Leaflet kemasan: Informasi untuk pengguna

Vaksin respiratory syncytial virus (bivalen, rekombinan)
ABRYSVO®

Baca isi leaflet ini dengan teliti sebelum Anda menggunakan produk ini karena berisi informasi penting untuk Anda.
- Simpan leaflet ini. Anda mungkin perlu membacanya kembali.
- Jika Anda memiliki pertanyaan lebih lanjut, tanyakan kepada dokter, apoteker, atau perawat Anda.
- Obat ini telah diresepkan hanya untuk Anda. Jangan memberikannya kepada orang lain. Produk ini dapat membahayakan mereka, sekali pun tanda-tanda penyakit mereka sama dengan Anda.
- Jika Anda mengalami efek samping apa pun, konsultasikan dengan dokter, apoteker, atau perawat Anda. Termasuk setiap kemungkinan efek samping yang tidak tercantum dalam leaflet ini. Lihat bagian 13.

Apa isi leaflet ini

1. Nama produk

ABRYSVO® serbuk injeksi dan pelarut
Vaksin respiratory syncytial virus (bivalen, rekombinan)

2. Bentuk sediaan

Serbuk injeksi dan pelarut

3. Deskripsi produk

ABRYSVO® disediakan sebagai

- serbuk injeksi putih di dalam vial kaca
- pelarut dalam syringe yang telah diisi untuk melarutkan serbuk injeksi

Setelah serbuk injeksi dilarutkan dalam pelarut, akan dihasilkan larutan yang jernih dan tidak berwarna.

4. Apa kandungan produk ini?

Protein F prefusi yang distabilkan RSV subkelompok A[1,2]	60 mikrogram
Protein F prefusi yang distabilkan RSV subkelompok B[1,2]	60 mikrogram

[1] Diproduksi dalam sel Ovarium Hamster Tiongkok melalui teknologi DNA rekombinan
[2] Glikoprotein F yang distabilkan dalam konformasi prefusi

Bahan lainnya adalah:
Serbuk injeksi
Trometamol
Trometamol hidroklorida
Sukrosa
Manitol (E421)
Polisorbat 80 (E433)
Natrium klorida

Pengencer
Air untuk injeksi

5. Kekuatan produk

0,5 ml

6. Apa kegunaan produk ini?

ABRYSVO® adalah vaksin yang bertujuan untuk mencegah penyakit paru (saluran pernapasan) yang disebabkan oleh respiratory syncytial virus (RSV). ABRYSVO® diberikan kepada:

- ibu hamil untuk melindungi bayi mereka sejak lahir hingga usia 6 bulan

atau

- individu berusia 60 tahun ke atas.

atau

- individu berusia 18 hingga 59 tahun yang berisiko lebih tinggi.

RSV adalah virus umum yang, dalam sebagian besar kasus, menyebabkan gejala seperti selesma yang ringan seperti nyeri telan, batuk, atau hidung tersumbat. Namun demikian, RSV pada bayi dapat menyebabkan gangguan paru serius. Pada orang dewasa dan penderita kondisi medis yang kronis, RSV dapat memperburuk penyakit seperti penyakit paru obstruktif kronis (PPOK) dan gagal jantung kongestif (GJK). Dalam kasus yang berat, RSV dapat menyebabkan seseorang menjalani rawat inap dan dalam beberapa kasus dapat berakibat fatal.

7. Berapa banyak dan seberapa sering Anda seharusnya menggunakan produk ini?

Anda akan menerima satu injeksi 0,5 ml ke dalam otot lengan atas Anda.

Jika Anda memiliki pertanyaan mengenai penggunaan ABRYSVO®, konsultasikan dengan dokter, apoteker, atau perawat Anda.

8. Kapan seharusnya Anda tidak menggunakan produk ini?

ABRYSVO® tidak boleh diberikan

- jika Anda alergi terhadap zat aktif atau bahan lain dalam vaksin ini (tercantum dalam bagian 4).

9. Apa yang harus dipertimbangkan saat menggunakan produk ini?

Peringatan dan tindakan pencegahan
Konsultasikan dengan dokter, apoteker, atau perawat sebelum Anda divaksin

- jika Anda pernah mengalami reaksi alergi berat atau masalah pernapasan setelah menerima injeksi vaksin lain atau setelah Anda diberi ABRYSVO® sebelumnya.
- jika Anda merasa gugup untuk menerima vaksin atau pernah pingsan setelah disuntik. Pingsan dapat terjadi sebelum atau sesudah injeksi
- jika Anda sedang mengalami infeksi disertai demam tinggi. Jika demikian kondisinya, vaksinasi akan ditunda. Tidak perlu menunda vaksinasi untuk infeksi ringan, seperti selesma, tetapi konsultasikan dengan dokter Anda terlebih dahulu.
- jika Anda menderita gangguan perdarahan atau mudah memar.
- jika sistem kekebalan tubuh Anda melemah sehingga menghalangi Anda untuk mendapatkan manfaat penuh ABRYSVO®.
- jika usia kehamilan Anda kurang dari 24 minggu.

Segera cari perhatian medis jika Anda mengalami kelemahan, nyeri, dan paralisis di ekstremitas Anda (sindrom Guillain-Barré) setelah menerima ABRYSVO®.

Jika ada di antara kondisi di atas yang berlaku pada Anda (atau Anda kurang yakin), sampaikan kepada dokter, apoteker, atau perawat Anda sebelum Anda menerima ABRYSVO®.

Seperti vaksin lainnya, ABRYSVO® mungkin tidak memberikan perlindungan penuh kepada semua orang yang menerimanya.

