PRIORIX

Measles, mumps, and rubella vaccine
Powder for injection and diluent

QUALITATIVE AND QUANTITATIVE COMPOSITION

Priorix is a lyophilised mixed preparation of the attenuated Schwarz measles, RIT 4385 mumps (derived from Jeryl Lynn strain) and Wistar RA 27/3 rubella strains of viruses, separately obtained by propagation either in chick embryo tissue cultures (mumps and measles) or MRC-5 human diploid cells (rubella).

Priorix meets the World Health Organisation requirements for manufacture of biological substances and for measles, mumps and rubella vaccines and combined vaccines (live).

Each 0.5 mL dose of the reconstituted vaccine contains not less than $\geq 10^{3.0}$ $CCID_{50}$ of the Schwarz measles, not less than $10^{3.7}$ of the RIT 4385 mumps, and not less than $10^{3.0}$ $CCID_{50}$ of the Wistar RA 27/3 rubella virus strains.

The powder is whitish to slightly pink coloured cake or powder, which may be partially yellowish to slightly orange.

The solvent is clear and colourless.

CLINICAL INFORMATION

Indications

Priorix is indicated for the active immunisation of children from the age of 9 months or older, adolescents and adults against measles, mumps and rubella.

For use in children between 9 to 12 months of age see sections "*Dosage and Administration*", "*Warnings and Precautions*" and "*Pharmacodynamics*".

Dosage and Administration

Posology

The use of ***Priorix*** should be based on official recommendations.

Individuals 12 months of age or older

The dose is 0.5 mL. A second dose should be given according to official recommendations. It is preferable to respect an interval of at least 6 weeks between doses.

Priorix may be used in individuals who have previously been vaccinated with another monovalent or combined measles, mumps and rubella vaccine.

Infants between 9 and 12 months of age

Infants in their first year of life may not respond sufficiently to the components of the vaccines. In case an epidemiological situation requires vaccinating infants in their first year of life (e.g. outbreak or travel to endemic regions), a second dose of ***Priorix*** should be given in the second year of life, preferably within three months after the first dose. Under no circumstances should the interval between doses be less than four weeks (see sections "*Warnings and Precautions*" and "*Pharmacodynamics*").

Infants less than 9 months of age

The safety and efficacy of ***Priorix*** in infants under 9 months of age has not been established.

Method of administration

Priorix is for subcutaneous injection, although it can also be given by intramuscular injection, in the deltoid region or in the anterolateral area of the thigh (see "*Warnings and Precautions*").

The vaccine should be administered subcutaneously in subjects with bleeding disorders (e.g. thrombocytopenia or any coagulation disorder).

For instructions on reconstitution of the medicinal product before administration, see "*Instructions for Use/Handling*".

Contraindications
Priorix is contraindicated in subjects with known systemic hypersensitivity to neomycin or to any other component of the vaccine (for egg allergy, see *"Warnings and Precautions").* A history of contact dermatitis to neomycin is not a contraindication.

Priorix is contraindicated in subjects having shown signs of hypersensitivity after previous administration of measles, mumps and/or rubella vaccines.

Priorix is contraindicated in subjects with severe humoral or cellular (primary or acquired) immunodeficiency e.g. symptomatic HIV infection (see also *"Warnings and Precautions"*).

Priorix is contraindicated in pregnant women. Pregnancy should be avoided for one month after vaccination (see *"Pregnancy and Lactation").*

Warnings and Precautions
As with other vaccines, the administration of ***Priorix*** should be postponed in subjects suffering from acute severe febrile illness. The presence of a minor infection, however, is not a contra-indication for vaccination.

Syncope (fainting) can occur following, or even before, any vaccination as a psychogenic response to the needle injection. It is important that procedures are in place to avoid injury from faints.

Alcohol and other disinfecting agents must be allowed to evaporate from the skin before injection of the vaccine since they can inactivate the attenuated viruses in the vaccine.

Limited protection against measles may be obtained by vaccination up to 72 hours after exposure to natural measles.

Infants below 12 months of age may not respond sufficiently to the measles component of the vaccine, due to the possible persistence of maternal measles antibodies. This should not preclude the use of the vaccine in younger infants (<12 months) since vaccination may be indicated in some situations such as high-risk areas. In these circumstances revaccination at or after 12 months of age should be considered.

