swissmedic

Date: 27 May 2025
Swissmedic, Swiss Agency for Therapeutic Products

Swiss Public Assessment Report

mRESVIA
Respiratory Syncytial Virus mRNA Vaccine

International non-proprietary name: mRNA-1345, a single-stranded 5' capped mRNA (messenger RNA) encoding the RSV-A glycoprotein F stabilised in the prefusion conformation

Pharmaceutical form:	Dispersion for injection in pre-filled syringe
Dosage strength(s):	One dose (0.5 ml) contains 50 µg of Respiratory Syncytial Virus (RSV) mRNA
Route(s) of administration:	Intramuscular injection
Marketing authorisation holder:	Moderna Switzerland GmbH
Marketing authorisation no.:	69995
Decision and decision date:	approved on 17.04.2025

Note:

This assessment report is as adopted by Swissmedic with all information of a commercially confidential nature deleted.

SwissPARs are final documents that provide information on submissions at a particular point in time. They are not updated after publication.

Table of contents

1 Terms, Definitions, Abbreviations

ADA	Anti-drug antibody
ADME	Absorption, distribution, metabolism, elimination
AE	Adverse event
ALT	Alanine aminotransferase
API	Active pharmaceutical ingredient
AST	Aspartate aminotransferase
ATC	Anatomical Therapeutic Chemical Classification System
AUC	Area under the plasma concentration-time curve
$AUC_{0\text{-}24h}$	Area under the plasma concentration-time curve for the 24-hour dosing interval
CI	Confidence interval
C_{max}	Maximum observed plasma/serum concentration of drug
CYP	Cytochrome P450
DDI	Drug-drug interaction
EMA	European Medicines Agency
ERA	Environmental risk assessment
FDA	Food and Drug Administration (USA)
GI	Gastrointestinal
GLP	Good Laboratory Practice
HPLC	High-performance liquid chromatography
IC/EC_{50}	Half-maximal inhibitory/effective concentration
ICH	International Council for Harmonisation
Ig	Immunoglobulin
INN	International non-proprietary name
ITT	Intention-to-treat
LoQ	List of Questions
MAH	Marketing authorisation holder
Max	Maximum
Min	Minimum
MRHD	Maximum recommended human dose
N/A	Not applicable
NO(A)EL	No observed (adverse) effect level
PBPK	Physiology-based pharmacokinetics
PD	Pharmacodynamics
PIP	Paediatric investigation plan (EMA)
PK	Pharmacokinetics
PopPK	Population pharmacokinetics
PSP	Pediatric study plan (US FDA)
RMP	Risk management plan
SAE	Serious adverse event
SwissPAR	Swiss Public Assessment Report
TEAE	Treatment-emergent adverse event
TPA	Federal Act of 15 December 2000 on Medicinal Products and Medical Devices (SR 812.21)
TPO	Ordinance of 21 September 2018 on Therapeutic Products (SR 812.212.21)

2 Background information on the procedure

2.1 Applicant's request(s)

New active substance status
The applicant requested new active substance status for mRNA-1345 in the above-mentioned medicinal product.

Authorisation as human medicinal product in accordance with Article 13 TPA
The applicant requested a reduced assessment procedure in accordance with Article 13 TPA.

2.2 Indication and dosage

2.2.1 Requested indication

mRESVIA is indicated for active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by Respiratory Syncytial Virus in adults 60 years of age and older.
The use of this vaccine should be in accordance with official recommendations.

2.2.2 Approved indication

mRESVIA is indicated for active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by Respiratory Syncytial Virus in adults 60 years of age and older.
The use of this vaccine should be in accordance with official recommendations.

2.2.3 Requested dosage

Summary of the requested standard dosage:
The recommended dose of mRESVIA is one single dose of 0.5 ml.
One dose (0.5 ml) contains 50 µg of Respiratory Syncytial Virus (RSV) mRNA (nucleoside modified) encapsulated in lipid nanoparticles.

2.2.4 Approved dosage

(see appendix)

2.3 Regulatory history (milestones)

Application	30 September 2024
Formal control completed	7 October 2024
Preliminary decision	15 January 2025
Response to preliminary decision	21 February 2025
Final decision	17 April 2025
Decision	approval

Swissmedic has not assessed the primary data (e.g. study reports) submitted with this application and relies for its decision on the assessment of the foreign reference authority, the EMA. This SwissPAR relates to the publicly available assessment report mResvia (Reference Number: EMA/329706/2024, 06.09.2024) issued by the EMA, EMA/CHMP/285703/2024.

3 Quality aspects

Swissmedic has not assessed the primary data relating to quality aspects submitted with this application and relies on the assessment of the foreign reference authority, the EMA. The SwissPAR relating to quality aspects refers to the publicly available assessment report mResvia (Reference Number: EMA/329706/2024, 06.09.2024) issued by the EMA, EMA/CHMP/285703/2024.