Pasien anak-anak dan remaja
ABRYSVO® tidak disarankan pada anak-anak dan remaja berusia di bawah 18 tahun kecuali selama kehamilan (lihat bagian 11 di bawah).

ABRYSVO® mengandung natrium
Obat ini mengandung kurang dari 1 mmol natrium (23 mg) per dosis, sehingga pada dasarnya bisa dikatakan ‘bebas natrium’.

10. Apa saja obat/produk lain atau makanan yang harus dihindari selama menggunakan produk ini?

Sampaikan kepada dokter atau apoteker Anda jika Anda sedang, belum lama ini, atau mungkin akan menggunakan obat lain atau baru saja menerima vaksin lain.

ABRYSVO® dapat diberikan bersamaan dengan vaksin flu. Disarankan untuk memberi jeda minimal dua minggu antara pemberian ABRYSVO® dengan pemberian vaksin tetanus, difteri, dan pertusis aseluler (batuk rejan).

11. Apakah produk ini aman untuk ibu hamil dan menyusui?

Ibu hamil dapat menerima vaksin ini di akhir trimester kedua atau ketiga (minggu ke-24 hingga 36). Mintalah saran dari dokter atau perawat Anda sebelum menerima vaksin ini jika Anda sedang menyusui.

12. Apakah pasien diperbolehkan mengemudi dan mengoperasikan mesin selama menggunakan produk ini?

ABRYSVO® kemungkinan tidak memengaruhi kemampuan Anda mengemudi atau menggunakan mesin.

13. Apa saja potensi efek yang tidak diinginkan dari penggunaan produk ini?

Seperti vaksin lainnya, vaksin ini dapat menimbulkan efek samping, sekalipun tidak semua orang mengalaminya.

Efek samping serius

Sangat langka (dapat dialami hingga 1 di antara 10.000 orang)
- reaksi alergi berat – tanda-tanda reaksi alergi berat antara lain pembengkakan wajah, bibir, lidah, atau tenggorokan, kesulitan bernapas atau menelan dan pusing. Lihat juga bagian 9.
- Sindrom Guillain-Barré (kelainan neurologis yang biasanya dimulai dengan kesemutan dan melemahnya anggota gerak dan dapat berkembang menjadi kelumpuhan sebagian atau seluruh tubuh). Lihat juga bagian 9.

Segera beri tahu dokter Anda jika Anda mengamati adanya tanda-tanda efek samping serius ini.

Berikut adalah efek samping yang dilaporkan oleh ibu hamil

Sangat umum (dapat dialami lebih dari 1 di antara 10 orang)
- nyeri di lokasi injeksi
- sakit kepala
- nyeri otot (mialgia).

Umum (dapat dialami hingga 1 di antara 10 orang)
- kemerahan di lokasi injeksi
- pembengkakan di lokasi injeksi.

Langka (dapat dialami hingga 1 di antara 1000 orang)
- reaksi alergi, seperti ruam atau kaligata
- pembengkakan kelenjar getah bening (limfadenopati).

Tidak ada efek samping yang dilaporkan pada bayi yang dilahirkan oleh ibu yang divaksin.

Berikut adalah efek samping yang dilaporkan pada individu berusia 18 tahun ke atas

Sangat umum (dapat dialami lebih dari 1 di antara 10 orang)
- kelelahan (keletihan)
- sakit kepala
- nyeri di lokasi injeksi
- nyeri otot (mialgia).

Umum (dapat dialami hingga 1 di antara 10 orang)
- nyeri sendi (artralgia)
- kemerahan di lokasi injeksi
- pembengkakan di lokasi injeksi.

Tidak umum (dapat dialami hingga 1 di antara 100 orang)
- demam (pireksia).

Langka (dapat dialami hingga 1 di antara 1000 orang)
- reaksi alergi, seperti ruam atau kaligata
- pembengkakan kelenjar getah bening (limfadenopati)
- memar di lokasi injeksi (hematoma)
- gatal-gatal di lokasi injeksi (pruritus).

Sangat langka (dapat dialami hingga 1 di antara 10.000 orang)
- reaksi alergi berat (lihat Efek samping serius, di atas)
- Sindrom Guillain-Barré (lihat Efek samping serius, di atas).

Melaporkan efek samping
Jika Anda mengalami efek samping apa pun, konsultasikan dengan dokter, apoteker, atau perawat Anda. Termasuk setiap kemungkinan efek samping yang tidak tercantum dalam leaflet ini. Dengan melaporkan efek samping, Anda bisa membantu memberikan informasi lainnya tentang keamanan produk ini.

Untuk melaporkan efek samping, hubungi www.pfizersafetyreporting.com atau email di IDN.AEReporting@pfizer.com

14. Bagaimana cara menyimpan produk ini?

Jauhkan obat ini dari pandangan dan jangkauan anak-anak.

Jangan menggunakan obat ini melebihi tanggal kedaluwarsa yang tertera pada karton dan label setelah tanda EXP. Tanggal kedaluwarsa mengacu pada tanggal terakhir pada bulan tersebut.

Simpan dalam lemari pendingin (2–8°C).

Jangan dibekukan. Buang karton jika telah dibekukan.

Setelah rekonstitusi, ABRYSVO® *harus segera diberikan atau dalam waktu 4 jam jika disimpan pada suhu antara* 15°C hingga 30°C. Jangan dibekukan.

