Arexvy

Recombinant Respiratory Syncytial Virus Pre-Fusion F Protein 120 mcg

Powder for suspension for injection

QUALITATIVE AND QUANTITATIVE COMPOSITION

After reconstitution, one dose (0.5 mL) contains :

RSVPreF3[1] antigen[2,3]	120 micrograms

[1]Respiratory Syncytial Virus recombinant glycoprotein F stabilised in the pre-fusion conformation = RSVPreF3
[2]RSVPreF3 produced in Chinese Hamster Ovary (CHO) cells by recombinant DNA technology
[3]adjuvanted with $AS01_E$ containing:

plant extract *Quillaja saponaria Molina*, fraction 21 (QS-21)	25 micrograms
3-O-desacyl-4'-monophosphoryl lipid A (MPL) from *Salmonella minnesota*	25 micrograms

For the full list of excipients, *see section List of Excipients*

PHARMACEUTICAL FORM

Powder and suspension for suspension for injection.
The powder is white.
The suspension is an opalescent, colourless to pale brownish liquid.

CLINICAL PARTICULARS

Therapeutic Indications

Arexvy is indicated for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus in

- adults 60 years of age and older
- adults 50 through 59 years of age who are at increased risk for RSV disease

The use of this vaccine should be in accordance with official recommendations.

Posology and Method of Administration

Posology

Arexvy is administered as a single dose of 0.5 mL.

The need for revaccination with a subsequent dose has not been established.

Paediatric population

The safety and efficacy of ***Arexvy*** in children have not been established.
No data are available.

Method of administration

For intramuscular injection only, preferably in the deltoid muscle.

For instructions on reconstitution of the medicinal product before administration, *see section Special Precautions for Disposal and Other Handling*.

Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section List of Excipients.

Special Warnings and Precautions for Use

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Prior to immunization
Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine. Close observation for at least 15 minutes is recommended following vaccination.

Vaccination should be postponed in individuals suffering from an acute severe febrile illness. 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.

Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions may occur in association with the vaccination process itself. It is important that precautions are in place to avoid injury from fainting.

Precautions for use
Do not administer the vaccine intravascularly or intradermally. No data are available on subcutaneous administration of ***Arexvy***.

As with other intramuscular injections, ***Arexvy*** should be given with caution to individuals with thrombocytopenia or any coagulation disorder since bleeding may occur following intramuscular administration to these individuals.

Systemic immunosuppressive medicinal products and immunodeficiency
Safety and immunogenicity data on ***Arexvy*** are not available for immunocompromised individuals. Patients receiving immunosuppressive treatment or patients with immunodeficiency may have a reduced immune response to ***Arexvy***.

Excipients
This medicinal product contains potassium, less than 1 mmol (39 mg) per dose, i.e. essentially ‘potassium-free’.

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free’.

Interactions with Other Medicinal Products and Other Forms of Interaction
Use with other vaccines
Arexvy may be administered concomitantly with seasonal influenza vaccine (quadrivalent, standard dose, unadjuvanted, inactivated). In a randomised study in adults 60 years of age and older, the criteria for non-inferiority of the immune responses in the co-administration versus the separate administration group were met. However, numerically lower RSV A and B neutralising titres and numerically lower influenza A and B haemagglutination inhibition titres were observed when ***Arexvy*** and inactivated seasonal influenza vaccine were co-administered than when they were administered separately. The clinical relevance of this finding is unknown. There are no data on co-administration with high dose or adjuvanted seasonal influenza vaccines.

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

Concomitant administration of ***Arexvy*** with other vaccines has not been studied.

Fertility, Pregnancy and Lactation
Pregnancy
There are no data from the use of ***Arexvy*** in pregnant women. After administration of an investigational unadjuvanted RSVPreF3 vaccine to 3,557 pregnant women in a single clinical study, an increase in preterm births was observed compared to placebo. Currently no conclusion on a causal relationship between administration of unadjuvanted RSVPreF3 and preterm birth can be drawn. Results from animal studies with an investigational unadjuvanted RSVPreF3 vaccine and results with ***Arexvy*** do not indicate direct or indirect harmful effects with respect to reproductive toxicity (*see section Preclinical Safety Data*). ***Arexvy*** is not recommended during pregnancy.