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

The measles and mumps components of the vaccine are produced in chick embryo cell culture and may therefore contain traces of egg protein. Persons with a history of anaphylactic, anaphylactoid, or other immediate reactions (e.g. generalised urticaria, swelling of the mouth and throat, difficulty breathing, hypotension, or shock) subsequent to egg ingestion may be at an enhanced risk of immediate-type hypersensitivity reactions after vaccination, although these types of reactions have been shown to be very rare. Individuals who have experienced anaphylaxis after egg ingestion should be vaccinated with extreme caution, with adequate treatment for anaphylaxis on hand should such a reaction occur.

Priorix should be given with caution to persons with a history or family history of allergic diseases or those with a history or family history of convulsions.

Transmission of measles and mumps virus from vaccinees to susceptible contacts has never been documented. Pharyngeal excretion of the rubella virus is known to occur about 7 to 28 days after vaccination with peak excretion around the 11th day. However, there is no evidence of transmission of this excreted vaccine virus to susceptible contacts.

A limited number of subjects received ***Priorix*** intramuscularly. An adequate immune response was obtained for all three components (see "*Dosage and Administration*").

PRIORIX MUST NOT BE ADMINISTERED INTRAVASCULARLY.

As with any vaccine, a protective immune response may not be elicited in all vaccinees.

Cases of worsening of thrombocytopenia and recurrence of thrombocytopenia in subjects who suffered thrombocytopenia after the first dose have been reported following vaccination with live measles, mumps

and rubella vaccines. In such cases, the risk-benefit of immunising with ***Priorix*** should be carefully evaluated.

There is limited data on the use of ***Priorix*** in immunocompromised subjects, therefore vaccination should be considered with caution and only when, in the opinion of the physician, the benefits outweigh the risks (e.g. asymptomatic HIV subjects).

Immunocompromised subjects who have no contraindication for this vaccination (see "*Contraindications*") may not respond as well as immunocompetent subjects, therefore some of these subjects may acquire measles, mumps or rubella despite appropriate vaccine administration. Immunocompromised subjects should be monitored carefully for signs of measles, mumps and rubella.

Interactions
If tuberculin testing has to be done it should be carried out before or simultaneously with vaccination since it has been reported that live measles (and possibly mumps) vaccine may cause a temporary depression of tuberculin skin sensitivity. This anergy may last for 4-6 weeks and tuberculin testing should not be performed within that period after vaccination to avoid false negative results.

Clinical studies have demonstrated that ***Priorix*** can be given simultaneously with any of the following monovalent or combination vaccines: varicella vaccine, hexavalent vaccine (DTPa-HBV-IPV/Hib), diphtheria-tetanus-acellular pertussis vaccine (DTPa), reduced antigen diphtheria-tetanus-acellular pertussis vaccine (dTpa), *Haemophilus influenzae* type b vaccine (Hib), inactivated polio vaccine (IPV), hepatitis B vaccine (HBV), hepatitis A vaccine (HAV), meningococcal serogroup B vaccine (MenB), meningococcal serogroup C conjugate vaccine (MenC), meningococcal serogroups A, C, W-135 and Y conjugate vaccine (MenACWY), varicella vaccine and pneumococcal conjugate vaccine (PCV).

In addition, it is generally accepted that combined measles, mumps and rubella vaccine may be given at the same time as the oral polio vaccine (OPV) or the diphtheria-tetanus-whole cell pertussis vaccine (DTPw).

If ***Priorix*** is to be given at the same time as another injectable vaccine, the vaccines should always be administered at different injection sites.

If ***Priorix*** cannot be given at the same time as other live attenuated vaccines, an interval of at least one month should be left between both vaccinations.

In subjects who have received human gammaglobulins or a blood transfusion, vaccination should be delayed for at least three months because of the likelihood of vaccine failure due to passively acquired mumps, measles and rubella antibodies.

Priorix may be given as a booster dose in subjects who have previously been vaccinated with another measles, mumps and rubella combined vaccine.

Pregnancy and Lactation
Fertility
No data available.

Pregnancy
Pregnant women must not be vaccinated with ***Priorix***.

However, fetal damage has not been documented when measles, mumps or rubella vaccines have been given to pregnant women.

Even if a theoretical risk cannot be excluded, no cases of congenital rubella syndrome have been reported in more than 3,500 susceptible women who were unknowingly in early stages of pregnancy when vaccinated with rubella containing vaccines. Therefore, inadvertent vaccination of unknowingly pregnant women with measles, mumps and rubella containing vaccines should not be a reason for termination of pregnancy.