15. Nomor izin edar

ABRYSVO® 1 vial, 1 adaptor vial, 1 syringe yang telah diisi, 1 jarum (No. Reg.:DKI2486102344A1)
ABRYSVO® 5 vial, 5 adaptor vial, 5 syringe yang telah diisi, 5 jarum (No. Reg.:DKI2486102344A1)

16. Nama dan alamat pemohon dan/atau pemilik produk sesuai dengan ketentuan yang berlaku

Diproduksi oleh:
Pfizer Manufacturing Belgium NV
Rijksweg 12
2870 Puurs-Sint-Amands
Belgia

Diimpor oleh:
PT. Pfizer Indonesia
Jakarta, Indonesia

17. Tanggal revisi

18/05/2026

18. Peringatan khusus

HARUS DENGAN RESEP DOKTER

Informasi berikut ini ditujukan untuk petugas kesehatan saja:

Keterlacakan

Untuk meningkatkan keterlacakan produk obat biologis, nama dan nomor batch produk yang diberikan harus dicatat dengan jelas.

Pemberian

ABRYSVO® hanya untuk penggunaan intramuskular.

Vial yang belum dibuka akan stabil selama 5 hari jika disimpan dalam rentang suhu 8°C hingga 30°C. Pada akhir periode ini, ABRYSVO® harus digunakan atau dibuang. Informasi ini digunakan untuk memandu petugas kesehatan hanya jika terjadi ekskursi suhu sementara.

Penyimpanan vaksin yang direkonstitusi

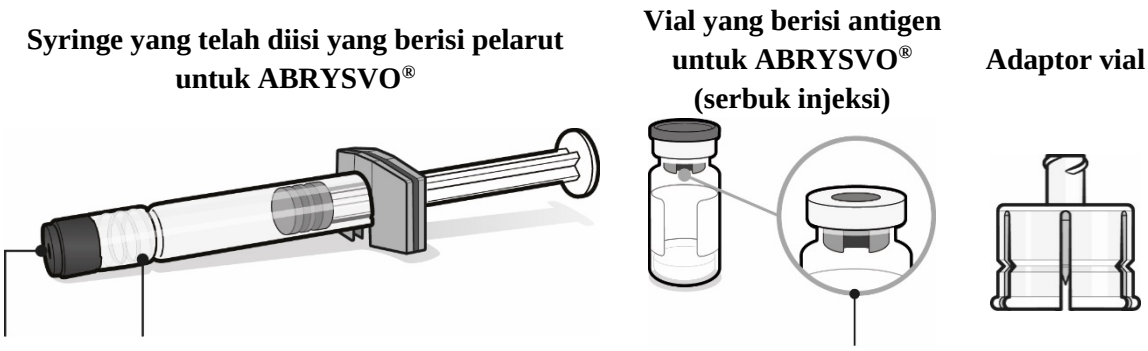
ABRYSVO® harus segera digunakan setelah rekonstitusi atau dalam waktu 4 jam. Simpan vaksin yang telah direkonstitusi antara suhu 15°C hingga 30°C. Jangan bekukan vaksin yang telah direkonstitusi.

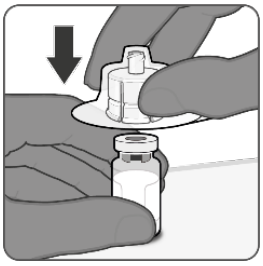
Stabilitas kimia dan fisika selama penggunaan telah ditunjukkan selama 4 jam antara suhu 15°C hingga 30°C. Dari sudut pandang mikrobiologi, produk harus segera digunakan. Jika tidak segera digunakan, waktu penyimpanan selama penggunaan dan kondisi sebelum penggunaan menjadi tanggung jawab pengguna.

Petunjuk pemberian

Untuk penggunaan vial antigen untuk ABRYSVO® (serbuk injeksi), syringe yang telah diisi pelarut, dan adaptor vial

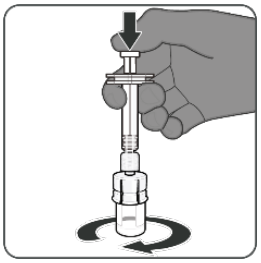
Serbuk injeksi harus direkonstitusi hanya dengan pelarut yang tersedia dalam syringe yang telah diisi menggunakan adaptor vial.





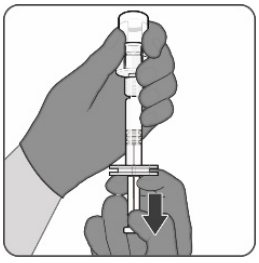
Langkah 1. Pasang adaptor vial

- Kelupas penutup atas dari kemasan adaptor vial dan lepaskan tutup flip-off dari vial.
- Sambil mempertahankan adaptor vial tetap dalam kemasannya, pusatkan adaptor vial di atas sumbat vial dan sambungkan dengan dorongan lurus ke bawah. Jangan dorong adaptor vial secara miring karena dapat menyebabkan kebocoran. Lepaskan kemasannya.



Langkah 2. Rekonstitusikan komponen serbuk injeksi (antigen) untuk membentuk ABRYSVO®

- Untuk semua langkah perakitan syringe, pegang syringe hanya pada bagian adaptor kunci Luer. Cara ini mencegah agar adaptor kunci Luer tidak terlepas saat digunakan.
- Putar untuk melepaskan tutup syringe, lalu putar untuk menyambungkan syringe ke adaptor vial. Berhentilah memutar jika Anda merasakan hambatan.
- Suntikkan seluruh isi syringe ke dalam vial. Tahan batang plunger ke bawah dan putar-putar vial perlahan hingga serbuk injeksi terlarut sempurna. Jangan mengocok vial.



Langkah 3. Tarik vaksin yang telah direkonstitusi

- Balik vial sepenuhnya dan tarik perlahan seluruh isinya ke dalam syringe untuk memastikan dosis ABRYSVO® sebanyak 0,5 ml.
- Putar untuk melepaskan syringe dari adaptor vial.
- Pasang jarum steril yang sesuai untuk injeksi intramuskular.