Breast-feeding
There are no data on the excretion of ***Arexvy*** in human or animal milk. ***Arexvy*** is not recommended in breast-feeding/lactating women.

Fertility
There are no data on the effects of ***Arexvy*** on human fertility. Animal studies with an investigational unadjuvanted RSVPreF3 vaccine or ***Arexvy*** do not indicate direct or indirect harmful effects with respect to reproductive toxicity (*see section Preclinical Safety Data*).

Effects on Ability to Drive and Use Machines
No studies on the effects of ***Arexvy*** on the ability to drive and use machines have been performed.

Arexvy has a minor influence on the ability to drive and use machines. Some of the effects mentioned under section "Undesirable effects" (e.g fatigue) may temporarily affect the ability to drive or use machines.

Undesirable Effects
Summary of the safety profile
The safety profile presented below is based on a pooled analysis of data generated in two placebo-controlled Phase III clinical study (conducted in Europe, North America, Asia and Southern hemisphere) in adults ≥ 60, and 50 through 59 years of age.

In study participants 60 years of age and older (more than 12,000 adults received one dose of ***Arexvy*** and more than 12,000 received placebo), the most commonly reported adverse reactions were injection site pain (61%), fatigue (34%), myalgia (29%), headache (28%), and arthralgia (18%). These adverse reactions were usually mild or moderate in intensity and resolved within a few days after vaccination. Most other adverse reactions were uncommon and similarly reported between the study groups.

In study participants 50 through 59 years of age (769 participants, including 386 participants with pre-defined, stable, chronic medical conditions leading to an increased risk for RSV disease), a higher incidence of injection site pain (76%), fatigue (40%), myalgia (36%), headache (32%), and arthralgia (23%) was observed, compared with those 60 years of age and older (381 participants) in the same study. However, the duration severity of these events were comparable across age groups in the study.

Tabulated list of adverse reactions
Adverse reactions are listed below by MedDRA system organ class and frequency:

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)

Table 1: Adverse Reactions

System Organ Class	Frequency	Adverse Reactions
Blood and lymphatic system disorders	Uncommon	lymphadenopathy
Immune system disorders	Uncommon	hypersensitivity reactions (such as rash)
Nervous system disorders	Very common	headache
Gastrointestinal disorders	Uncommon	nausea, abdominal pain, vomiting
Musculoskeletal and connective tissue disorders	Very common	myalgia, arthralgia
General disorders and administration site conditions	Very common	injection site pain, injection site erythema,fatigue
	Common	injection site swelling, fever, chills
	Uncommon	injection site pruritus, pain, malaise

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
No case of overdose has been reported in the clinical studies.

PHARMACOLOGICAL PROPERTIES
Pharmacodynamics Properties
Pharmacotherapeutics group: Vaccines, other viral vaccines, ATC code: J07BX05.

Mechanism of action
By combining the RSV-specific antigen, F-protein in prefusion conformation, with an adjuvant system ($AS01_E$), ***Arexvy*** is designed to enhance antigen-specific cellular immune response and neutralizing antibodies response in individuals with pre-existing immunity against RSV. The adjuvant $AS01_E$ facilitates the recruitment and activation of antigen presenting cells carrying vaccine-derived antigens in the draining lymph node, which in turn leads to the generation of RSVPreF3-specific CD4+ T cells.

Efficacy
Efficacy against RSV-associated LRTD in adults 60 years and older was evaluated in an ongoing, Phase III, randomised, placebo-controlled, observer-blind clinical study conducted in 17 countries from Northern and Southern Hemispheres. Participants are planned to be followed for up to 36 months.

