Bundesministerium Soziales, Gesundheit, Pflege und Konsumentenschutz

Information and documentation form for passive immunisation against RSV with Beyfortus (nirsevimab)

Version 1.0, as at: 09/12/2024

Please complete the mandatory fields (marked with "*") for the vaccination register.

Personal data	of the pe	erson to be i	mmunised (alte	ernatively,	use patient	sticker)		
Surname*				First name*				
Social insurance nu	mber* (all 1	0 digits, if availa	ble)	Date of birth	(DD/MM/YYYY	<u>'</u>)*		
Gender*	female	O male	Other	inter	Open	ono entry		
Personal data	of their l	egal represe	entative					
Surname				First name				
Address (postcode, to	own, street,	house number, sta	aircase, door number)	Telephone nu	ımber			
Email address								
Please answer If the person to be im actual immunisation a certificate, vaccinatio 1. In the past 7 day from any acute illnot fyes, please provide details. 2. Is the person to medicinal product If yes, please provide details. 3. Has the person to severe breathless of the person to severe bre	munised has appointment, in card) of the s, has the pess or inference be immunis (see inform to be immured).	s had an illness or in please inform the e person to be immorerson to be immorerson (e.g. fever, sed allergic to an anation leaflet)?	received other immun doctor before the immunised should be prenunised been suffering cough, common co	isations or vacci munisation. All v esented at the in ng, or are the ld, sore throat o an ingredien	nations between vaccination record nmunisation apports of the still suffering, other)?	ds (e.g. vaccination	n passport, '	
provide details. 4. Is there any other vaccinations, treatness.			ut the person to be	immunised (e	.g. illnesses,		O Yes	○ No
If yes, please provide details.								

Informed consent for the passive immunisation against RSV

Following the immunisation against RSV, reactions may occur, which usually disappear within a few days. Occasionally (≥ 1/1000, < 100), individuals may experience a rash, fever or reactions (e.g. pain, hardening, swelling) at the injection site. Serious hypersensitivity reactions, including anaphylaxis, have been observed with monoclonal antibodies.

The relevant, up-to-date and complete version of the medicinal product information leaflet is part of this information and documentation form and is to be made available electronically, and, upon request, also as a paper copy. Medicinal product information leaflets that are provided as part of the public vaccination programmes run by the federal government, the federal Länder and the social insurance providers, are available at: https://www.sozialministerium.at/Themen/Gesundheit/Impfen/Gebrauchsinformationen-der-Impfstoffe-im-kostenfreien-Impfprogramm.html For further information and the relevant vaccine recommendations for Austria, please refer to the website of the Federal Ministry of Social Affairs, Health, Care and Consumer Protection at: www.sozialministerium.at/impfen.



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Should you have any further questions, please get in touch with your doctor for a personal consultation before signing this form.

If it is not possible to have a personal consultation with a doctor, please contact the medical service/public health department of your local administrative authority and only sign the informed consent once you have obtained sufficient information.

By signing, I confirm that:

- I have had the opportunity for an informed consent discussion.
- I have read and understood the medicinal product information leaflet, or that I was otherwise provided with sufficient information about the medicinal product.
 - I have informed myself about the potential adverse effects of the medicinal product and any circumstances under which the child ought not to be immunised.
- · I have sufficient understanding of the benefits and risks of the immunisation and accordingly do not require any further personal consultation.
- I consent to the immunisation being administered.
- I am aware that my personal data will be processed in the vaccination register in accordance with the Gesundheitstelematikgesetz 2012 [Health Telematics Act] (see https://www.elga.gv.at/datenschutzerklaerung).

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Date (DD/MM/YYYY)	Signature of the legal representative

Important information: For the child's safety, you and the child should stay near the doctor for 20 minutes after the immunisation, on the off-chance that they experience any adverse reactions (collapse, allergic reactions, etc.). If you suspect that they are experiencing any adverse reactions, please contact your doctor or pharmacist. They are obliged to report any suspected adverse reactions. However, you or members of your family may report adverse reactions as well. More information is available online at https://www.basg.gv.at/en/market-surveillance/reporting/adverse-reactions/nebenwirkungsmeldung-human; or you can also call +43 (0) 50 555 36600.



Administering centre/organisation	Space for doctor's notes
(contract partner number, if available)*	Space for doctor's notes
Child's body mass	
Dose administered*	
Beyfortus 50 mg solution for injection	
Beyfortus 100 mg solution for injection	
Batch number (LOT or Ch.B)*	Date of administration (DD/MM/YYYY)*
Name of doctor	Name of person administering the immunisation (if not the
in charge*	same as doctor in charge)
_ ·	nature of doctor in charge
cannot be clearly identified.	