Vaksin yang disiapkan merupakan larutan yang bening dan tidak berwarna. Periksa vaksin secara visual untuk melihat adanya bahan partikulat besar dan perubahan warna sebelum pemberian dilakukan. Jangan gunakan jika ada partikulat besar dan perubahan warna.

Pembuangan

Setiap produk yang tidak terpakai atau bahan limbah harus dibuang sesuai persyaratan setempat.

CDS v14 dan v16

ABRYSVO®

Respiratory syncytial virus vaccine (bivalent, recombinant)

1. NAME OF THE MEDICINAL PRODUCT

ABRYSVO powder for injection and solvent

Respiratory syncytial virus vaccine (bivalent, recombinant)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

After reconstitution, one dose (0.5 mL) contains:

RSV subgroup A stabilised prefusion F protein[1,2]	60 micrograms
RSV subgroup B stabilised prefusion F protein[1,2]	60 micrograms

[1] Produced in Chinese Hamster Ovary cells by recombinant DNA technology
[2] Glycoprotein F stabilised in the prefusion conformation

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder for injection and solvent.

The powder for injection or cake is white.
The solvent is a clear, colourless liquid.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

ABRYSVO is indicated for:

- Passive protection against lower respiratory tract disease caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age following maternal immunisation during pregnancy. See sections 4.2 and 5.1.

- Active immunisation of individuals 60 years of age and older for the prevention of lower respiratory tract disease caused by RSV.

- Active immunization for the prevention of lower respiratory tract disease (LRTD) caused by RSV in individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV. See section 5.1.

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

4.2. Posology and method of administration

Posology

Pregnant individuals
A single dose of 0.5 mL should be administered between weeks 24 and 36 of gestation.

Individuals 18 years of age and older
A single dose of 0.5 mL should be administered.

Immunocompromised individuals
A single dose of 0.5 mL should be administered. The need for a second dose has not been established (see section 5.1).

Paediatric population
The safety and efficacy of ABRYSVO in children (from birth to less than 18 years of age) have not yet been established. Limited data are available in pregnant adolescents and their infants.

Method of administration

ABRYSVO is for intramuscular injection into the deltoid region of the upper arm.

ABRYSVO is not to be administered intravascularly, intradermally or subcutaneously.

The vaccine should not be mixed with any other vaccines or medicinal products.

For instructions on reconstitution and handling of the medicinal product before administration, see section 6.6.

4.3. Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

4.4. 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.

Guillain-Barré syndrome

Guillain-Barré syndrome has been reported rarely following vaccination with ABRYSVO in individuals ≥60 years of age.

Healthcare professionals should be alert to signs and symptoms of Guillain-Barré syndrome to ensure correct diagnosis, in order to initiate adequate supportive care and treatment, and to rule out other causes.

Hypersensitivity and anaphylaxis

Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.

Concurrent illness

Vaccination with ABRYSVO should be postponed in individuals suffering from an acute febrile illness. However, the presence of a minor infection, such as a cold, should not result in the deferral of vaccination.

Anxiety-related reactions

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. It is important that procedures are in place to avoid injury from fainting.

Thrombocytopenia and coagulation disorders

ABRYSVO should be given with caution to individuals with thrombocytopenia or any coagulation disorder since bleeding or bruising may occur following an intramuscular administration to these individuals.

Immunocompromised individuals

Safety and immunogenicity have been assessed in immunocompromised individuals, including those receiving immunosuppressant therapy (see sections 4.8 and 5.1). The efficacy of ABRYSVO may be lower in immunosuppressed individuals.

Individuals less than 24 weeks of gestation

ABRYSVO has not been studied in pregnant individuals less than 24 weeks of gestation. Since protection of the infant against RSV depends on transfer of maternal antibodies

across the placenta, ABRYSVO should be administered between weeks 24 and 36 of gestation (see sections 4.2 and 5.1).

Limitations of vaccine effectiveness

As with any vaccine, a protective immune response may not be elicited after vaccination.

Excipient

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

4.5. Interaction with other medicinal products and other forms of interaction

Use with other vaccines

ABRYSVO can be administered concomitantly with seasonal quadrivalent influenza vaccine (QIV, surface antigen, inactivated, adjuvanted). In a randomised study in adults 65 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 ABRYSVO and inactivated adjuvanted seasonal influenza vaccine were co-administered than when they were administered separately. The clinical relevance of this finding is unknown.

A minimum interval of two weeks is recommended between administration of ABRYSVO and administration of a tetanus, diphtheria and acellular pertussis vaccine (Tdap). There were no safety concerns when ABRYSVO was co-administered with Tdap in healthy non-pregnant women. Immune responses to RSV A, RSV B, diphtheria and tetanus on co-administration were non-inferior to those after separate administration. However, the immune responses to the pertussis components were lower on co-administration compared to separate administration and did not meet the criteria for non-inferiority. The clinical relevance of this observation is unknown.

Data on concomitant administration of ABRYSVO and vaccines other than those listed above are not available.

Different injectable vaccines should always be given at different vaccination sites.

Do not mix ABRYSVO with other vaccines/medicinal products in the same syringe.

4.6. Fertility, pregnancy and lactation

Pregnancy

Data on pregnant women (more than 4,000 exposed outcomes) indicate no malformative nor feto/ neonatal toxicity.

Results from animal studies with ABRYSVO do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3).

In a phase 3 study (Study 1), maternal adverse events reported within 1 month after vaccination were similar in the ABRYSVO group (14%) and the placebo group (13%).