The primary population for efficacy analysis (referred to as the modified Exposed Set, included adults 60 years of age and older receiving 1 dose of ***Arexvy*** or placebo and who did not report an RSV-confirmed acute respiratory illness (ARI) prior to Day 15 after vaccination) included 24,960 participants randomised equally to receive 1 dose of ***Arexvy*** (N = 12,466) or placebo (N = 12,494). At the time of the primary efficacy analysis, participants had been followed for the development of RSV-associated LRTD for a median of 6.7 months.

The median age of participants was 69 years (range: 59 to 102 years), with approximately 74% over 65 years of age, approximately 44% over 70 years of age and approximately 8% over 80 years of age. Approximately 52% were female. At baseline, 39.3% of participants had at least one comorbidity of interest; 19.7% of participants had an underlying cardiorespiratory condition (COPD, asthma, any chronic respiratory/pulmonary disease, or chronic heart failure) and 25.8% of participants had endocrinometabolic conditions (diabetes, advanced liver or renal disease).

Efficacy against RSV-associated LRTD
The primary objective was to demonstrate the efficacy in the prevention of a first episode of confirmed RSV-A and/or B associated LRTD during the first season. Confirmed RSV cases were determined by quantitative Reverse Transcription Polymerase Chain Reaction (qRT-PCR) on nasopharyngeal swab. LRTD was defined based on the following criteria: the participant must have experienced at least 2 lower respiratory symptoms/signs including at least 1 lower respiratory sign for at least 24 hours, or experienced at least 3 lower respiratory symptoms for at least 24 hours. Lower respiratory symptoms included: new or increased sputum, new or increased cough, new or increased dyspnea (shortness of breath). Lower respiratory signs included: new or increased wheezing, crackles/rhonchi, respiratory rate ≥20 respirations/min, low or decreased oxygen saturation (O_2 saturation <95% or ≤90% if baseline is <95%) or need for oxygen supplementation.

The vaccine efficacy overall and by subgroups is presented in Table 2.

Efficacy in preventing first RSV-associated LRTD with an onset from 15 days after vaccination compared to placebo was 82.6% (96.95% confidence interval of 57.9% to 94.1%) in participants 60 years of age and older. Vaccine efficacy against RSV-LRTD was observed through the median follow-up period of 6.7 months. The vaccine efficacy against RSV A-associated LRTD cases and RSV B-associated LRTD cases was 84.6% (95% CI [32.1, 98.3]) and 80.9% (95% CI [49.4, 94.3]), respectively.

Table 2: Efficacy analysis: First RSV-associated LRTD overall, by age and co-morbidity subgroups (modified exposed set)

	Arexvy	**Placebo**	

Subgroup	N	n	Incidence rate per 1,000 person years	N	n	Incidence rate per 1,000 person years	% Efficacy (CI)[a]
Overall (≥ 60 years)[b]	12,466	7	1.0	12,494	40	5.8	82.6 [57.9; 94.1]
60-69 years	6,963	4	1.0	6,979	21	5.5	81.0 [43.6; 95.3]
70-79 years	4,487	1	0.4	4,487	16	6.5	93.8 [60.2; 99.9]
Participants with at least 1 comorbidity of interest	4,937	1	0.4	4,861	18	6.6	94.6 [65.9; 99.9]

[a]CI = Confidence Interval (96.95% for the overall (≥ 60 years) and 95% for all subgroup analyses). Two-sided exact CI for vaccine efficacy is derived based on Poisson model adjusted by age categories and regions.
[b]Primary confirmatory objective with pre-specified success criterion of lower limit of the 2-sided CI for vaccine efficacy above 20%.
N = Number of participants included in each group.
n = Number of participants having first occurrence of RSV-confirmed LRTD occurring from Day 15 post vaccination.

The vaccine efficacy in the subgroup of participants 80 years of age and older (1,016 participants in ***Arexvy*** vs 1,028 participants in placebo) cannot be concluded due to the low number of total cases accrued (5 cases).

