靈活接種時間表，最早可於1歲完成接種，最快可於2個月內完成[1]。

年齡		2至5個月	6至11個月	12至23個月	2歲或以上
針數	基本				
	加強劑	加強針需在12至15個月之間接種，與基本針相隔最少6個月	加強針需在13至23個月之間接種，與基本針相隔最少2個月	加強針需在完成基本針後的12至23個月內接種	根據建議，為減低受腦膜炎球菌病感染風險應考慮接種加強針

Bexsero保適腦安全資訊

- 2個月以下的嬰兒不可接種Bexsero保適腦
- Bexsero保適腦不可用於靜脈注射
- 常見的副作用如下表

Bexsero保適腦已在
全球42個地方[1,17]使用，
其中7個[2,18,19,20,21]
被納入為疫苗接種計劃

注射次數	病人組別	
	嬰兒和兒童 (最多10歲)	青少年和成人 (11歲以上)
十分常見 (≥1/10)	**飲食失調、疲倦、不尋常的哭鬧、頭痛、腹瀉、嘔吐** (加強劑量後舞得不常見) **皮疹** (12-23個月嬰兒，加強劑量後不常見) **關節痛、發燒** (≥38°C) **注射部位疼痛** (在四肢處注射時哭泣) **注射部位出現紅斑、腫脹、硬結** **情緒煩躁不安**	**頭痛、噁心、注射部位疼痛**(無法正常進行日常活動) **注射部位腫脹、注射部位出現硬結、注射部位紅斑** **全身乏力、肌肉痛、關節痛**
常見 (≥1/100 to <1/10)	**皮疹** (2-10歲)	/
不常見 (≥1/1,000 to <1/100)	**癲癇發作** (包括發燒引起的痙攣)、 **面色蒼白** (加強劑量後變得罕見)、 **溫疹、發燒** (≥40°C)	/
罕見 (≥1/10,000 to <1/1,000)	**川崎綜合症、蕁麻疹**	/
未知 (無法從現有數據估計)	**過敏反應、低張力低反應發作** (肌肉低張力)， **注射部位周圍出現水皰、腦膜刺激症**	**過敏反應、暈厥或注射後暈針** (血管迷走神經反應) **發燒、注射部位 /周圍起水皰、腦膜刺激症**

禁忌

Bexsero保適腦不適用於對任何Bexsero保適腦賦形劑過敏的人士。關於Bexsero保適腦詳盡的賦形劑列表，請參考產品資訊的6.1部分

警告和注意事項

熱性疾病：與其他疫苗一樣，若患有急性嚴重熱性疾病者，應該延遲接種Bexsero保適腦。若只是輕微受到感染，例如感冒，疫苗接種就不應延期

Abbreviated Prescribing Information

Product Name: Bexsero. **Active Ingredient:** 1 dose (0.5ml) contains 50 µg recombinant Neisseria meningitidis group B NHBA fusion protein; 50 µg recombinant Neisseria meningitidis group B NadA protein; 50 µg recombinant Neisseria meningitidis group B fHbp fusion protein; 25 µg outer membrane vesicles (OMV) from Neisseria meningitidis group B strain NZ98/254 measured as amount of total protein containing the PorA P1.4. **Indication:** active immunisation of individuals from 2 months of age and older against invasive meningococcal disease caused by Neisseria meningitidis group B. **Posology and method of administration:** Please refer to the posology in the full prescribing information of Bexsero for details. The vaccine is given by deep intramuscular injection, preferably in the anterolateral aspect of the thigh in infants or in the deltoid muscle region of the upper arm in older subjects. Separate injection sites must be used if more than one vaccine is administered at the same time. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients. **Special warnings and precautions for use:** As with other vaccines, administration of Bexsero should be postponed in subjects suffering from an acute severe febrile illness. However, the presence of a minor infection, such as cold, should not result in the deferral of vaccination. Do not inject intravascularly. As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine. Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions may occur in association with vaccination as a psychogenic response to the needle injection (see section 4.8). It is important that procedures are in place to avoid injury from fainting. This vaccine should not be given to individuals with thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injection, unless the potential benefit clearly outweighs the risk of administration. As with any vaccine, vaccination with Bexsero may not protect all vaccine recipients. Bexsero is not expected to provide protection against all circulating meningococcal group B strains. (see section 5.1). As with many vaccines, healthcare professionals should be aware that a temperature elevation may occur following vaccination of infants and children (less than 2 years of age). Prophylactic administration of antipyretics at the time and closely after vaccination can reduce the incidence and intensity of post-vaccination febrile reactions. Antipyretic medication should be initiated according to local guidelines in infants and children (less than 2 years of age). Individuals with impaired immune responsiveness, whether due to the use of immune-suppressive therapy, a genetic disorder, or other causes, may have reduced antibody response to active immunisation. Immunogenicity data are available in individuals with complement deficiencies, asplenia, or splenic dysfunctions (see section 5.1). There are no data on the use of Bexsero in subjects above 50 years of age and limited data in patients with chronic medical conditions. The potential risk of apnoea and the need for respiratory monitoring for 48-72 hours should be considered when administering the primary immunisation series to very premature infants (born ≤ 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity. As the benefit of vaccination is high in this group of infants, vaccination should not be withheld or delayed. Kanamycin is used in early manufacturing process and is removed during the later stages of manufacture. If present, kanamycin levels in the final vaccine are less than 0.01 micrograms per dose. The safe use of Bexsero in kanamycin-sensitive individuals has not been established. **Interaction with other medicinal products and other forms of interaction:** Clinical studies demonstrated that the immune responses of the co-administered routine vaccines were unaffected by concomitant administration of Bexsero, based on non-inferior antibody response rates to the routine vaccines given alone. Due to an increased risk of fever, tenderness at the injection site, change in eating habits and irritability when Bexsero was co administered with the above vaccines, separate vaccinations can be considered when possible. When given concomitantly with other vaccines Bexsero must be administered at separate injection sites. **Pregnancy and lactation: Pregnancy:** Insufficient clinical data on exposed pregnancies are available. The potential risk for pregnant women is unknown. Nevertheless, vaccination should not be withheld when there is a clear risk of exposure to meningococcal infection. **Lactation:** Information on the safety of the vaccine to women and their children during breast-feeding is not available. The benefit-risk ratio must be examined before making the decision to immunise during breast-feeding. **Fertility:** There are no data on fertility in humans. **Undesirable effects:** Infants and children (up to 10 years of age): eating disorders; sleepiness; unusual crying; headache; seizures (including febrile seizures); pallor; Kawasaki syndrome; diarrhoea; vomiting; rash; eczema; urticaria; arthralgia; fever ≥38°C, fever ≥40°C), injection site tenderness (including severe injection site tenderness defined as crying when injected limb is moved), injection site erythema, injection site swelling, injection site induration, irritability. Adolescents (from 11 years of age) and adults: headache; nausea; myalgia; arthralgia; injection site pain (including severe injection site pain defined as unable to perform normal daily activity), injection site swelling, injection site induration, injection site erythema, malaise.