No safety signals were detected in infants up to 24 months of age. The incidences of adverse events reported within 1 month after birth in infants were similar in the ABRYSVO group (37%) and the placebo group (35%). Major birth outcomes assessed in the ABRYSVO group compared to placebo included premature birth (201 (6%) and 169 (5%), respectively), low birth weight (181 (5%) and 155 (4%), respectively) and congenital anomalies (174 (5%) and 203 (6%), respectively).

Breast-feeding

It is unknown whether ABRYSVO is excreted in human milk. No adverse effects of ABRYSVO have been shown in breastfed newborns of vaccinated mothers.

Fertility

No human data on the effect of ABRYSVO on fertility are available.

Animal studies do not indicate direct or indirect harmful effects with respect to female fertility (see section 5.3).

4.7. Effects on ability to drive and use machines

ABRYSVO has no or negligible influence on the ability to drive and use machines.

4.8. Undesirable effects

Summary of the safety profile

Pregnant individuals

In pregnant women at 24-36 weeks of gestation the most frequently reported adverse reactions were vaccination site pain (41%), headache (31%) and myalgia (27%). The majority of local and systemic reactions in maternal participants were mild to moderate in severity and resolved within 2-3 days of onset.

Individuals 18 years of age and older

In individuals 18 years of age and older the most frequently reported adverse reactions were fatigue (23%), headache (20%), vaccination site pain (19%) and myalgia (16%). The majority of reactions were mild to moderate in severity and resolved within 1-2 days of onset.

Tabulated list of adverse reactions

The safety of administering a single dose of ABRYSVO to pregnant women at 24-36 weeks of gestation (n=3698) and to individuals 18 years of age and older (n=20275) was evaluated in clinical trials.

Adverse reactions are listed according to the following frequency categories:
Very common (≥1/10);
Common (≥1/100 to <1/10);
Uncommon (≥1/1000 to <1/100);
Rare (≥1/10000 to <1/1000);
Very rare (<1/10000);
Not known (cannot be estimated from the available data).

Adverse reactions reported are listed per system organ class, in decreasing order of seriousness.

Table 1 Adverse reactions following administration of ABRYSVO

System organ class	**Adverse reactions pregnant individuals ≤49 years**	**Adverse reactions individuals ≥18 years**
Blood and lymphatic system disorders		
Lymphadenopathy	Rare	Rare
Immune system disorders		
Anaphylaxis		Very rare
Hypersensitivity reactions (includes rash, urticaria)	Rare	Rare
Nervous system disorders		
Headache	Very common	Very common
Guillain-Barré syndrome		Very rare
Musculoskeletal and connective tissue disorders		
Myalgia	Very common	Very common
Arthralgia		Common
General disorders and administration site conditions		
Fatigue		Very common
Vaccination site pain	Very common	Very common
Vaccination site redness	Common	Common

System organ class	Adverse reactions pregnant individuals ≤49 years	Adverse reactions individuals ≥18 years
Vaccination site swelling	Common	Common
Pyrexia		Uncommon
Vaccination site pruritus		Rare
Vaccination site bruising		Rare
Vaccination site haematoma		Rare

Special populations

Immunocompromised individuals 18 years of age and older

Reactogenicity was consistent with the known profile of ABRYSVO. There were no unexpected safety findings.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via:

Pusat Farmakovigilans/MESO Nasional
Direktorat Pengawasan Keamanan, Mutu, dan Ekspor lmpor Obat, Narkotika, Psikotropika, Prekursor dan Zat Adiktif
Badan Pengawas Obat dan Makanan
JI. Percetakan Negara No. 23, Jakarta Pusat, 10560
Email: pv-center@pom.go.id
Website: https://e-meso.pom.go.id/

PT Pfizer Indonesia
Email: IDN.AEReporting@pfizer.com
Website: www.pfizersafetyreporting.com

4.9. Overdose

Overdose with ABRYSVO is unlikely due to its single dose presentation.

There is no specific treatment for an overdose with ABRYSVO. In the event of an overdose, the individual should be monitored and provided with symptomatic treatment as appropriate.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacological class, therapeutic class

Vaccines, other viral vaccines; ATC code: J07BX05.

Mechanism of action

ABRYSVO contains two recombinant stabilised RSV prefusion F antigens representing subgroups RSV-A and RSV-B. Prefusion F is the primary target of neutralising antibodies that block RSV infection. Following intramuscular administration, the prefusion F antigens elicit an immune response, which protects against RSV-associated lower respiratory tract disease.

In infants born to mothers who were vaccinated with ABRYSVO between weeks 24 and 36 of gestation, protection against RSV-associated lower respiratory tract disease is due to transplacental transfer of RSV neutralising antibodies. Adults 60 years of age and older, adults 18 through 59 years of age who are at increased risk for LRTD caused by RSV, are protected by active immunisation.

Clinical efficacy and safety

Infants from birth through 6 months of age by active immunisation of pregnant individuals

Study 1 is a phase 3, multicentre, randomised (1:1), double-blind, placebo-controlled study to assess the efficacy of a single dose of Abrysvo in the prevention of RSV-associated lower respiratory tract disease in infants born to pregnant individuals vaccinated between weeks 24 and 36 of gestation. The need for revaccination with subsequent pregnancies has not been established.

RSV-associated lower respiratory tract illness was defined as a medically attended visit with a reverse transcription-polymerase chain reaction (RT-PCR) confirmed RSV illness with one or more of the following respiratory symptoms: fast breathing, low oxygen saturation (SpO_2 <95%) and chest wall indrawing. RSV-associated severe lower respiratory tract illness was a subset defined as meeting the lower respiratory tract illness-RSV criteria plus at least one of the following: very fast breathing, low oxygen saturation (SpO_2 <93%), high-flow nasal cannula or mechanical ventilation, ICU admission for >4 hours and/or failure to respond/unconscious.