Amongst 18 RSV-LRTD cases with at least 2 lower respiratory signs or preventing everyday activities, 4 cases of severe RSV-LRTD requiring oxygen supplementation occurred in the placebo group, while there were none in the RSVPreF3 group.

Immunogenicity in adults 50 through 59 years of age at increased risk for RSV disease
The non-inferiority of the immune response to ***Arexvy*** in adults 50 through 59 years of age compared to adults 60 years of age and older, where vaccine efficacy against RSV-associated LRTD was demonstrated, was evaluated in a Phase III, observer-blind, randomised, placebo-controlled study.

Cohort 1 consisted of participants 50 through 59 years of age separated in 2 sub-cohorts (Adults-AIR and Adults-non-AIR) according to their medical history. Adults-AIR (adults at increased risk) sub- cohort consisted of participants with pre-defined, stable, chronic medical conditions leading to an increased risk for RSV disease (***Arexvy***, N = 386; placebo, N = 191) such as chronic pulmonary disease, chronic cardiovascular disease, diabetes, chronic kidney or liver disease. Adults-non-AIR sub- cohort consisted of participants without pre-defined, stable, chronic medical conditions (***Arexvy***, N = 383; placebo, N = 192). Cohort 2 (OA; older adults) consisted of participants 60 years of age and older (***Arexvy***, N= 381).

The primary immunogenicity objectives were to demonstrate non-inferiority of the humoral immune response (in terms of RSV-A and RSV-B neutralising titers) following the administration of ***Arexvy*** at 1-month post-vaccination in participants 50 through 59 years of age with and without pre-defined, stable, chronic medical conditions leading to an increased risk for RSV disease, compared to participants 60 years of age and older.

Table 3. Summary of adjusted GMT and SRR values, and adjusted GMT ratios and SRR differences in terms of RSV-A and RSV-B neutralising titers (ED60) in adults 60 years of age and older (OA) relative to adults 50 through 59 years of age with (Adults-AIR) and without (Adults- non-AIR) pre-defined, stable, chronic medical conditionsa leading to an increased risk for RSV disease – Per Protocol Set

RSV-A neutralising titers (ED60)

	Adjusted GMT (95% CI)	Adjusted GMT ratio (95% CI) [b]	SRR (%) (95% CI)	SRR difference (95% CI) [c]
OA	7 440.1 (6 768.4, 8 178.5)	0.8 (0.7, 1.0)	80.4 (75.8, 84.5)	-6.5 (-12.1, -0.9)
Adults-AIR	8 922.7 (8 118.2, 9 806.9)		86.9 (82.8, 90.3)	
OA	7 492.6 (6 819.1, 8 232.7)	1.0 (0.8, 1.1)	80.4 (75.8, 84.5)	-2.4 (-8.3, 3.5)
Adults-non-AIR	7 893.5 (7 167.5, 8 692.9)		82.8 (78.3, 86.8)	
RSV-B neutralising titers (ED60)				
	Adjusted GMT (95% CI)	**Adjusted GMT ratio[b]**	**SRR (95% CI)**	**SRR difference c**
OA	8 062.8 (7 395.9, 8 789.9)	0.8 (95% CI [0.7, 0.9])	74.5 (69.5, 79.0)	-7.2 (95% CI [-13.3, -0.9])
Adults-AIR	10 054.7 (9 225.4, 10 958.7)		81.6 (77.1, 85.6)	
OA	8 058.2 (7 373.1, 8 807.0)	0.9 (97.5% CI [0.8, 1.0])	74.5 (69.5, 79.0)	-3.7 (97.5% CI [-11.1, 3.7])
Adults-non-AIR	9 009.5 (8 226.8, 9 866.6)		78.2 (73.3, 82.6)	