Pregnancy should be avoided for one month after vaccination. Women who intend to become pregnant should be advised to delay pregnancy.

Lactation
There is no human data regarding use in breast-feeding women. Persons can be vaccinated where the benefit outweighs the risk.

Effects on Ability to Drive and Use Machines
Not applicable.

Adverse Reactions
In controlled clinical studies, signs and symptoms were actively monitored during a 42-day follow-up period. The vaccinees were also requested to report any clinical events during the study period.

The safety profile presented below is based on a total of approximately 12,000 subjects administered ***Priorix*** in clinical trials.

Frequencies are reported as:

Very common (≥1/10)/Common (≥1/100 to <1/10)/Uncommon (≥1/1,000 to <1/100)/Rare (≥1/10,000 to <1/1,000)/Very rare (<1/10,000)

System Organ Class	Frequency	Adverse events
Infections and infestations	Common	upper respiratory tract infection
	Uncommon	otitis media
Blood and lymphatic system disorders	Uncommon	lymphadenopathy
Immune system disorders	Rare	allergic reactions
Metabolism and nutrition disorders	Uncommon	anorexia
Psychiatric disorders	Uncommon	nervousness, abnormal crying, insomnia
Nervous system disorders	Rare	febrile convulsions
Eye disorders	Uncommon	conjunctivitis
Respiratory, thoracic and mediastinal disorders	Uncommon	bronchitis, cough
Gastrointestinal disorders	Uncommon	parotid gland enlargement, diarrhoea, vomiting
Skin and subcutaneous tissue disorders	Common	rash
General disorders and administration site conditions	Very common	redness at the injection site, fever ³38°C (rectal) or ³37.5°C (axillary/oral)
	Common	pain and swelling at the injection site, fever >39.5°C (rectal) or >39°C (axillary/oral)

In general, the frequency category for adverse reactions was similar for the first and second vaccine doses. The exception to this was pain at the injection site which was “Common” after the first vaccine dose and “Very common” after the second vaccine dose.

During post-marketing surveillance, the following reactions have been reported additionally in temporal association with ***Priorix*** vaccination:

System Organ Class	Frequency	Adverse events
Infections and infestations	Rare	meningitis, measles-like syndrome, mumps-like syndrome (including orchitis, epididymitis and parotitis)
Blood and lymphatic system disorders	Rare	thrombocytopenia, thrombocytopenic purpura
Immune system disorders	Rare	anaphylactic reactions
Nervous system disorders	Rare	encephalitis, cerebellitis, cerebellitis like symptoms (including transient gait disturbance and transient ataxia), Guillain Barré syndrome, transverse myelitis, peripheral neuritis
Vascular disorders	Rare	vasculitis (including Henoch Schonlein purpura and Kawasaki syndrome)
Skin and subcutaneous tissue	Rare	erythema multiforme

disorders		
Musculoskeletal and connective tissue disorders	Rare	arthralgia, arthritis

Accidental intravascular administration may give rise to severe reactions or even shock. Immediate measures depend on the severity of the reaction (see "*Warnings and Precautions*").

In the comparative studies, a statistically significant lower incidence of local pain, redness and swelling was reported with ***Priorix*** compared with the comparator. The incidence of other adverse reactions listed above was similar in both vaccines.

Adverse events should be reported to GSK Indonesia via website https://gsk.public.reportum.com and Pusat Farmakovigilans/MESO Nasional Direktorat Pengawasan Keamanan, Mutu, dan Ekspor Impor Obat, Narkotika, Psikotropika, Prekursor dan Zat Adiktif Badan Pengawas Obat dan Makanan.
Jl. Percetakan Negara No. 23, Jakarta Pusat, 10560
Email: pv-center@pom.go.id
Phone: +62-21-4244691 Ext.1079
Website: https://e-meso.pom.go.id/ADR

Overdose
Cases of overdose (up to 2 times the recommended dose) have been reported during post-marketing surveillance. No adverse events have been associated to the overdose.

PHARMACOLOGICAL PROPERTIES
Pharmacodynamics
Pharmaco-therapeutic group: Viral vaccine, ATC code J07BD52

Immune response in children 12 months and older
In clinical studies in children aged from 12 months to 2 years ***Priorix*** has been demonstrated to be highly immunogenic.