In this study, 3695 pregnant individuals with uncomplicated, singleton pregnancies were randomised to the ABRYSVO group and 3697 to placebo.

Vaccine efficacy (VE) was defined as the relative risk reduction of the endpoint in the ABRYSVO group compared to the placebo group for infants born to pregnant individuals who received the assigned intervention. There were two primary efficacy endpoints, assessed in parallel, severe RSV positive medically attended lower respiratory tract illness and RSV positive medically attended lower respiratory tract illness, occurring within 90, 120, 150 or 180 days after birth.

Of the pregnant women who received Abrysvo, 65% were White, 20% were Black or African American and 29% were Hispanic/Latino. The median age was 29 years (range 16-45 years); 0.2% of participants were under 18 years of age and 4.3% were under 20 years of age. The median gestational age at vaccination was 31 weeks and 2 days (range 24 weeks and 0 days to 36 weeks and 4 days). The median infant gestational age at birth was 39 weeks and 1 day (range 27 weeks and 3 days to 43 weeks and 6 days).

Vaccine efficacy is presented in Table 2 and Table 3.

Table 2 Vaccine efficacy of ABRYSVO against severe medically attended lower respiratory tract illness caused by RSV - infants from birth through 6 months of age by active immunisation of pregnant individuals (Study 1)

Time period	ABRYSVO Number of cases N=3,495	Placebo Number of cases N=3,480	VE % (CI)[a]
90 days	6	33	81.8 (40.6, 96.3)
120 days	12	46	73.9 (45.6, 88.8)
150 days	16	55	70.9 (44.5, 85.9)
180 days	19	62	69.4 (44.3, 84.1)

CI = confidence interval; VE = vaccine efficacy

[a] 99.5% CI at 90 days; 97.58% CI at later intervals

Table 3 Vaccine efficacy of ABRYSVO against medically attended lower respiratory tract illness caused by RSV - infants from birth through 6 months of age by active immunisation of pregnant individuals (Study 1)

Time period	ABRYSVO Number of cases N=3,495	Placebo Number of cases N=3,480	VE % (CI)[a]
90 days	24	56	57.1 (14.7, 79.8)
120 days	35	81	56.8 (31.2, 73.5)
150 days	47	99	52.5 (28.7, 68.9)
180 days	57	117	51.3 (29.4, 66.8)

CI = confidence interval; VE = vaccine efficacy

[a] 99.5% CI at 90 days; 97.58% CI at later intervals

A post-hoc analysis of VE by maternal gestational age was conducted. For severe medically attended lower respiratory tract illness occurring within 180 days, VE was 57.2% (95% CI 10.4, 80.9) for women vaccinated early in pregnancy (24 to <30 weeks) and 78.1% (95% CI 52.1, 91.2) for women vaccinated later in the pregnancy eligible window (30 to 36 weeks). For medically attended lower respiratory tract illness occurring

within 180 days, VE was 30.9% (95% CI -14.4, 58.9) for women vaccinated early in pregnancy (24 to <30 weeks) and 62.4% (95% CI 41.6, 76.4) for women vaccinated later in the pregnancy eligible window (30 to 36 weeks).

Active immunisation of individuals 60 years of age and older

Study 2 is a Phase 3, multicentre, randomised, double-blind, placebo-controlled study to assess the efficacy of ABRYSVO in the prevention of RSV-associated lower respiratory tract illness in individuals 60 years of age and older.

RSV-associated acute respiratory tract illness was defined as RT-PCR confirmed RSV illness with two or more or three or more of the following respiratory symptoms within 7 days of symptom onset and lasting more than 1 day during the same illness – new or increased cough, wheezing, sputum production, or shortness of breath or tachypnoea (≥25 breaths/min or 15% increase from resting baseline).

Participants were randomised (1:1) to receive ABRYSVO (n=18,488) or placebo (n=18,479). Enrollment was stratified by age, 60-69 years (63%), 70-79 years (32%) and ≥80 years (5%). Subjects with stable chronic underlying conditions were eligible for this study and 52% of participants had at least 1 prespecified condition; 16% of participants were enrolled with stable chronic cardiopulmonary conditions such as asthma (9%), chronic obstructive pulmonary disease (7%) or congestive heart failure (2%). Immunocompromised individuals were ineligible.

The primary objective was assessment of vaccine efficacy (VE), defined as the relative risk reduction of first episode of RSV-associated lower respiratory tract illness in the ABRYSVO group compared to the placebo group in the first RSV season.

Of the participants who received ABRYSVO, 51% were male and 80% were White, 12% were Black or African American and 41% were Hispanic/Latino. The median age of participants was 67 years (range 59-95 years).

At the end of the first RSV season the analysis demonstrated statistically significant efficacy for ABRYSVO for reduction of RSV-associated lower respiratory tract illness with ≥2 symptoms and with ≥3 symptoms.

Vaccine efficacy is presented in Table 4.

Table 4 Vaccine efficacy of ABRYSVO against RSV disease - active immunisation of individuals 60 years of age and older (Study 2)

Efficacy endpoint	ABRYSVO Number of cases N=18,058	Placebo Number of cases N=18,076	VE (%) (95% CI)
First episode of RSV-associated lower respiratory tract illness with ≥2 symptoms[a]	15	43	65.1 (35.9, 82.0)
First episode of RSV-associated lower respiratory tract illness with ≥3 symptoms[b]	2	18	88.9 (53.6, 98.7)

CI – confidence interval; RSV – respiratory syncytial virus; VE – vaccine efficacy

[a] In an exploratory analysis in RSV subgroup A (ABRYSVO n=3, placebo n=16) VE was 81.3% (CI 34.5, 96.5); and in RSV subgroup B (ABRYSVO n=12, placebo n=26) VE was 53.8% (CI 5.2, 78.8).