[a] Pre-defined, stable, chronic medical conditions such as chronic pulmonary disease, chronic cardiovascular disease, diabetes, chronic kidney or liver disease.
[b,c] The prespecified criteria for non-inferiority of the immune responses were defined as the 2-sided 95% or 97.5% CI upper limits (UL) on the adjusted GMT ratios (OA over Adults-AIR or Adults-non-AIR) ≤ 1.5 and the UL of the 2-sided 95% or 97.5% CI on the SRR difference (OA minus Adults-AIR or Adults-non-AIR) ≤ 10% in participants 60 years of age and older (OA) relative to participants 50 through 59 years of age with (Adults-AIR) or without (Adults-non-AIR) pre-defined, stable, chronic medical conditions leading to an increased risk for RSV disease
ED60: Estimated dilution 60; CI = Confidence interval; GMT = Geometric mean titer; SRR = Seroresponse rate

The non-inferiority criteria of the immune responses for the RSV-A and RSV-B neutralising titers were met. The efficacy of ***Arexvy***, in adults 50 through 59 years of age at increased risk for RSV disease, can be inferred following comparison of the immune response in adults 50 through 59 years of age with the immune response in adults 60 years of age and older in whom vaccine efficacy was demonstrated.

Pharmacokinetic Properties
Not applicable

Preclinical Safety Data
Non-clinical data reveal no special hazard for humans based on conventional studies of repeated dose toxicity.

Reproductive and developmental studies with an unadjuvanted RSVPreF3 vaccine as well as results from a study with ***Arexvy*** in rabbits did not reveal vaccine-related effects on female fertility, pregnancy, or embryo-foetal or offspring development.

PHARMACEUTICAL PARTICULARS
List of Excipients
Powder (RSVPreF3 antigen)
Trehalose dihydrate
Polysorbate 80 (E 433)
Potassium dihydrogen phosphate (E 340)
Dipotassium phosphate (E 340)

Suspension ($AS01_E$ Adjuvant System)
Dioleoyl phosphatidylcholine (E 322)
Cholesterol
Sodium chloride
Disodium phosphate anhydrous (E 339)
Potassium dihydrogen phosphate (E 340)
Water for injections

For adjuvant *see also section QUALITATIVE AND QUANTITATIVE COMPOSITION*.

Incompatibilities
In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

Shelf Life
The expiry date is indicated on the packaging.

After reconstitution:
Chemical and physical in-use stability has been demonstrated for 4 hours at 2 °C – 8 °C or at room temperature up to 25 °C.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should not be longer than 4 hours.

Special Precautions for Storage
Store in a refrigerator (2 °C – 8 °C).

Do not freeze.

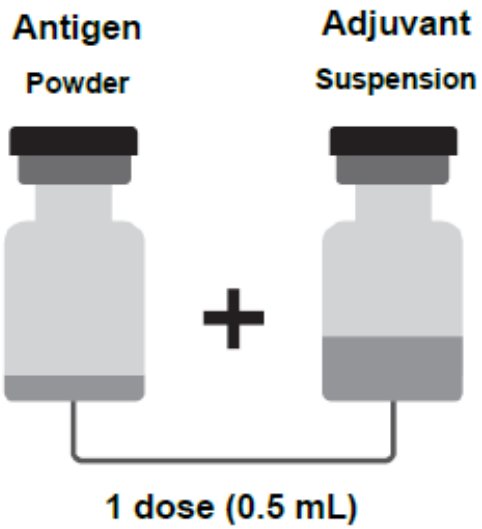
Store in the original package in order to protect from light.

For storage conditions after reconstitution of the medicinal product, *see section Shelf Life*.

Nature and Contents of Container
Arexvy is presented as:
- Powder for 1 dose in a vial (type I glass) with a stopper (butyl rubber) and a mustard green flip-off cap (antigen).
- Suspension for 1 dose in a vial (type I glass) with a stopper (butyl rubber) and a brown flip-off cap (adjuvant).

Arexvy is available in a pack size of 1 vial of powder plus 1 vial of suspension.

Special Precautions for Disposal and Other Handling
The powder and the suspension must be reconstituted prior to administration.



