CR regimens were 1,532.7 (43.2%) ng/mL and 548.3 (58.9%) ng/mL, respectively, and the areas under the plasma concentration-time curves within dosing intervals (AUC_{τ}, geometric mean (CV%)) were 17,060.7 (39.2%) h*ng/mL and 7,485.7 (55.0%) h*ng/mL, respectively. The geometric mean ratios (cilostazol SR/cilostazol CR) of the $C_{max,ss}$ and AUC_{τ} values were 2.7954 (90% confidence interval: 2.3561 - 3.3166) and 2.2791 (90% confidence interval: 1.9770 - 2.6273), respectively. Both cilostazol SR and cilostazol CR were well tolerated in all subjects, and no serious adverse events occurred. The total incidence of headache, which is the most common adverse drug reaction, was significantly higher with **cilostazol SR** (**63.0%**) **than cilostazol CR** (**25.9%**).

已上市的競爭品項

CILOSTAN CR TAB. 200 MG Tablet

Therapeutic Class

Anticoagulants, Antiplatelets & Fibrinolytics (Thrombolytics)

Manufacturer

Korea United Pharm. Inc

Packaging

3 x 10's / Box

Dosage Form

Tablet

Country of Origin

Korea

Chemical Composition

Cilostazol 200 mg



Philippines:

Cilostan CR

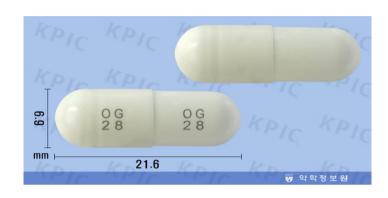
Available Forms and Retail Price

Controlled-release tablet 200 mg - Php 84.70 (NT\$46.6)

Japan: NO APPROVED



已上市的競爭品項



Pletaal SR Cap 200mg, Approved on 2016/3/16, Price 1046 KRW/cap. (NT\$25.1)

- 在韓國的學名藥(100 mg與200 mg)總共有98張藥證。
- 原廠Otsuka也在周邊國家(印尼、泰國、馬來西亞、菲律賓、印度)上市此緩釋劑型。
- JAPAN: NOT APPROVED

BRIEF-Korea United Pharm signs contract worth 74.34 bln won HEALTHCARE SECTOR 2016年11月15日3:56 下午

路透新聞部(Reuters)

Korean United Pharm Inc.

- Says it signs contract with Beijing Meone Pharma 北京墨元醫藥技術有限
 公司 to provide incrementally modified drug in China on Nov. 15, 2016.
- Deal Value is 74.34 billion won (NT\$1,755M).

Source text in Korea: goo.gl/yiU5IE

Further company coverage: (Beijing Headline News)

2019年中國公立醫院硫酸氫氨吡格雷片Clopidogrel的銷售額達115.72億元(2017年氨吡格雷片的銷售額為153.901億元),遠遠超過第二的利伐沙班片Rivaroxaban(25.06億元)。

New Formulation New Drug PMR

- Patented "once-a-day" extended-release of Cilostazol for the treatment of Intermittent Claudication (IC).
- The global market of IC treatments is over US\$500M and about US\$18B for antiplatelet treatments. The global sales of Cilostazol is about US\$250M.
- Taiwan pharmacokinetic study showed that in comparison to Cilostazol bid,
 PMR had
 - Lower Cmax
 - Lower Cmax/Cmin ratio
- Taiwan PhII study nicely demonstrated the trend of better efficacy and safety profile (including less headache, diarrhea and palpitation, the leading causes of treatment discontinuation) comparing to Cilostazol bid.
- US FDA's written responses dated 23 Mar 2020 to the Pre-NDA meeting were received.
- Further work has been ongoing to address FDA questions in an effort to target
 NDA submission in due course.

PMR專利狀態

專利名稱

用於減緩周邊血管疾病病患間歇性跛行症狀的屬喹啉酮衍生物之西洛他唑(CILOSTAZOL)的新穎調配物 NOVEL FORMULATION OF CILOSTAZOL, A QUINOLINONE-DERIVATIVE USED FOR ALLEVIATING THE SYMPTOM OF INTERMITTENT CLAUDICATION IN PATIENTS WITH PERIPHERAL VASCULAR DISEASE