[b] In an exploratory analysis in RSV subgroup A (ABRYSVO n=1, placebo n=5) VE was 80.0% (CI -78.7, 99.6); and in RSV subgroup B (ABRYSVO n=1, placebo n=12) VE was 91.7% (CI 43.7, 99.8).

In Study 2, three participants in the ABRYSVO group had serious adverse events, two cases of variants of Guillain-Barré syndrome (chronic inflammatory demyelinating polyneuropathy reported 7 days after vaccination and Miller Fisher syndrome reported 8 days after vaccination) and one case of hypersensitivity reported 8 hours after vaccination. Available information is insufficient to determine a causal relationship between ABRYSVO and Guillain-Barré syndrome

Immunogenicity in individuals 18 through 59 years of age

Study 3 (C3671023 Substudy A) was a Phase 3, multicentre, randomised, double-blind, placebo-controlled study to assess the safety and immunogenicity of ABRYSVO in individuals 18 through 59 years of age considered to be at high risk of developing severe lower respiratory tract disease caused by RSV. Study 3 enrolled individuals who had chronic pulmonary (including asthma), cardiovascular (excluding isolated hypertension), renal, hepatic, neurologic, haematologic or metabolic disorders (including diabetes mellitus and hyper/hypothyroidism). Participants were randomised (2:1) to receive a single dose of ABRYSVO (n=437) or placebo (n=217).

Demographic characteristics in study 3 were generally similar with regard to age, race and ethnicity among participants who received ABRYSVO and those who received placebo. Fifty-three percent (53%) were 18 to 49 years and 47% were 50 to 59 years. The vaccine and placebo groups were similar with regards to having at least one prespecified medical condition, which included 53% with ≥1 chronic pulmonary condition, 8% with ≥1 cardiovascular condition, 42% with diabetes and 31% ≥1 other disease (liver, renal, neurologic, haematologic or other metabolic disease).

Vaccine efficacy in individuals 18 through 59 years of age is inferred by immunobridging to study 2 where vaccine efficacy was demonstrated in individuals 60 years of age and older. The non-inferiority criteria were met for high risk individuals 18 through 59 years

of age compared to a randomly selected immunogenicity subset (external control group) of individuals ≥60 years of age from study 2 for the ratio of RSV neutralising geometric mean titres (GMTs) by the lower bounds of the 2-sided 95% CIs >0.667 (1.5-fold non-inferiority margin), and for the difference in seroresponse rates by the lower bounds of the 2-sided 95% CIs > -10% for both RSV A and RSV B.

Table 5 Comparison of model adjusted RSV neutralising titre GMTs at 1 month after vaccination with ABRYSVO, 18 through 59 years at high risk (Study 3) versus 60 years and older (Study 2)

	Study 3 18-59 years of age at high risk		Study 2 ≥60 years		ANCOVA comparison
RSV subgroups	**n**	**Adjusted GMT (95% CI)**	**n**	**Adjusted GMT (95% CI)**	**Adjusted GMR (95% CI)**
A	435	41097 (37986, 44463)	408	26225 (24143, 28486)	1.57 (1.396, 1.759)
B	437	37416 (34278, 40842)	408	24680 (22504, 27065)	1.52 (1.333, 1.725)

CI – confidence interval; GMR – geometric mean ratio; GMT – geometric mean titre

Table 6 Comparison of RSV neutralising titre seroresponse rates 1 month after vaccination with ABRYSVO, 18 through 59 years at high risk (Study 3) versus 60 years and older (Study 2)

	Study 3 18-59 years of age at high risk		Study 2 ≥60 years		Comparison
RSV subgroups	**n/N (%)**	**95% CI**	**n/N (%)**	**95% CI**	**Difference (95% CI)**
A	405/435 (93)	90.3, 95.3	359/408 (88)	84.4, 91.0	5.1 (1.2, 9.2)
B	408/437 (93)	90.6, 95.5	347/408 (85)	81.2, 88.4	8.3 (4.2, 12.6)

CI – confidence interval

Immunogenicity in immunocompromised individuals 18 years of age and older

Study 4 (C3671023 Substudy B) was a Phase 3, single-arm, open-label, multicentre study to assess the safety and immunogenicity of ABRYSVO in immunocompromised individuals ≥18 years of age. Participants had history of a solid organ transplant (kidney, liver, lung or heart) at least 3 months prior to enrollment; end stage renal disease and on haemodialysis; autoimmune inflammatory disorders with active immunomodulator therapy; or advanced non-small cell lung cancer and receiving active immunomodulator therapy. Participants received 2 doses of ABRYSVO with an interval of 1 month.

A single dose of ABRYSVO was sufficient to elicit robust neutralising responses approximately 8- or 9-fold above baseline against RSV A and RSV B in participants ≥18 years of age with immunocompromising conditions (n=188). Responses did not further increase with a second dose of ABRYSVO 1 month after the first dose.

5.2. Pharmacokinetic properties

Not applicable.

5.3. Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of repeated dose toxicity and toxicity to reproductive and developmental.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Powder for injection
Trometamol
Trometamol hydrochloride
Sucrose
Mannitol (E421)
Polysorbate 80 (E433)
Sodium chloride

Diluent
Water for injections

6.2. Incompatibilities

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

6.3. Shelf life

48 months in a refrigerator (2℃-8℃)

The unopened vial is stable for 5 days when stored at temperatures from 8℃ to 30℃. At the end of this period ABRYSVO should be used or discarded. This information is used to guide healthcare professionals in case of temporary temperature excursions only.