The powder and suspension should be inspected visually for any foreign particulate matter and/or variation of appearance. If either is observed, do not reconstitute the vaccine.

How to prepare ***Arexvy***
Arexvy must be reconstituted prior to administration.

1. Withdraw the entire contents of the vial containing the suspension into the syringe.
2. Add the entire contents of the syringe into the vial containing the powder.
3. Gently swirl until the powder is completely dissolved.

The reconstituted vaccine is an opalescent, colourless to pale brownish liquid.

The reconstituted vaccine should be inspected visually for any foreign particulate matter and/or variation of appearance. If either is observed, do not administer the vaccine.

Chemical and physical in-use stability has been demonstrated for 4 hours at 2 °C – 8 °C or at room temperature up to 25 °C.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should not be longer than 4 hours.

Before administration
1. Withdraw 0.5 mL of the reconstituted vaccine into the syringe.
2. Change the needle so that you are using a new needle.

Administer the vaccine intramuscularly

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

Presentations
Box, 1 vial of powder injection RSVPreF3 Antigen (1 dose) + 1 vial of suspension injection AS01$_E$ Adjuvant @ 0,5 mL Reg. No. DKI2476704144A1

HARUS DENGAN RESEP DOKTER

Manufactured by:
GlaxoSmithKline Biologicals s.a.
20, Avenue Fleming – 1300 Wavre
Belgium

Released by :
GlaxoSmithKline Biologicals s.a.
89, rue de l'Institut - 1330 Rixensart
Belgium

Imported by:
PT Glaxo Wellcome Indonesia
Jakarta, Indonesia

Version number	: 02
Reference	:EMEA/H/C/006054 + Arexvy: EPAR – Product Information (last updated:09/10/2024)
Date of local revision	: 28 Oct 2024

PACKAGE LEAFLET: INFORMASI UNTUK PASIEN

Arexvy

Recombinant Respiratory Syncytial Virus Pre-Fusion F Protein 120 mcg

Serbuk untuk suspensi injeksi

Baca Leaflet Ini Dengan Saksama Sebelum Anda Mendapatkan Vaksin Ini.
- Simpan leaflet ini. Anda mungkin butuh untuk membacanya lagi
- Jika Anda memiliki pertanyaan lebih lanjut, Anda dapat menghubungi dokter atau apoteker Anda
- Vaksin ini 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

Pada Leaflet Ini:

1. Apakah *Arexvy* Itu dan Digunakan untuk Apa

Arexvy adalah vaksin yang digunakan untuk melindungi orang dewasa 60 tahun ke atas terhadap virus yang disebut 'Respiratory Syncytial Virus' (RSV).

Arexvy juga membantu melindungi terhadap RSV pada orang dewasa 50 hingga 59 tahun yang berisiko tinggi terkena penyakit RSV.

RSV adalah virus pernapasan yang menyebar dengan sangat mudah.
- RSV dapat menyebabkan penyakit saluran pernapasan bagian bawah – infeksi paru-paru dan bagian tubuh lainnya yang membantu Anda bernapas.

Infeksi RSV dapat terjadi pada usia berapapun, dan biasanya menyebabkan gejala ringan seperti pilek pada orang dewasa. Tetapi dapat juga:
- Menyebabkan penyakit pernapasan yang lebih serius pada bayi dan orang dewasa yang lebih tua.
- Memperburuk beberapa penyakit, seperti penyakit pernapasan jangka panjang atau penyakit jantung.

Bagaimana ***Arexvy*** bekerja
Arexvy membantu pertahanan alami tubuh Anda dengan membentuk antibodi dan sel darah putih khusus. Ini melindungi Anda dari RSV.
Arexvy tidak mengandung virus, sehingga tidak dapat menyebabkan infeksi.

2. Apa yang Perlu Anda Ketahui Sebelum Mendapatkan *Arexvy*

Jangan gunakan *Arexvy*
- Jika Anda memiliki reaksi alergi terhadap zat aktif atau bahan lain dalam vaksin ini (tercantum pada *Bagian 5)*.