The material is for the reference and use by healthcare professionals only.

Please read the full prescribing information prior to administration.
Full prescribing information is available on request from GlaxoSmithKline Ltd, 23/F, Tower 6, The Gateway, 9 Canton Road, Tsimshatsui, Kowloon, Hong Kong.

Abbreviated Prescribing Information prepared in Jul 2019 based on version K052020(GDS11,EMA20200505).
For adverse event reporting, please call GlaxoSmithKline Limited at (852) 3189 8989 (Hong Kong) or (853) 2871 5569 (Macau), or send an email to us at HKAdverseEvent@gsk.com.

PM-HK-BEX-LBND-220002 (07/2024) Date of preparation: 15/08/2022

BEXSERO
Meningococcal Group B Vaccine
(rDNA, component, adsorbed)

參考資料： **1.** Bexsero Hong Kong Prescribing information. **2.** Pfizer Ltd. Trumenba. Annex I: Summary of product characteristics. **3.** CHP. Number of notifiable infectious diseases by month. Available at: https://www.chp.gov.hk/en/static/24012.html (Accessed on 28 Jan 2019). **4.** CHP. Communicable Diseases Watch. Jan 27-Feb 9 2019 Weeks 5-6. Vol 16 Issue No. 3. **5.** WHO. Meningococcal meningitis fact sheet. Available at:https://www.who.int/news-room/fact-sheets/detail/meningococcal-meningitis (Accessed on 2 APR 2019) **6.** Peterson ME et al. J Glob Health. 2019; 9: 010409. **7.** Rosenstein NE, et al. N Engl J Med. 2001 **8.** Viner RM, et al. Lancet Neurol. 2012; 11:774-783 **9.** Meningococcal Australia. The Facts. Available at: http://www.meningococcal.org.au/new-page-1 (Accessed on 2 APR 2019) **10.** Centers for Disease Control and Prevention. VPD manual Chapter 8: Meningococcal disease. **11.** MacNeil Jr et al. Pediatrics. 2015;135:e305-11 **12.** Archer BN et al. Med J Aust 2017; 207 (9):382-7 **13.** Lahra MM et al. Commun Dis Intell 2014;40:E503-E511; **14.** Australian Bureau of Statistics. Population by age and sex, Australian states and territories, June 2015. http://www.abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/3101.0Jun%2020151?OpenDocument (all accessed Aug 2019) **15.** Data on file, GSK **16.** Chen M et al. Scientific Reports. 2018; 8:12334 **17.** Data on file - 2016N297580002 **18.** Meningococcal B. Health and Safety Executive (HSE). National Immunization office. Dublin, Ireland **19.** Piano Nazionale Prevezione Vaccinate PNPV 2017-2019. Ministero della salute website **20.** Moreno-Perez D, Alvarez et al. Spanish Association of Pediatric

Safety Information:

Hypersensitivity to any components of BEXSERO is a contraindication to administration. Administration of BEXSERO should be postponed 1n subjects suffering from an acute severe febrile illness. Minor infection, such as cold, should not result in the deferral of vaccination. BEXSERO should not be given to individuals with thrombocytopenia_ or any coagulation disorder that would contraindicate intramuscular injection, unless the potential benefit clearly outweighs the risk of administration. Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following administration of BEXSERO.