After reconstitution:
ABRYSVO should be administered immediately after reconstitution or within 4 hours if stored between 15℃ and 30℃. Do not freeze.

Chemical and physical in-use stability has been demonstrated for 4 hours between 15℃ and 30℃. 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.

6.4. Special precautions for storage

Store carton in a refrigerator (2°C to 8°C).

Do not freeze. Discard if the carton has been frozen.

Store in original package.

For storage conditions after reconstitution of the medicinal product, see section 6.3.

6.5. Nature and contents of container

Vial of antigens for ABRYSVO (powder for injection) and pre-filled syringe of solvent

Powder for injection for 1 dose in a vial (type 1 glass or equivalent) with a stopper (synthetic chlorobutyl rubber) and a flip off cap

Solvent for 1 dose in a pre-filled syringe (type 1 glass) with a stopper (synthetic chlorobutyl rubber) and a tip cap (synthetic isoprene/bromobutyl blend rubber)

Vial adaptor

Pack size

Carton containing 1 vial of powder for injection, 1 pre-filled syringe of diluent, 1 vial adapter with needles.
Carton containing 5 vials of powder for injection, 5 pre-filled syringes of diluent, 5 vial adapters with needles.

Not all pack sizes may be marketed.

6.6. Special precautions for disposal and other handling

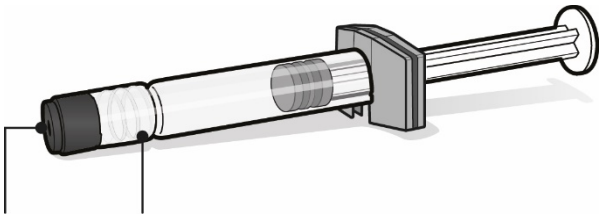
For use of vial of antigens for ABRYSVO (powder for injection), pre-filled syringe of solvent and vial adaptor

ABRYSVO must be reconstituted prior to administration by adding the entire contents of the pre-filled syringe of solvent to the vial containing the powder for injection using the vial adaptor.

The vaccine must be reconstituted only with the solvent provided.

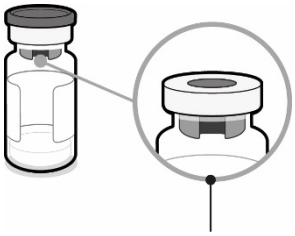
Preparation for administration

Pre-filled syringe containing solvent for ABRYSVO



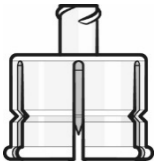
Syringe cap Luer lock adaptor

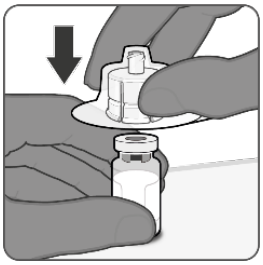
Vial containing antigens for ABRYSVO (powder for injection)



Vial stopper (with flip off cap removed)

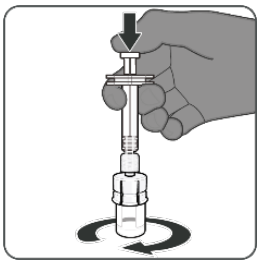
Vial adaptor





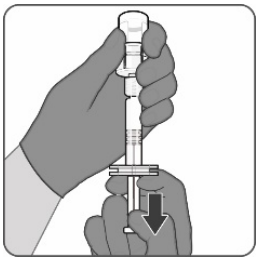
Step 1. Attach vial adaptor

- Peel off the top cover from the vial adaptor packaging and remove the flip off cap from the vial.
- While keeping the vial adaptor in its packaging, centre over the vial's stopper and connect with a straight downward push. Do not push the vial adaptor in at an angle as it may result in leaking. Remove the packaging.



Step 2. Reconstitute the powder for injection component (antigens) to form ABRYSVO

- For all syringe assembly steps, hold the syringe only by the Luer lock adaptor. This will prevent the Luer lock adaptor from detaching during use.
- Twist to remove the syringe cap, then twist to connect the syringe to the vial adaptor. Stop turning when you feel resistance.
- Inject the entire contents of the syringe into the vial. Hold the plunger rod down and gently swirl the vial until the powder for injection is completely dissolved. Do not shake.



Step 3. Withdraw reconstituted vaccine

- Invert the vial completely and slowly withdraw the entire contents into the syringe to ensure a 0.5 mL dose of ABRYSVO.
- Twist to disconnect the syringe from the vial adaptor.
- Attach a sterile needle suitable for intramuscular injection.

The prepared vaccine is a clear and colourless solution. Visually inspect the vaccine for large particulate matter and discolouration prior to administration. Do not use if large particulate matter or discolouration is found.

Disposal

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

7. MARKETING AUTHORISATION HOLDER

Manufactured by:
Pfizer Manufacturing Belgium NV
Rijksweg 12
2870 Puurs-Sint-Amands
Belgium

Imported by:
PT. Pfizer Indonesia
Jakarta, Indonesia

8. MARKETING AUTHORISATION NUMBER(S)

ABRYSVO® 1 vial, 1 vial adaptor, 1 pre-filled syringe, 1 needle (Reg. No.: DKI2486102344A1)
ABRYSVO® 5 vials, 5 vial adaptors, 5 pre-filled syringes, 5 needles (Reg. No.: DKI2486102344A1)

HARUS DENGAN RESEP DOKTER

9. DATE OF REVISION OF THE TEXT

18/05/2026

CDS v14 and v16