VARILRIX™ SPECIAL OFFER ORDER FORM

OFFER VALID UNTIL 24 DECEMBER 2004

SPECIAL OFFER: Chickenpox Kit & special priced vaccine. Order now and you will be eligible for a continuation of this volume based discount price throughout 2005! - FAX NOW to 09 367 2933

HCL Account Number: _____

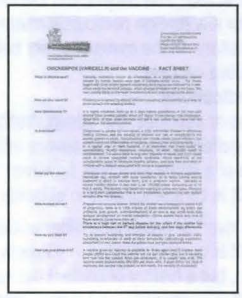
Telephone: _____ **FAX:** _____

☐ Yes, Please send me a Chickenpox Kit. *(Each kit contains)*

Vaccine Price List/Pad

Varilrix Patient Leaflets

Varilrix Poster



FACTS on ChickenPox
(Immunisation Advisory Centre)

Varilrix Data Sheet – see reverse

Yes please, I would like to take advantage of the Varilrix special offer.

Chickenpox Kit and special priced vaccine.

Order now and you will be eligible for a continuation of this volume based discount price throughout 2005!

2+ units Varilrix @ (5% disc) is $47.50 +GST each

Minimum order qty is 2 units

_____
please indicate QTY

ORDERS MUST BE PLACED BEFORE 24 DECEMBER 2004

TAPS No: DA4413AH/04NO/262

For internal use only: ☐ HCL ☐ Penrose - Att Derrell

SPECIAL OFFER:

Chickenpox Kit and special priced vaccine. Order now and you will be eligible for a continuation of this volume based discount price throughout 2005!

GlaxoSmithKline NZ Limited
8th Floor Quay Tower
Cnr Albert & Customs Streets
Private Bag 106600, Downtown
Auckland
New Zealand

Tel. +64 9 367 2900
Fax. +64 9 367 2910

www.gsk.co.nz

DOES CHICKENPOX REALLY HAVE TO BE PART OF GROWING UP?

Each year in NZ there is an estimated 50,000 varicella infections: 150-200 result in hospitalization and one or two cases cause long-term disability and death[1]. As a healthcare professional you will have experienced first hand the misery of chickenpox and know how irritating it can be for children and families.

BEAT THE MISERY OF CHICKENPOX

Chickenpox (varicella) vaccines have been used around the world for *over 20 years*. According to WHO, the positive results of extensive safety, efficacy and cost–effectiveness analyses have warranted introducing these vaccines into the childhood immunization programmes of many countries including Australia, Canada, Europe, Japan, Korea and the USA.[2,3,4,5,6]

THE SIMPLE SOLUTION – VARILRIX™

Varilrix is well tolerated, reactions are infrequent and mild (redness, swelling and pain at the injection site are mild and transient).[7]

Varilrix offers single dosing in children from 9 months to 12 years or age and can be administered subcutaneously at the same time as measles-mumps-rubella or DTPa (at different injection sites).[7]

Recent NZ touchpoll research of 87 parents shows:[8]

- 45% were not aware there was a chickenpox vaccine available in New Zealand.
- 63% of NZ parents were prepared to pay between $60- $80 after reading of the availability of a chickenpox vaccine.

Order 2+ Varilrix and get 5% discount (valid until Dec 24th 2004)

We will be reviewing our vaccine prices early 2005, so why not order 2+ Varilrix and receive a 5% discount. Order your Chickenpox kit now so that you have up to date information on Varilrix and patient information on the attached fax order form.

Kind regards

Airey

Stacey Airey, Vaccines Product Manager

P.S. This offer will expire on Dec 24 so order NOW and you will be eligible for an extension of this discounted price throughout all of 2005.
More details to follow in the New Year!

DATA SHEET

Name of Medicinal Product

VARILRIX

Live attenuated varicella vaccine

Presentation

VARILRIX is a lyophilised preparation of the live attenuated Oka strain of varicella-zoster virus, obtained by propagation of the virus in MRC_5 human diploid cell culture.

VARILRIX meets the World Health Organisation requirements for biological substances and for varicella vaccines.

Each dose of the reconstituted vaccine contains not less than $10^{3.3}$ plaque-forming units (PFU) of the varicella-zoster virus.

VARILRIX is presented as a slightly pink-coloured pellet in a glass vial. The sterile diluent is clear and colourless and presented in ampoules and prefilled syringes.

Clinical Particulars

Therapeutic indications

VARILRIX is indicated for active immunisation and prophylaxis against varicella in healthy infants (from the age of 9 months), children, adolescents and adults.