Vaccination with a single dose of ***Priorix*** induced antibodies against measles in 98.1%, against mumps in 94.4% and against rubella in 100% of previously seronegative vaccinees.

Two years after primary vaccination seroconversion rates were 93.4% for measles, 94.4% for mumps and 100% for rubella.

Although there are no data available concerning the protective efficacy of ***Priorix***, immunogenicity is accepted as an indication of protective efficacy. However, some field studies report that the effectiveness against mumps may be lower than the observed seroconversion rates to mumps.

Immune response in children aged 9 to 10 months
A clinical trial enrolled 300 healthy children 9 to 10 months of age at the time of first vaccine dose. Of these 147 subjects received ***Priorix*** and ***Varilrix*** concomitantly. Seroconversion rates for measles, mumps and rubella were 92.6%, 91.5% and 100%, respectively. The seroconversion rates reported following the second dose given 3 months after the first dose were 100% for measles and 99.2% for mumps. Therefore a second dose of ***Priorix*** should be given within three months to provide optimal immune responses.

Adolescents and adults
The safety and immunogenicity of a second dose of PRIORIX in adolescents and adults has been specifically studied in a clinical trial including subjects of 7-59 years of age. Seroresponse rates for measles, mumps and rubella were 99.5%, 99.8% and 100%, respectively.

Intramuscular route of administration
A limited number of subjects received ***Priorix*** intramuscularly in clinical trials. The seroconversion rates to the three components were comparable to those seen after subcutaneous administration.
Pharmacokinetics
An evaluation of pharmacokinetics in vaccines is not necessary.

Non-clinical Safety Data
Non-clinical data reveal no special hazard for humans based on general safety studies.

PHARMACEUTICAL INFORMATION

List of Excipients

Excipients of the vaccine are: amino acids, lactose, mannitol, sorbitol.
Solvent: Water for injections.
Neomycin sulphate is present as a residual from the manufacturing process.

Shelf Life

The expiry date of the vaccine is indicated on the label and packaging.

The vaccine should be injected promptly after reconstitution. If this is not possible, it must be stored at 2°C-8°C and used within 8 hours of reconstitution.

Special Precautions for Storage

Priorix should be stored in a refrigerator at 2°C – 8°C.
The solvent can be stored in the refrigerator or at ambient temperature.
Do not freeze the lyophilised vaccine nor the solvent.
Store in the original packaging in order to protect from light.
During transport, recommended conditions of storage should be respected, particularly in hot climates.
The storage conditions are detailed on the packaging.

Nature and Contents of Container

Priorix is presented in a glass vial (type I glass). The powder is available in monodose vial.

The sterile solvent is presented in a glass pre-filled syringe (type I glass).

Incompatibilities

Priorix should not be mixed with other vaccines in the same syringe.

Instruction for Use/Handling

Due to minor variation of its pH, the reconstituted vaccine may vary in colour from clear peach to fuchsia pink without deterioration of the vaccine potency.

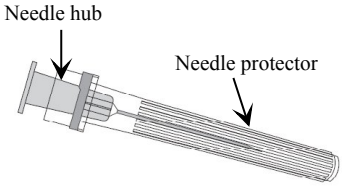
The solvent and the reconstituted vaccine should be inspected visually for any foreign particulate matter and/or variation of physical aspects prior to reconstitution or administration. In the event of either being observed, do not use the solvent or the reconstituted vaccine.

Inject the entire contents of the syringe, using a new needle for administration.

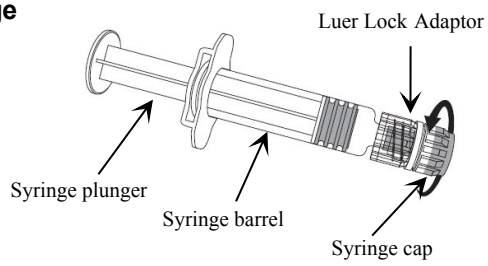
Priorix must be reconstituted by adding the entire contents of the pre-filled syringe of solvent to the vial containing the powder.

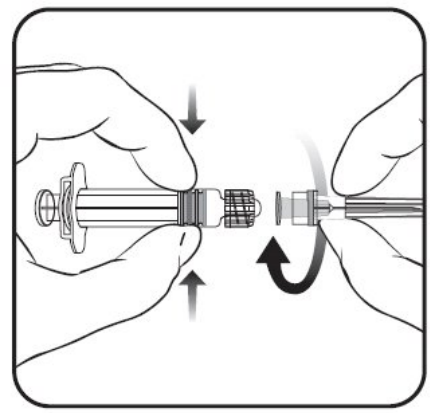
To attach the needle to the syringe, carefully read the instructions given with pictures 1 and 2. However, the syringe provided with ***Priorix*** might be slightly different than the syringe illustrated.