專利狀態

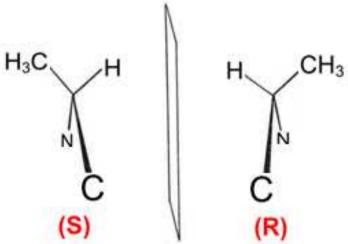
CN105596304 (B)	2020-9-4核准;2020-10-16公告
TWI 728960 (B)	2021-3-29 核准;2021-6-1 公告
	2021-7-14 核准
	➡ 進入三個內國 (英、法、德)
EP3023094 (B1)	DE (2021-8-5) 專利公告生效
	FR (2021-10-4) 專利公告生效
	UK將於近日通知公告生效
JP2016098230 (A)	2016-05-30 公開(審查中)
KR20160059442 (A)	2016-05-26 公開(審查中)

S-(+)-Hydroxychloroquine-掌性分子









GX17 對心臟影響較小

- 心肌的收縮舒張乃是經過內外離子電位差去極化及再極化作用而 完成。
- HCQ及CQ這類藥物會阻斷hERG基因控制的鉀離子通道,使心肌細胞活動電位持續的時間(QTc)延長(QTc prolongation),擾亂心臟正常的收放電活動,從而導致潛在的惡性心律不整。

2020.05 健亞 hERG離子通道試驗(IonChannelProfiler™HEK hERG Manual Patch Clamp Assay)

結果:

GX17對鉀離子通道有較低的阻隔性,其對心臟預期安全性為CQ的11倍、HCQ和R-HCQ的2.5倍以上。

GX17-具開發潛力的利基新藥

● 與HCQ比較

項目	GX17	HCQ
血中濃度穩定性	高	低
藥效	高	低
安全性	高	低
對心臟影響	低	高

- 可依需要,開發為自主免疫失調相關疾病的505b2新藥與COVID-19新冠病毒非住院確診病患的口服治療藥物選項,如:
 - ➤默克 Molnupiravir 治療新冠肺炎,可降低住院或死亡風險50%
 - ▶輝瑞 Paxlovid 治療新冠肺炎,可降低住院或死亡風險89%
- 完成多項專利申請
- 進行申請美國 FDA的IND相關工作。

臨床階段之口服COVID-19治療藥物於非住院確診病人

研發項目	作用機轉	企業	臨床階段	臨床試驗地區
AT-527	抑制病毒複製 (RNA聚合酶抑制劑)	Atea Pharmaceuticals, Inc./Hoffmann-La Roche	Phase 3	德、法、印等28國
PF-07321332	抑制病毒複製 (蛋白酶抑制劑)	Pfizer	 Phase 3 Phase 2/3 	美、日、南韓、台 等 16 國
molnupiravir (MK-4482)	抑制病毒複製 (核糖核苷類似物)	Merck Sharp & Dohme Corp./Ridgeback Biotherapeutics	Phase 2/3	美、日、德、法、 台等 22 國
HCQ vs Azithromycin for outpatients (HyAzOUT) NCT04334382	阻斷病毒進入人體 抑制病毒複製 抗發炎	Intermountain Health Care, Inc. Univ. of Utah	Phase 3 (1550位)	美國
High-dose HCQ NCT04351620	阻斷病毒進入人體 抑制病毒複製 抗發炎	U. Of Chicago	Phase 1/2 (20位)	美國

臨床階段之口服COVID-19治療藥物於非住院確診病人

研發項目	作用機轉	企業	臨床階段	臨床試驗地區
HCQ and Lopinavir/Ritonavir NCT04403100	去除病 毒 免疫調節	Cardresearch Cytel	Phase 3 (1968位)	巴西
HCQ and Favipiravir NCT04981379	去除病 毒 免疫調節	Health Institute of Turkey	Phase 3 (1120位)	土耳其
HCQ with Azitromicina NCT04964583	抗病 毒 免疫調節	Ultra laboratorios SA. de CV	Phase 2 (105位)	墨西哥
HCQ as PEP NCT04858633	阻斷病毒進入人體 抑制病毒複製 抗發炎	Postgraduate Institute of Medical Education and Research	Phase 4 (1000位)	印度
GX17 (S-HCQ)	阻斷病毒進入人體 抑制病毒複製 抗發炎	健亞/華宇	IND	台灣

DPP4 Inhibitor GBL121

- A novel and patented DPP4 inhibitor with better efficacy and safety profiles against Januvia in preclinical evaluation.
- China market rights licensed to China Shijiazhuang Pharma Company (CSPC) which is listed in Hong Kong and a top three pharma in China. The Golden Technology Transfer Award of 2015 Bio Taipei Awards was granted to our collaboration with CSPC.
- PhIa and PhIb studies completed under US IND;
 PhI and PhII completed, PhIII ongoing in China by CSPC.
- As a late-comer into DPP4 inhibitors market, GBL121 is positioned as a "friendly" anti-diabetic drug for Chinese patients.