There are socioeconomic benefits for the more extensive use of VARILRIX in the community eg. health workers, school teachers and others exposed to children should be vaccinated with VARILRIX if there is no history of varicella. Working mothers should have their children vaccinated.

Posology and method of administration

0.5ml of reconstituted vaccine contains one immunising dose.

From the age of 9 months up to and including 12 years of age: 1 dose.

From 13 years and up: 2 doses with an interval between doses of a minimum of 6 weeks.

VARILRIX SHOULD NEVER BE ADMINISTERED INTRAVENOUSLY.

VARILRIX should be administered by **subcutaneous injection** only. The upper arm (deltoid region) is the preferred site of injection.

VARILRIX must be reconstituted by adding the contents of the supplied container of diluent to the vial containing the vaccine pellet. The mixture should be well shaken until the vaccine is completely dissolved in the diluent. The entire contents of the vial are to be injected.

After reconstitution, VARILRIX should be administered immediately. Alcohol and other disinfecting agents must be allowed to evaporate from the skin before injection of the vaccine since they may inactivate the virus.

Due to minor variations of its pH, the colour of the reconstituted vaccine may vary from pink to red. The diluent and the reconstituted vaccine should be inspected visually for any foreign particulate matter and/or variation of physical aspect prior to administration. In the event of either being observed, discard the diluent or the reconstituted vaccine.

Contraindications

As with other vaccines, the administration of VARILRIX should be postponed in subjects suffering from acute severe febrile illness. In healthy subjects the presence of a minor infection, however, is not a contraindication for vaccination.

VARILRIX is contraindicated in subjects with a total lymphocyte count less than 1200 per mm^3 or presenting other evidence of lack of cellular immune competence.

VARILRIX is contraindicated in subjects with known systemic hypersensitivity to neomycin, but a history of contact dermatitis to neomycin is not a contraindication.

VARILRIX is contraindicated during pregnancy. Furthermore, pregnancy should be avoided for three months after vaccination.

Special warnings and special precautions for use

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic reaction following the administration of the vaccine.

Transmission of the Oka vaccine virus has been shown to occur at a very low rate in seronegative contacts of vaccinees.

Vaccinees who develop papulo-vesicular eruptions within the first 4 weeks post vaccination should avoid contact with patients known to be immune suppressed for the duration of the rash.

Care should be exercised in the immunocompromised and patients under immunosuppressive treatment (including corticosteroid therapy) for malignant solid tumour or for serious chronic diseases (such as chronic renal failure, autoimmune diseases, collagen diseases, severe bronchial asthma).

VARILRIX should not be administered intradermally. VARILRIX must under no circumstances be administered intravenously.

Interactions with other medicaments and other forms of interaction

In subjects who have received immune globulins or a blood transfusion, vaccination should be delayed for at least three months because of the likelihood of vaccine failure due to passively acquired varicella antibodies.

Salicylates should be avoided for 6 weeks after varicella vaccination as Reye's Syndrome has been reported following the use of salicylates during natural varicella infection.

VARILRIX can be administered at the same time as any other vaccine. Different injectable vaccines should always be administered at different injection sites.

Inactivated vaccines can be administered in any temporal relationship to VARILRIX.

Should a measles containing vaccine not be given at the same time as VARILRIX, it is recommended that an interval of at least one month should be respected since it is recognised that measles vaccination may lead to short lived suppression of the cell mediated immune response.

Pregnancy and lactation

Pregnancy

It is contraindicated to administer VARILRIX to pregnant women, because the possible effects on foetal development are unknown. Furthermore, pregnancy should be avoided for three months after vaccination.

Lactation

There are no data regarding use in breastfeeding women.

Effects on ability to drive and use machines

The vaccine is unlikely to produce an effect on the ability to drive and use machines.

Undesirable effects

VARILRIX is a vaccine of low overall reactogenicity in all age groups.

Redness, swelling and pain at the site of injection of VARILRIX are mild and transient.

In clinical studies involving more than 2000 subjects from the age of 9 months, papulo-vesicular eruptions were reported in aproximately 5% of the vaccinees. Most of them occur during the first three weeks after vaccination, and the number of lesions was generally below ten. Temperature above 37.5°C (axillary) / 38°C (rectal) was reported in approximately 5% of subjects during a six week follow-up of the vaccinees. The reactogenicity after the second dose in adolescents and adults was not higher than after the first dose. No difference was seen between the reactogenicity in initially seropositive and seronegative subjects.

In a four week follow-up double-blind placebo-controlled study including 513 children between 12-30 months of age, there was no significant difference in nature or incidence of symptoms in subjects receiving vaccine or placebo.