Needle



Syringe





Picture 2

Picture 1

Always hold the syringe by the barrel, not by the syringe plunger or the Luer Lock Adaptor (LLA), and maintain the needle in the axis of the syringe (as illustrated in picture 2). Failure to do this may cause the LLA to become distorted and leak.

During assembly of the syringe, if the LLA comes off, a new vaccine dose (new syringe and vial) should be used.

1. Unscrew the syringe cap by twisting it anticlockwise (as illustrated in picture 1).
2. Attach the needle to the syringe by gently connecting the needle hub into the LLA and rotate a quarter turn clockwise until you feel it lock (as illustrated in picture 2).
3. Remove the needle protector, which may be stiff.
4. Add the solvent to the powder. The mixture should be well shaken until the powder is completely dissolved in the solvent.

After reconstitution, the vaccine should be used promptly.

5. Withdraw the entire contents of the vial.
6. A new needle should be used to administer the vaccine. Unscrew the needle from the syringe and attach the injection needle by repeating step 2 above.

Any unused product or waste material should be disposed of in accordance with local requirements.

After reconstitution, the vaccine should be injected immediately. If not used immediately, the reconstituted vaccine must be stored in a refrigerator (2°C – 8°C) and used within:

- 8 hours of reconstitution for the monodose presentation

Presentations
Box, 1 vial of powder injection (1 dose) + 1 PFS of diluent @ 0.5 mL Reg. No. DKIXXXXXXXXXXXX

HARUS DENGAN RESEP DOKTER

Manufactured by
GlaxoSmithKline Biologicals s.a.
Rixensart, Belgium

Imported by
PT Glaxo Wellcome Indonesia
Jakarta, Indonesia

Version number : 01
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INFORMASI UNTUK PASIEN

PRIORIX, serbuk injeksi dan pelarut
Measles, mumps, and rubella vaccine (live, attenuated)

Baca leaflet ini dengan seksama sebelum Anda atau anak Anda mendapatkan vaksin ini karena mengandung informasi penting untuk Anda.
- Simpan leaflet ini. Anda mungkin butuh untuk membacanya lagi
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakan pada dokter, perawat atau apoteker
- Vaksin ini hanya diresepkan untuk Anda. Jangan diberikan untuk orang lain
- Jika ada kejadian ikutan pasca imunisasi (KIPI) yang menjadi serius atau jika Anda mengalami KIPI yang tidak tercantum pada leaflet ini, harap hubungi dokter atau apoteker Anda

Apa Saja yang Ada Dalam Brosur Ini:

1. Apa Itu *Priorix* dan Digunakan Untuk Apa
Priorix adalah vaksin yang digunakan untuk pada anak berusia mulai dari 9 bulan, remaja, dan orang dewasa terhadap penyakit yang disebabkan oleh virus campak, gondongan, dan rubela.

Vaksin ***Priorix*** terdiri dari 1 vial serbuk injeksi dan 1 pfs pelarut. Sebelum dicampurkan, serbuk injeksi berupa padatan keputihan dengan sedikit warna merah muda hingga sedikit oranye. Pelarut jernih dan tidak berwarna.

Setelah dicampurkan, vaksin memiliki variasi warna dari jingga bening hingga merah muda fuscia.

Cara Kerja ***Priorix***
Priorix membantu pertahanan tubuh Anda membuat antibodi yang akan melindungi Anda dari virus campak, gondongan, dan rubela.

Walaupun ***Priorix*** mengandung virus hidup, virus tersebut terlalu lemah untuk menyebabkan penyakit campak, gondongan, dan rubela pada orang yang sehat.