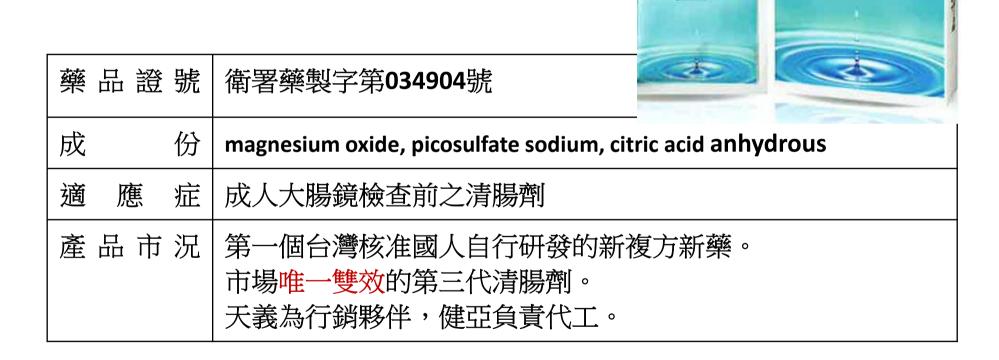
GMP Manufacturing

- Development and manufacture of proprietary products
 - ➤ New drugs, such as GenetaxylTM (patented new formulation of Paclitaxel), BowkleanTM marketed by UIC Group, LinicorTM (Niacin ER/Lovastatin marketed by TSH), MycostatinTM (Nystatin powder for oral solution).
 - Niche generic drugs, injectable preparation such as Atracurium, Rocuronium, and Cisatracurium as adjunct to general anaesthesia.
- Professional contract manufacturing services
 - Major clients including DSTW, TSH, etc.
- Professional contract development and manufacturing services
 - Major clients including SyneuRx (NaBen®), UIC Group (Bowklean™
 Sodium Picosulfate/Magnesium Oxide/Anhydrous Citric Acid), etc.
- Drug export to Korea and Southeast Asia since 2003.

Linicor「理脂」(降血脂治療藥)



Bowklean「保可淨」(大腸鏡檢查用藥)



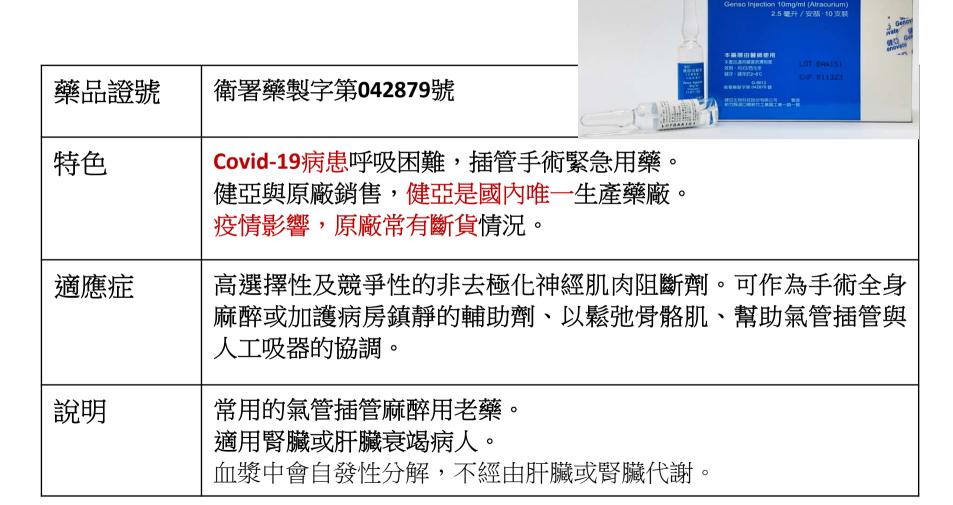
保可淨®

Bouklean Powder

保可淨數

Bouklean Powder

插管三箭 Genso 健舒注射液



"健亞"

健舒注射液10毫克/毫升

插管三箭 Winbest 衛平適注射液



藥品證號	衛部藥製字第060359號 本產品週用與審教演制度 本產品週用與審教演制度	
特色	Covid-19病患呼吸困難,插管手術緊急用藥。 健亞和外商銷售,健亞是國內唯一生產藥廠。 疫情影響,國外常有斷貨情況。	
適應症	高選擇性及競爭性的非去極化神經肌肉阻斷劑。可作為手術全身 麻醉劑之輔助劑或加護病房使用,用以鬆弛骨骼肌,幫助氣管插 管及與人工呼吸器的協調。	
說明	適用腎臟或肝臟衰竭病人。 恢復時間不受年齡、肝腎功能的影響。 老藥atracurium新異構物,不產生組織胺的副作用,病患不會有 臉部皮膚發紅、低血壓及支氣管痙攣的危險。	

