SHINGRIX
(ZOSTER VACCINE
RECOMBINANT, ADJUVANTED)

美國疾控中心[1]
★推薦★

擊退「生蛇」危機

首選新一代疫苗[1]

唯一擁有
超過90%
預防功效的
帶狀皰疹疫苗[2,3*]

參考資料： 1. Centers for Disease Control and Prevention. MMWR. 2018 Jan;67(3):103-8. 2. SHINGRIX Hong Kong Prescribing Information. GDS03. 3. MSD Live-attenuated Zoster Vaccine Product Circular. 4. Harpaz R, et al. MMWR Recomm Rep. 2008 June;57(RR-5):1-30. 5. Dworkin RH, Johnson RW, Breuer J et al. Recommendations for the management of herpes zoster. Clin Infect Dis 2007;44 Suppl 1:S1-26. 6. Bruxelle J, Pinchinat S. Effectiveness of antiviral treatment on acute phase of herpes zoster and development of post herpetic neuralgia: review of international publications. Med Mal Infect 2012;42:53-58. 7. Wallis KA, Hood LJ, Rao K. Herpes zoster: when do patients present and who gets antiviral treatment? J Prim Health Care 2014;6:108-113. 8. Centre of Health Protection. Seroprevalence rate of Varicella zoster virus antibodies in Hong Kong. Available at https://urldefense.com/v3/__https://www.chp.gov.hk/en/statistics/data/10/641/701/3691.html__;!!AoaiBx6H!gqeYSoPa8CJjFU1S7qC_E81HhjZqN8MtwO1yrktI5voUITD8IQjVINUMsYMHGQ$ (Accessed in May 2021.). 9. Kimberlin DW, et al. N Engl J Med. 2007 Mar;356(13):1338-43. 10. Mueller NH, Gilden DH, Cohrs RJ et al. Varicella zoster virus infection: clinical features, molecular pathogenesis of disease, and latency. Neurol Clin 2008;26:675-697. 11. Katz J, et al. Surg Clin North Am. 1999;79(2):231-252. 12. Johnson RW, et al. BMC Med. 2010 Jun;8:37. 13. Curran D, et al. BMC Infect Dis. 2018 Aug. 14. Devor M;Chapter 13;Springer;2017;1-31. 15. Kim JH, et al. The adjuvented recombinant zoster vaccine is efficacious and safe in Asian adults ≥ 50 years of age: a sub-cohort analysis of the ZOE-50 and ZOE-70 randomized trials. Hum Vaccin Immunother. 2021 Jul 3;17(7):2050-2057. 16. Abstract - 049; Boutry C;ZOE-LTFU_Y2_Interim;2020;1-4. ClinicalTrials.gov. NCT02723773. https://clinicaltrials.gov/ct2/show/NCT02723773. 17. GSK Data on File. 18. HKSAR Health Care Voucher. https://urldefense.com/v3/__https://www.hcv.gov.hk/tc/pub_background.htm__;!!AoaiBx6H!gqeYSoPa8CJjFU1S7qC_E81HhjZqN8MtwO1yrktI5voUITD8IQjVINWG90IHVNw$. (Accessed in May2021).