2. Apa yang Perlu Diketahui Sebelum Anda atau Anak Anda Menggunakan *Priorix*
Jangan gunakan *Priorix*:
- Jika Anda atau anak Anda alergi terhadap salah satu kandungan dari vaksin ini (*Lihat Bagian 5*). Salah satu tanda reaksi alergi adalah ruam kulit yang gatal, sesak napas, dan bengkak pada wajah dan lidah;
- Jika Anda atau anak Anda pernah mengalami reaksi alergi terhadap neomisin (salah satu obat antibiotik). Reaksi dermatitis kontak (ruam kulit yang terjadi saat kulit bersentuhan langsung dengan obat penyebab alergi, salah satunya neomisin) seharusnya tidak menjadi masalah, namun, konsultasikan lebih dahulu dengan dokter Anda;
- Jika Anda atau anak Anda sedang mengalami infeksi parah yang disertai demam tinggi. Pada kasus ini, vaksinasi sebaiknya ditunda hingga kondisi membaik. Infeksi ringan seperti pilek seharusnya tidak menjadi masalah, namun, konsultasikan lebih dahulu dengan dokter Anda;
- Jika Anda atau anak Anda memiliki penyakit atau sedang mengonsumsi obat-obatan yang melemahkan sistem imun, diantaranya: *human immunodeficiency virus* (HIV) dan *acquired immunodeficiency syndrome* (AIDS). Pemberian vaksin ***Priorix*** akan bergantung pada tingkat pertahanan kekebalan tubuh Anda atau anak Anda;

- ***Priorix*** tidak boleh diberikan pada wanita hamil. Kehamilan harus dihindari selama satu bulan setelah vaksinasi. Jika wanita hamil secara tidak sengaja diberikan vaksin ***Priorix***, hal ini tidak boleh dijadikan alasan untuk mengakhiri kehamilan.

Perhatian dan pencegahan
Konsultasikan dengan dokter atau apoteker sebelum Anda atau anak Anda menggunakan ***Priorix***:
- Jika Anda atau anak Anda memiliki gangguan pada sistem saraf pusat, memiliki riwayat kejang yang disertai dengan demam tinggi, atau riwayat kejang di keluarga. Apabila Anda atau anak Anda mengalami demam tinggi setelah vaksinasi, segera konsultasikan dengan dokter Anda;
- Jika Anda atau anak Anda pernah mengalami reaksi alergi berat terhadap protein pada telur;
- Jika Anda atau anak Anda pernah mengalami KIPI setelah vaksinasi campak, gondongan, dan rubela yang melibatkan memar dan pendarahan yang lebih lama dari biasanya (*Lihat Bagian 4*);
- Jika Anda atau anak Anda memiliki sistem imun yang lemah (seperti contohnya dikarenakan infeksi HIV), Anda atau anak Anda memerlukan pengawasan ketat karena respons terhadap vaksin mungkin tidak cukup untuk menjamin perlindungan terhadap penyakit (*Lihat Bagian 2*).

Jika Anda atau anak Anda divaksinasi dalam 72 jam setelah kontak dengan penderita campak, ***Priorix*** akan melindungi Anda dari penyakit ini sampai batas tertentu.

Anak berusia di bawah 12 bulan
Anak-anak yang divaksinasi di bawah usia 12 bulan mungkin tidak sepenuhnya terlindungi. Dokter Anda akan menyarankan apabila diperlukan dosis vaksinasi tambahan.

Seperti semua vaksin lainnya, ***Priorix*** mungkin tidak sepenuhnya melindungi semua orang yang divaksinasi.

Pengobatan lain dan *Priorix*
Informasikan kepada dokter Anda jika Anda sedang, baru saja atau mungkin akan menggunakan obat lain (atau vaksin lain).

Priorix dapat diberikan bersamaan dengan vaksin lainnya seperti vaksin difteri, tetanus, pertussis, *Haemophilus influenzae type b*, polio oral atau polio terinaktivasi, hepatitis A dan B, vaksin konjugat *meningococcal serogroup C*, varicella, dan vaksin konjugat *pneumonia 10-valent*.

Jika diberikan bersamaan dengan vaksin lain, masing-masing vaksin akan disuntikkan pada tempat suntikan yang berbeda. Dokter akan memberikan arahan terkait hal ini.

Apabila tidak diberikan bersamaan, dianjurkan untuk memberi jarak setidaknya satu bulan antara vaksinasi ***Priorix*** dan vaksinasi dengan vaksin hidup yang dilemahkan (*live attenuated vaccine*) lainnya.

Dokter Anda mungkin akan menunda vaksinasi dengan ***Priorix*** selama setidaknya tiga bulan jika Anda atau anak Anda baru saja mendapat transfusi darah atau antibodi manusia (immunoglobulins).