Anxiety-related reactions, including vasovagal reactions (syncope), hyper-ventilation or stress-related reactions may occur in association with vaccination as a psychogenic response to the needle injection. It is important that procedures are in place to avoid injury from fainting.

The safety and efficacy of BEXSERO in individuals above 50 years of age have not been established. There are limited data in patients with chronic medical cond111ons and with impaired immune responsiveness (complement deficiency, asplenia or splenic dysfunction). In immunocompromised individuals, vaccination may not result in a protective antibody response. Insufficient clinical data on exposed pregnancies are available and there are no data on fertility in humans.

BEXSERO is not expected to provide protection against all circulating meningococcal group B strains.

The most common adverse reactions observed in clinical trials of infants and children were tenderness and erythema at the injection site, fever, and irritability. Fever occurred more frequently when BEXSERO was co-administered with other routine infant vaccines than when it was given alone.

Higher rates of antipyretic use were also reported for infants vaccinated with BEXSERO and routine vaccines. When BEXSERO was given alone, the frequency of fever was similar to that associated with routine infant vaccines administered during clinical trials. When fever occurred, it generally followed a predictable pattern, with the majority resolving by the day after vaccination.

Prophylactic use of paracetamol reduces the incidence and severity of fever without affecting the immunogenicity of either BEXSERO or routine vaccines. Ant1pyret1c med1cat1on should be initiated according to local guidelines in infants and children (less than 2 years of age).

Due to an increased risk of fever, tenderness at the injection site, change in eating habits and irritability when BEXSERO was co-administered with routine vaccines, separate vaccinations can be considered when possible.

In adolescents and adults, the most common local and systemic adverse reactions observed were pain at the injection site, malaise and headache.

Less commonly, some serious events can occur after BEXSERO: seizures (including febrile seizures) and allergic reactions.

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B型腦膜炎雙球菌疫苗

新接種時間表

BEXSERO
Meningococcal Group B Vaccine
(rDNA, component, adsorbed)

公仔手腳無咗可以再配，但寶寶呢？

及早預防B型腦膜炎雙球菌，以免後悔一生

美國FDA及歐盟EMA批准

唯一可用於幼兒[1,2]

佔香港腦膜炎雙球菌50%個案[3,4]

只供醫護人員使用

B型腦膜炎雙球菌疫苗

甚麼是B型腦膜炎雙球菌？

它是一種因細菌感染而引起的疾病，有可能引致入侵性腦膜炎。腦膜炎雙球菌分為ABCWXY六種，當中**B型佔香港五成感染**[3]。

病程進展迅速，患者可能會在**出現症狀後24小時內死亡**[5]。

每10個患者有1個
死於腦膜炎雙球菌感染[5,6]

每5個患者有1個[5,7]
可能會有嚴重的長期殘疾[8]

- 腦部損害
- 智力受損
- 失去肢體
- 失聰

它是如何傳播？

腦膜炎雙球菌
可存活於**喉嚨和鼻子中**[9]

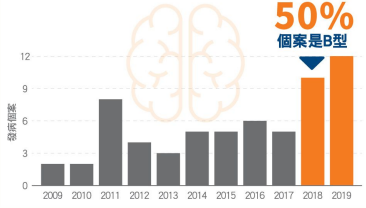
10% 有**十分之一**人口是**長期帶菌者**[10]

青少年和年輕的成年人
帶菌的**比例最高**[10]

它可以透過以下傳播[11,12]

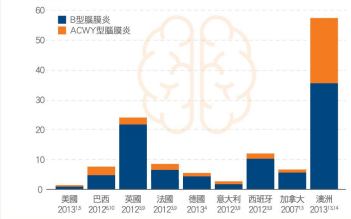
各地B型腦膜炎雙球菌感染數據

香港腦膜炎雙球菌感染數字(2009-2019)[3,4]

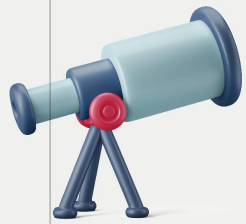


截至2018年12月，一共有**10宗感染病例**，
超過了過去10年的年度病例
*2019年至7月為止，已經有12宗感染

歐美腦膜炎雙球菌感染數字(2008-2019)[3,4]

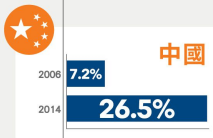


在美國超過200間大學建議接種
B型腦膜炎雙球菌疫苗
(包括哈佛大學，耶魯大學及史丹福大學等)。
其中30間更列為必須接種[15]



引入
A型及C型
二價腦膜炎雙球菌
疫苗接種計劃

中國



上海的
B型腦膜炎雙球菌感染率
上升至63.2%[16]

2008 **2014** **2016**

C型腦膜炎雙球菌感染的比例開始下降，
但**B型腦膜炎雙球菌感染率上升**：
由2006年的7.2%上升至2014年的26.5%[16]

獲美國FDA及歐盟EMA批准

唯一 批准可供**10歲以下兒童**接種的
B型腦膜炎雙球菌疫苗[1,2]