Jangan gunakan ***Arexvy*** jika salah satu dari hal tersebut di atas terjadi pada Anda. Jika Anda tidak yakin, konsultasikan dengan dokter atau apoteker Anda.

Peringatan dan tindakan pencegahan
Konsultasikan dengan dokter atau apoteker Anda sebelum menerima ***Arexvy***:
- Jika Anda pernah mengalami reaksi alergi berat setelah penyuntikan vaksin lain

- Jika Anda mengalami infeksi berat dengan panas tinggi (demam). Jika ini terjadi, vaksinasi dapat ditunda sampai keadaan membaik. Infeksi ringan seperti pilek seharusnya tidak menjadi masalah, namun demikian konsultasikan dengan dokter Anda terlebih dahulu
- Jika Anda mengalami masalah pendarahan atau mudah mengalami memar
- Jika Anda pingsan dengan suntikan sebelumnya. Pingsan dapat terjadi sebelum atau sesudah suntikan.

Jika salah satu dari hal di atas berlaku untuk Anda (atau Anda tidak yakin), konsultasikan dengan dokter atau apoteker Anda sebelum Anda diberikan ***Arexvy.***

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

Obat Lain dan *Arexvy*
Beritahu dokter atau apoteker Anda jika:
- Anda sedang atau baru saja menggunakan obat lain, termasuk obat didapatkan tanpa resep
- Anda baru saja menerima vaksin lain.

Arexvy dapat diberikan bersamaan dengan vaksin flu.
Jika ***Arexvy*** diberikan bersamaan dengan vaksin suntik lainnya, direkomendasikan untuk disuntikkan pada tempat suntikan yang berbeda, yang berarti lengan yang berbeda untuk setiap suntikan.

Kehamilan dan menyusui
Jika Anda sedang hamil atau menyusui, atau Anda kemungkinan hamil atau berencana untuk mempunyai anak, konsultasikan dengan dokter atau apoteker Anda sebelum Anda diberikan vaksin ini.
Arexvy tidak direkomendasikan diberikan selama kehamilan atau menyusui.

Mengemudi dan menggunakan mesin
Beberapa efek yang disebutkan pada bagian 4. “Kemungkinan Kejadian Ikutan Pasca Imunisasi (KIPI)” dapat mempengaruhi kemampuan mengemudi atau menggunakan mesin untuk sementara. Jangan mengemudi atau menggunakan mesin jika Anda merasa kurang sehat.

***Arexvy* mengandung natrium dan kalium**
Obat ini mengandung kurang dari 1 mmol natrium (23 mg) per dosis, artinya ‘bebas natrium’
Obat ini mengandung kurang dari 1 mmol kalium (39 mg) per dosis, artinya ‘bebas kalium’.

3. Bagaimana Cara Pemberian *Arexvy*

Arexvy diberikan sebagai suntikan dosis tunggal 0,5 mL ke dalam otot, biasanya lengan atas.

Jika Anda memiliki pertanyaan lebih lanjut tentang penggunaan vaksin ini, tanyakan kepada dokter atau apoteker Anda.

4. Kemungkinan Kejadian Ikutan Pasca Imunisasi (KIPI)

Seperti obat-obatan lain, ***Arexvy*** dapat menyebabkan KIPI, walaupun tidak semua orang akan mengalami KIPI.

Berikut KIPI yang mungkin terjadi setelah menggunakan ***Arexvy***:

Sangat umum (ini dapat terjadi lebih dari 1 dalam 10 dosis vaksin):
- rasa sakit di tempat suntikan
- merasa lelah (*fatigue*)
- sakit kepala
- nyeri otot (*myalgia*)
- nyeri sendi (*arthralgia*)
- kemerahan pada tempat suntikan diberikan

Umum (ini dapat terjadi hingga 1 dari 10 dosis vaksin):
- bengkak pada tempat suntikan diberikan
- demam
- menggigil