Jika Anda berencana menjalani tes untuk pemeriksaan tuberkulosis, sebaiknya tes ini dilakukan sebelum, secara bersamaan, atau 6 minggu setelah mendapatkan vaksinasi dengan ***Priorix***.

Kehamilan, menyusui dan kesuburan
Priorix tidak boleh diberikan pada wanita hamil. Kehamilan harus dihindari selama satu bulan setelah vaksinasi. Jika wanita hamil secara tidak sengaja diberikan vaksin ***Priorix***, hal ini tidak boleh dijadikan alasan untuk mengakhiri kehamilan.

Apabila Anda sedang hamil atau menyusui, akan hamil maupun merencanakan kehamilan, konsultasikan dengan dokter atau apoteker Anda sebelum menggunakan ***Priorix***.

***Priorix* mengandung sorbitol**
Jika dokter menginformasikan bahwa Anda atau anak Anda memiliki intoleransi terhadap beberapa jenis gula, konsultasikan dengan dokter Anda sebelum menggunakan obat ini.

3. Bagaimana Cara Pemberian *Priorix*

Priorix diberikan melalui suntikan di bawah kulit (subkutan) atau ke otot (intra-muskular).

Priorix diindikasikan untuk imunisasi untuk anak-anak berusia 9 bulan atau lebih, remaja, dan dewasa terhadap campak, gondongan, dan rubela.

Untuk penggunaan pada anak-anak berusia 9 hinggal 12 bulan, lihat bagian “Perhatian dan pencegahan”.

Waktu dan jumlah (dosis) vaksinasi yang akan diberikan kepada Anda ataupun anak Anda akan dianjurkan oleh dokter Anda dan didasarkan oleh rekomendasi vaksinasi yang sesuai.

Individu berusia 12 bulan atau lebih
Dosis vaksin adalah 0.5 mL. Dosis kedua harus diberikan sesuai dengan rekomendasi resmi, dengan jarak pemberian setidaknya 6 minggu antar dosis.

Priorix dapat digunakan pada individu yang sebelumnya telah divaksinasi dengan vaksin campak, gondongan, dan rubella monovalen atau kombinasi lainnya.

Bayi berusia antara 9 dan 12 bulan
Bayi berusia antara 9 dan 12 bulan mungkin tidak merespons secara maksimal terhadap komponen vaksin. Jika situasi dan kondisi yang mengharuskan vaksinasi pada bayi di tahun pertama kehidupannya (misalnya, wabah atau perjalanan ke daerah endemik), dosis kedua ***Priorix*** harus diberikan pada tahun kedua kehidupannya, sebaiknya dalam waktu tiga bulan setelah dosis pertama. Dalam keadaan apa pun, jarak antar dosis tidak boleh kurang dari empat minggu (lihat bagian "Peringatan dan Pencegahan").

Bayi berusia kurang dari 9 bulan
Keamanan dan khasiat ***Priorix*** pada bayi di bawah usia 9 bulan belum diketahui secara pasti.

Vaksin ini tidak boleh disuntikkan ke pembuluh darah.

4. Kemungkinan Kejadian Ikutan Pasca Imunisasi (KIPI)

Seperti obat-obatan lain, ***Priorix*** dapat menyebabkan KIPI, walaupun tidak semua orang akan mengalami KIPI. Berikut KIPI yang mungkin terjadi dengan vaksin ini:

Kejadian ikutan pasca imunisasi (KIPI) yang terjadi selama uji klinik dengan *Priorix* adalah sebagai berikut:
Sangat umum (dapat terjadi pada lebih dari 1 dalam 10 dosis vaksin):
- kemerahan pada tempat penyuntikan
- demam 38°C atau lebih (suhu pada dubur) atau 37.5°C atau lebih (suhu pada pangkal lengan/rongga mulut)

Umum (dapat terjadi hingga 1 dari 10 dosis vaksin):
- infeksi saluran pernapasan bagian atas
- ruam
- nyeri dan pembengkakan pada tempat penyuntikan
- demam >39,5°C (suhu pada dubur) atau >37.5°C (suhu pada pangkal lengan/rongga mulut)

Tidak Umum (dapat terjadi hingga 1 dari 100 dosis vaksin):
- radang pada telinga bagian tengah (*otitis media*)
- pembesaran kelenjar getah bening, atau pembengkakan kelenjar di leher, ketiak atau selangkangan (*lymphadenopathy*)
- gangguan makan (*anorexia*)
- merasa gelisah, menangis secara tidak wajar, gangguan tidur (insomnia)
- peradangan pada mata, mata merah, bengkak, berair (*conjunctivitis*)
- bronkitis, batuk
- pembesaran pada kelenjar parotid, diare, muntah