Abbreviated Prescribing Information

Name of the Medicinal Product: Shingrix vaccine powder and suspension for suspension for injection. Herpes zoster vaccine (recombinant, adjuvanted) **Qualitative and Quantitative Composition:** After reconstitution, 1 dose (0.5 ml) contains 50 micrograms of gE antigen adjuvanted with AS01B. Varicella Zoster Virus (VZV) glycoprotein E (gE) produced by recombinant DNA technology in Chinese Hamster Ovarian (CHO) cells. The GlaxoSmithKline proprietary $AS01_B$ Adjuvant System is composed of the plant extract *Quillaja saponaria* Molina, fraction 21 (QS-21) (50 micrograms) and 3-O-desacyl-4'-monophosphoryl lipid A (MPL) from *Salmonella minnesota* (50 micrograms) **Indications:** Shingrix is indicated for prevention of herpes zoster (HZ) and post-herpetic neuralgia (PHN), in adults 50 years of age or older. **Posology and Administration:** The primary vaccination schedule consists of two doses of 0.5 ml each: an initial dose followed by a second dose 2 months later. **Method of administration:** Intramuscular injection. **Contraindications:** Hypersensitivity to the active substances or to any component of the vaccine. **Special Warnings and Precautions for Use:** 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. As with other vaccines, vaccination with Shingrix should be postponed in subjects suffering from an acute severe febrile illness. However, the presence of a minor infection, such as a cold, should not result in the deferral of vaccination. As with any vaccine, a protective immune response may not be elicited in all vaccinees. Do not administer the vaccine intravascularly or intradermally. Subcutaneous administration is not recommended. Maladministration via the subcutaneous route may lead to an increase in transient local reactions. Shingrix should be given with caution to individuals with thrombocytopenia or any coagulation disorder since bleeding may occur following intramuscular administration to these subjects. Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints. **Interactions:** Shingrix can be given concomitantly with unadjuvanted inactivated seasonal influenza vaccine, 23-valent pneumococcal polysaccharide vaccine (PPV23) or reduced antigen diphtheria-tetanus-acellular pertussis vaccine (dTpa). The vaccines should be administered at different injection sites. **Fertility, pregnancy and Lactation: Pregnancy:** There are no data from the use of Shingrix in pregnant women. The effect on breast-fed infants of administration of Shingrix to their mothers has not been studied. **Undesirable effects:** lymphadenopathy, hypersensitivity reactions including rash, urticaria, angioedema, headache, gastrointestinal symptoms (including nausea, vomiting, diarrhoea and/or abdominal pain), myalgia, arthralgia, injection site reactions (such as pain, redness, swelling), fatigue, chills, fever, injection site pruritus, malaise. **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 7 Dec 2020 based on version HK052020(GDS03/EMA20200109). 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.

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醫療券
Health Care Voucher
香港特別行政區政府
The Government of the Hong Kong Special Administrative Region

65歲或以上持有有效香港身份證，
可於已登記的醫療機構使用醫療券，
支付預防性醫療服務相關的費用[18]

gsk

*50歲或以上人士
此資料只供醫護人員參閱或使用

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SHINGRIX
(ZOSTER VACCINE
RECOMBINANT, ADJUVANTED)

新一代 生蛇疫苗

「生蛇」隨時復發

「帶狀皰疹」俗稱「生蛇」，是由水痘帶狀皰疹病毒所引致的傳染病。病毒會於水痘痊癒後潛藏在體內的神經系統，凡感染過水痘，即使健康人士，都有機會生蛇[4]！治療方案包括於紅疹出現首72小時內服用抗病毒藥物。然而，初期病徵未必明顯，患者或因而錯過黃金治療期[5-7]。

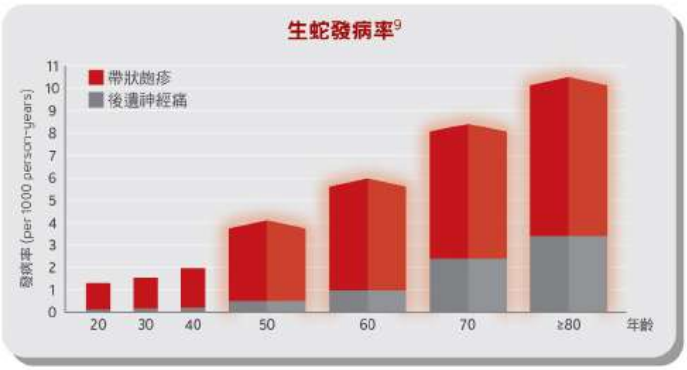
幾乎每個成年人 都有機會「生蛇」

98%的香港成年人
曾患水痘[8§]

約1/3成人
會經歷「生蛇」[4]

年齡增長是誘發「生蛇」的重要因素[4,9]

50歲起，生蛇風險倍增，應盡早預防[4,9]

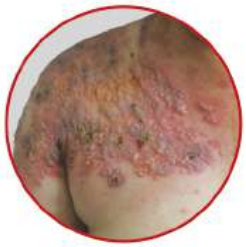


§ 於39歲或以上體內水痘帶狀皰疹病毒抗體呈陽性

「生蛇」纏身痛苦難擋

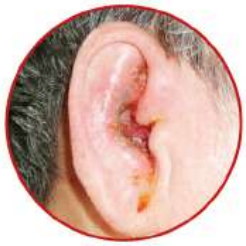
一旦發病，潛藏在體內的病毒會沿著神經線蔓延到皮膚或身體不同部位[4,5,9]。

身體患處[5,10]