Tidak umum (ini dapat terjadi hingga 1 dari 100 dosis vaksin)
- gatal pada tempat suntikan
- nyeri
- merasa tidak enak badan (malaise)
- pembesaran kelenjar getah bening, atau pembengkakan kelenjar di leher, ketiak atau selangkangan (lymphadenopathy)
- reaksi alergi seperti ruam
- merasa mual (nausea)
- muntah
- sakit perut

Beri tahu dokter atau apoteker Anda jika Anda mengalami KIPI yang tercantum di atas. Sebagian besar KIPI ini memiliki intensitas ringan hingga sedang dan tidak bertahan lama.

Jika KIPI menjadi serius, atau jika Anda melihat terdapat KIPI yang tidak tercantum dalam leaflet ini, segera konsultasikan pada dokter atau apoteker Anda.

Laporkan Kejadian Tidak Diinginkan (KTD) ke GSK Indonesia melalui situs web https://gsk.public.reportum.com.

5. Cara Penyimpanan *Arexvy*

- Simpan dalam lemari es (2°C - 8°C).
- Jangan dibekukan.
- Simpan dalam kemasan asli untuk melindungi dari cahaya.

6. Informasi Lain

Apa kandungan *Arexvy*

Zat aktif:

Setelah rekonstruksi, 1 dosis (0,5 mL) mengandung:

RSVPreF3[1] antigen[2,3]	120 micrograms

[1]*Respiratory Syncytial Virus recombinant glycoprotein F stabilised in the pre-fusion conformation = RSVPreF3*

[2]*RSVPreF3 produced in Chinese Hamster Ovary (CHO) cells by recombinant DNA technology*

[3]adjuvan $AS01_E$ mengandung:

Plant extract Quillaja saponaria Molina, fraction 21 (QS-21)	25 micrograms
3-O-desacyl-4'-monophosphoryl lipid A (MPL) from Salmonella minnesota	25 micrograms

RSVPreF3 adalah protein yang ada dalam *Respiratory Syncytial* Virus. Protein ini tidak menular.

Adjuvan digunakan untuk meningkatkan respon tubuh terhadap vaksin.

Bahan lain:
- **Serbuk (RSVPreF3 antigen):** *trehalose dihydrate, polysorbate 80 (E 433), potassium dihydrogen phosphate (E 340), dipotassium phosphate (E 340)*
- **Suspensi:** *dioleoyl phosphatidylcholine (E 322), cholesterol, sodium chloride, disodium phosphate anhydrous (E 339), potassium dihydrogen phosphate (E 340) and water for injection.*

Lihat bagian 2 "***Arexvy*** mengandung natrium dan kalium".

Bagaimana bentuk dari *Arexvy* dan isi kemasan
- Serbuk dan suspensi untuk suspensi injeksi.
- Serbuk berwarna putih.
- Suspensi *opalescent*, tidak berwarna hingga cairan kecoklatan pucat.

Kemasan ***Arexvy*** terdiri dari:
- Serbuk (RSVPreF3 antigen) untuk 1 dosis dalam vial
- Suspensi (adjuvan $AS01_E$) untuk 1 dosis dalam vial

HARUS DENGAN RESEP DOKTER

Diproduksi oleh:

GlaxoSmithKline Biologicals s.a.
20, Avenue Fleming – 1300
Wavre, Belgia.

Dirilis oleh:
GlaxoSmithKline Biologicals s.a.
89, rue de l'Institut – 1330
Rixensart, Belgia.

Diimpor oleh:
PT Glaxo Wellcome Indonesia
Jakarta, Indonesia.

Dus, 1 vial serbuk injeksi RSVPreF3 Antigen (1 dosis) + 1 vial suspensi injeksi AS01$_E$ Adjuvant @ 0,5 mL Reg. No. DKI2476704144A1

Version number	: 02
Reference	: EMEA/H/C/006054 + Arexvy: EPAR – Product Information (last updated:09/10/2024)
Date of local revision	: 29 Oct 2024