插管三箭 Rocuron 若可麻注射劑



藥品證號	衛部藥製字第058097號
特色	Covid-19病患呼吸困難,插管手術緊急用藥。 健亞:唯一擁有 3種常用氣管插管用藥。 疫情影響,國外常有斷貨情況。
適應症	全身麻醉的輔佐藥,以幫助支氣管內插管、提供手術需快速麻醉 誘導時骨骼肌肉鬆弛狀態,加護病房中需插管及使用人工呼吸器 時。
說明	呼吸困難插管手術之警急用藥。 用於血液動力學不穩定的重症病患,輔助人工呼吸器治療。 作用快速 (90秒),幫助支氣管插管,可用於緊急狀況或禁食時間 不夠的病患。

救心雙寶 Gendobu 健多博注射液



藥品證號	衛署藥製字第042141號	EMP 031123 12.5mg/ml (Dobutamine) 20ml/Vial 本樂限由醫師使用本產品換用樂習報酬制度 效期:月/日/西元年	10Vials/盖 (Sandou Injerior) 12.5元分子子子子子子子子子子子子子子子子子子子子子子子子子子子子子子子子子子子子
特色	唯一上市且必備的品牌藥。		
適應症	增強心肌收縮力而適用於短期活起心肌收縮力抑制而導致之心臟		ふ臓外科手術引
說明	醫院必備的心臟急救藥品。 原廠已退出市場,國內唯一一家 適合用於治療心臟輸出量低和開 增強心肌收縮力,對冠狀動脈血管有 臟內壁張力,助於減輕心肌對氧氣的	i臟充血的病人。 育舒張作用,助於冠狀動	派血流。降低心

救心雙寶 Angidil 怡心通注射液



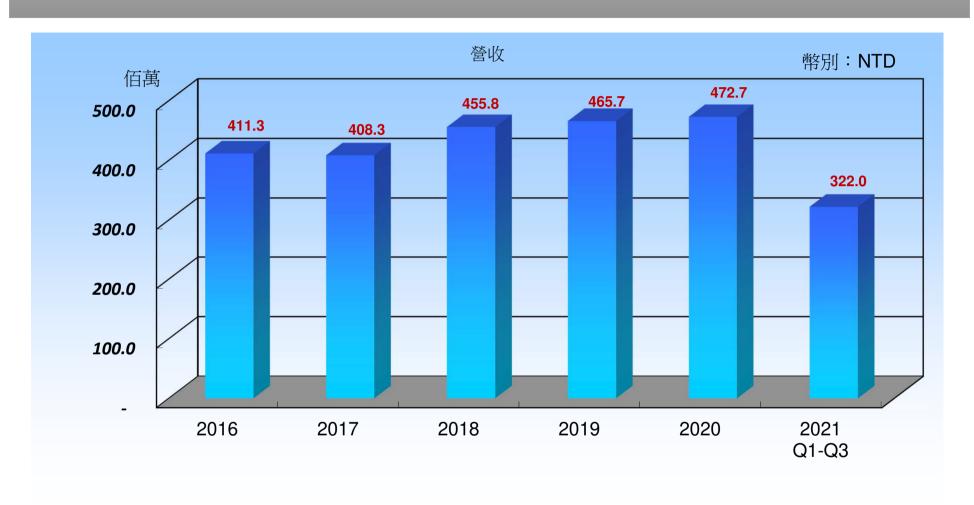
藥品證號	衛署藥製字第044974號
特色	國內第一家取得藥品許可證。市佔率第一的品牌藥。
適應症	治療狹心症發作。
說明	原廠已退出市場,目前僅 3 家藥廠上市。 狹心症發作之緊急症狀急救藥品,醫療院所使用後反應良好且持續使 用本產品。

戰腎一軍 Mycocep 喜妥善膠囊



藥品證號	衛署藥製字第050866號
特色	唯一通過TFDA 查核之台灣狼瘡性腎炎臨床試驗。 五年行政保護期。
適應症	預防或緩解腎臟移植之器官排斥, 預防心臟和肝臟移植之器官排斥。 狼瘡性腎炎的前導及維持治療。
說明	狼瘡新藥開發的領頭羊,執行三期臨床試驗的經驗豐富。 Geniquin: 免疫科第一線常用的特色學名藥。

營業收入 (2016~2021Q1-Q3)



資料來源:公開資訊觀測站/合併營收

稅前淨利 (2016~2021Q3)