胸背


面部


眼睛


耳朵

不同患處可引起不同的病徵。嚴重可導致面部神經麻痺，視力下降甚至失明或失聰[5,10]。

痛楚的等級[11]

「生蛇」急性痛楚的等級**大於分娩和手術後的疼痛**[11]。

多達**30%**患者會出現**後遺神經痛**

患者往往承受著幾個月、甚至持續幾年的神經痛，如[12]：

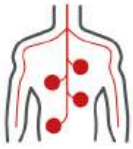
針刺 **火燒** **電擊**

有時即使輕輕觸碰皮膚，患者都會感覺異常劇痛，需要長期服用止痛藥以減輕痛楚，嚴重影響日常生活和質量[13-14]。

潛在併發症[4]

急性病毒性腦炎

中風



後遺神經痛

生蛇上眼

防護效能不再受年齡規限*

於18個國家進行的臨床研究顯示，Shingrix保護效能超過90%[2]

韓國
日本
香港
台灣

亞洲數據[15]

於亞洲進行研究的數據顯示，Shingrix的功效對50歲或以上的人士高達95.6%，而70歲或以上亦達94.7%。

接種時間[2]

第1劑 — 相隔2-6個月 — 第2劑

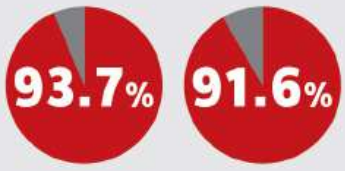
- 適合50歲或以上人士接種
- 對免疫功能低下人士沒有禁忌
- 常見的副作用包括注射部位疼痛，肌肉疼痛，疲勞和頭痛，平均持續2-3天。

額外保護[2]

預防後遺神經痛

50歲或以上人士　70歲或以上人士

預防生蛇引起的併發症‡



50歲或以上人士　70歲或以上人士

‡ 併發症包括：帶狀皰疹相關血管炎、播散性疾病、眼科疾病、神經系統疾病、內臟疾病和中風

* 50歲或以上人士

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獲國際權威美國疾控中心
推薦為生蛇疫苗之首選[1]

✓ 50歲或以上人士　✓ 不論有否曾接種帶狀皰疹減毒活疫苗

均建議接種Shingrix重組帶狀皰疹疫苗，以得到更強保護[1]！

唯一擁有超過**90%**預防功效的帶狀皰疹疫苗[2-3]

能預防「生蛇」及「生蛇」引起的後遺神經痛，並降低其他併發症的風險[2]。

ANTIGEN Glycoprotein E (gE) **非活抗原**

SHINGRIX
(ZOSTER VACCINE
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提供**超卓及長效**的保護效能[2]

ADJUVANT SYSTEM AS01$_B$ **佐劑系統**

持續效能達>90%[16≠]

相比安慰劑，嚴重不良反應並無分別[2]

獲美國FDA及歐盟EMA批准[17]

≠ 至少7.1年持續效能[16]

「生蛇」Q&A

Q：我以前曾生蛇，可再接種Shingrix嗎？

A：CDC建議注射Shingrix，以預防疾病再次發生[1]。

Q：如果我過去曾經接種過「帶狀皰疹減毒活疫苗」，須要再次接種Shingrix嗎？

A：CDC建議您應重新接種Shingrix非活性重組帶狀皰疹疫苗[1]。

Q：如果我不確定自己曾否患有水痘，我可以接種Shingrix疫苗嗎？

A：CDC建議50歲或以上的人，即使不確定曾否患過水痘，均可接種 Shingrix[1]。

Q：我應接種多少劑Shingrix「帶狀皰疹」預防疫苗？

A：CDC建議50歲或以上未接種任何帶狀皰疹疫苗，接種重組帶狀皰疹疫苗之人士，應接種兩劑Shingrix重組帶狀皰疹疫苗[1]。

CDC：美國疾病管制與預防中心

安全信息[2]：

- Shingrix預防帶狀皰疹和皰疹後神經痛，適用於50歲或以上的成人。
- 已知對疫苗中的活性物質或任何成分過敏的患者不應使用Shingrix。
- Shingrix僅適用於肌肉注射，最好的注射部位是三角肌。
- 常見的副作用包括注射部位疼痛，肌肉疼痛，疲勞和頭痛。