Overdose

Not applicable.

Pharmacological Properties

Pharmacodynamic properties

VARILRIX produces an attenuated clinically inapparent varicella infection in susceptible subjects.

Some protection may be obtained by immunisation up to 72 hours after exposure to natural varicella.

The presence of antibodies is accepted to be an indication of protection.

In subjects aged 9 months to 12 years, the overall seroconversion rate was >98% when measured at 6 weeks post-vaccination. In children vaccinated at 12-15 months of age, antibodies persisted for at least 7 years postvaccination.

In subjects aged 13 years and above, the seroconversion rate was 100% when measured 6 weeks after the second dose. One year after vaccination, all subjects tested were still seropositive.

In an efficacy study in 10- to 30-month-old children during a follow-up of 29.3 months, the protective efficacy was 100% against common clinical cases of varicella (30 vesicles). Against any cases of varicella (mild case with at least 1 vesicle or papule) protective efficacy was 88%. However, cases were mild (median number of vesicles was 1; no fever was reported).

If primary varicella infection is delayed until adolescence or adulthood, the illness is usually more severe, and may result in complications such as pneumonia, haemorrhagic varicella, encephalitis, visceral dissemination and cosmetic sequelae from superinfection of skin lesions. Complications can occur at any age but the risk increases with age.

Pharmacokinetic properties

Evaluation of pharmacokinetic properties is not required for vaccines.

Preclinical safety data

Appropriate safety tests have been performed.

Pharmaceutical Particulars

Special precautions for storage

The lyophilised vaccine should be stored in a refrigerator between +2°C to +8°C. The diluent can be stored in the refrigerator or at ambient temperature (maximum 25°C). The lyophilised vaccine is not affected by freezing.

When supplies of VARILRIX are distributed from a central cold store, it is good practice to arrange transport under refrigerator conditions especially in hot climates.

Shelf life

The shelf life of VARILRIX is 24 months from the date of manufacture if stored between temperatures of +2°C to +8°C. The expiry date of the vaccine is indicated on the label and packaging.

Medicine Classification

Prescription Medicine

Package Quantities

VARILRIX vaccine: monodose glass vials in packs of 1.

Diluent: glass ampoules or prefilled syringes, 0.5mL in packs of 1.

Name and Address

GlaxoSmithKline NZ Ltd
Quay Tower
Cnr Albert & Customs Street
Private Bag 106600
Downtown Auckland
NEW ZEALAND
ph (09) 367 2900
fax (09) 367 2506

Date of Preparation

23 October 2002. Ref: MDS Version 2 Dated 21/08/2000

Varilrix (live attenuated varicella vaccine) is available as an injection, 0.5mL per dose. Varilrix is a private purchase medicine – a prescription charge will apply. Prescription Medicine for the immunisation and prophylaxis against varicella in adults and children older than nine months of age. Contraindications: acute severe febrile illness, lack of cellular immunity, known systemic hypersensitivity to neomycin, or pregnancy. Pregnancy should also be avoided for three months after vaccination. Precautions: medical treatment should be readily available in case of rare anaphylactic reaction following administration; caution in immunocompromised or patients under immunosuppressive treatment; do not administer intradermally or intravenously. Avoid salicylates for 6 weeks after vaccination. Common side effects include local reactions such as pain, redness and swelling at the injection site; other reported reactions include small numbers of papulo-vesicular eruptions or a low-grade fever. Before prescribing this medicine, please review the attached Data sheet. Varilrix is a trademark of the GlaxoSmithKline group of companies. Marketed by GlaxoSmithKline NZ Limited, Auckland.
TAPS No DA4413AH/04NO/262.

References:

1. Ministry of Health, Immunisation Handbook 2002, chapter 17: Varicella
2. WHO. The WHO position paper on Varicella vaccines: Weekly Epidemiological Record 1998, (73): 241–248.
3. The Australian Standard Vaccination Schedule, adapted from Chapter 1.7 of The Australian Immunisation Handbook. 8th Edition. 2003.
4. Canada Communicable Disease Report. Vol. 25 (ACS-1) 1 May 1999. Downloaded from www.hc-sc.gc.ca, 12 October 2004.
5. Rentier R et al. Pediatr Infect Dis J. 2004; 23(5);379- 388.
6. ACIP. Recommended Childhood Immunisations Schedule. United States 2002. www.cdc.gov/nip/acip.
7. Varilrix Product Information
8. Parent and Child Show Touchpoll Survey. October 2004. Prepared for GSK NZ.