Jarang (dapat terjadi hingga 1 dari 1.000 dosis vaksin):
- reaksi alergi

- kejang disertai demam tinggi

Setelah pemasaran ***Priorix***, tambahan kejadian ikutan pasca imunisasi (KIPI) berikut dilaporkan pada orang yang divaksinasi dengan ***Priorix***:
Jarang (dapat terjadi hingga 1 dari 1.000 dosis vaksin):

- meningitis
- gejala seperti campak dan gejala seperti gondongan
- lebih mudah terjadi perdarahan atau memar daripada keadaan normal karena penurunan keping darah (trombositopenia)
- reaksi alergi berat yang dapat mengancam jiwa, mengakibatkan tekanan darah menurun secara drastis dan disertai penyempitan saluran pernapasan
- infeksi atau peradangan otak, saraf tulang belakang dan saraf tepi yang mengakibatkan kesulitan sementara saat berjalan (tidak seimbang) dan/atau kehilangan kendali gerakan tubuh sementara
- penyempitan atau penyumbatan pembuluh darah. Hal ini mungkin termasuk perdarahan yang tidak biasa atau memar di bawah kulit (*Henoch Schonlein purpura*) atau demam yang berlangsung selama lebih dari lima hari, terkait dengan ruam pada badan kadang diikuti dengan pengelupasan kulit pada tangan dan jari, mata merah, bibir, tenggorokan dan lidah (penyakit Kawasaki)
- *erythema multiforme* (gejala meliputi bercak kemerahan, seringkali terasa gatal, ruam seperti pada campak yang dimulai dari tangan atau kaki, beberapa kasus terdapat pada wajah dan menyebar ke seluruh badan).
- nyeri dan peradangan pada sendi

Jika Anda atau anak Anda mengalami salah satu kejadian ikutan paska imunisasi (KIPI), segera konsultasikan dengan dokter, apoteker, atau perawat. Hal ini termasuk kemungkinan KIPI lain yang belum disebutkan pada leaflet ini.

Laporkan kejadian tidak diinginkan (KTD) ke GSK Indonesia melalui website https://gsk.public.reportum.com.

Overdosis (Penggunaan Vaksin Melebihi Dosis yang Dianjurkan)
Kasus overdosis (penggunaan vaksin hingga 2 kali dosis yang direkomendasikan) dilaporkan pada pengawasan pasca pemasaran produk ***Priorix***. Tidak ada kejadian yang tidak diinginkan yang terkait dengan overdosis tersebut.

5. Cara Penyimpanan Priorix

- Simpan dalam lemari es (2°C - 8°C).
- Jangan dibekukan.
- Simpan dalam kemasan asli untuk melindungi dari cahaya.
- Vaksin yang sudah dicampur (direkonstitusi) harus segera disuntikkan. Jika hal ini tidak memungkinkan, vaksin harus disimpan pada suhu (2°C - 8°C) dan digunakan dalam waktu 8 jam setelah direkonstitusi.

6. Informasi Lain

Kandungan pada *Priorix:*
Zat aktif:
Tiap 0.5 mL vaksin yang sudah direkonstitusi mengandung:

Live attenuated measles virus[1] (Schwarz strain)	*not less than $10^{3.0}$ $CCID_{50}$[3]*
Live attenuated mumps virus[1] (RIT 4385 strain, derived from Jeryl Lynn strain)	*not less than $10^{3.7}$ $CCID_{50}$[3]*
Live attenuated rubella virus[2] (Wistar RA 27/3 strain)	*not less than $10^{3.0}$ $CCID_{50}$[3]*

[1] *produced in chick embryo cells*
[2] *produced in human diploid (MRC-5) cells*
[3] *Cell Culture Infective Dose 50%*

Bahan lain:
Asam amino, laktosa, mannitol, sorbitol

Pelarut:
Air untuk injeksi

Residu:
Neomisin sulfat (*Lihat Bagian 2*).

HARUS DENGAN RESEP DOKTER

Dus, 1 vial serbuk injeksi (1 vial) + 1 PFS pelarut @ 0.5 mL Reg. No. DKIXXXXXXXXXXXX

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