4 Nonclinical aspects

Swissmedic has not assessed the primary data relating to nonclinical aspects submitted with this application and relies on the assessment of the foreign reference authority, the EMA. The nonclinical aspects in this SwissPAR refer to the publicly available assessment report mResvia (Reference Number: EMA/329706/2024, 06.09.2024) issued by the EMA, EMA/CHMP/285703/2024.

5 Clinical aspects

Swissmedic has not assessed the primary data relating to clinical aspects submitted with this application and relies on the assessment of the foreign reference authority, the EMA. The clinical aspects in this SwissPAR refer to the publicly available assessment mResvia (Reference Number: EMA/329706/2024, 06.09.2024) issued by the EMA, EMA/CHMP/285703/2024.

6 Risk management plan summary

The RMP summaries contain information on the medicinal products′ safety profiles and explain the measures that are taken to further investigate and monitor the risks, as well as to prevent or minimise them.
The RMP summaries are published separately on the Swissmedic website. It is the responsibility of the marketing authorisation holder to ensure that the content of the published RMP summaries is accurate and correct. As the RMPs are international documents, their summaries might differ from the content in the Information for healthcare professionals / product information approved and published in Switzerland, e.g. by mentioning risks that occur in populations or indications not included in the Swiss authorisations.

7 Appendix

Approved Information for healthcare professionals

Please be aware that the following version of the Information for healthcare professionals for mResvia was approved with the submission described in the SwissPAR. This Information for healthcare professionals may have been updated since the SwissPAR was published.

Please note that the valid and relevant reference document for the effective and safe use of medicinal products in Switzerland is the Information for healthcare professionals currently authorised by Swissmedic (see www.swissmedicinfo.ch).

Note:
The following Information for healthcare professionals has been translated by the MAH. It is the responsibility of the authorisation holder to ensure the translation is correct. The only binding and legally valid text is the Information for healthcare professionals approved in one of the official Swiss languages.

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected new or serious adverse reactions. See the "Undesirable effects" section for advice on the reporting of adverse reactions. The following product information will be regularly updated as soon as new data and safety reports are available.

mRESVIA dispersion for injection in pre-filled syringe
Respiratory Syncytial Virus mRNA Vaccine

Composition

Active substances

Respiratory Syncytial Virus (RSV) mRNA vaccine (nucleoside modified) contains as active substance a single-stranded 5’ capped mRNA (*messenger RNA*) encoding the RSV-A glycoprotein F stabilised in the prefusion conformation. The mRNA is encapsulated in lipid nanoparticles.

Excipients

Heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate (SM-102), cholesterol, 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC), 1,2-dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000-DMG), trometamol, trometamol hydrochloride, acetic acid, sodium acetate trihydrate, sucrose, water for injections.

Each 0.5 ml dose contains 0.0017 mg sodium.

Pharmaceutical form and active substance quantity per unit

Dispersion for injection in pre-filled syringe.
White to off-white dispersion (pH: 7.0 – 8.0).

Each single-dose pre-filled syringe contains 0.5 ml of the vaccine.

One dose (0.5 ml) contains 50 µg of Respiratory Syncytial Virus (RSV) mRNA (nucleoside modified) encapsulated in lipid nanoparticles.

Indications/Uses

mRESVIA is indicated for active immunisation for the prevention of lower respiratory tract disease (LRTD) caused by Respiratory Syncytial Virus in adults 60 years of age and older.

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

Dosage/Administration

This medicinal product should be administered by a trained healthcare professional using aseptic techniques to ensure sterility.

Posology

The recommended dose of mRESVIA is one single dose of 0.5 ml.

Method of administration

For intramuscular injection only.

mRESVIA should be administered preferably in the deltoid muscle of the upper arm. The injection should be given using standard aseptic technique.

The vaccine must not be injected intravenously, subcutaneously or intradermally.

The vaccine should not be mixed with any other vaccines or medicinal products in the same syringe.

For instructions for preparation of the medicinal product before administration and special handling requirements, see section “Other information”.

Traceability

To ensure traceability of biotechnological medicinal products, it is recommended that the trade name and batch number should be documented for each treatment.

Special dosing instructions

Children and adolescents

mRESVIA is not indicated for use in the paediatric population.

The safety and efficacy of mRESVIA in children (from birth to less than 18 years of age) have not yet been established. No data are available.

Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section “Composition”.

Warnings and precautions

Hypersensitivity and anaphylaxis

Appropriate medical treatment and supervision should always be readily available in case of a severe hypersensitivity reaction, including anaphylaxis, following administration of the vaccine.

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 precautions are in place to avoid injury from fainting.

Concurrent illness

Vaccination should be postponed in individuals suffering from acute infection or febrile illness. The presence of a minor infection, such as a cold, should not delay vaccination.

Thrombocytopenia and coagulation disorders

As with other intramuscular injections, the vaccine should be given with caution in individuals receiving anticoagulant therapy or those with thrombocytopenia or any coagulation disorder (such as haemophilia) because bleeding or bruising may occur following an intramuscular administration in these individuals.

Immunocompromised individuals

Safety and immunogenicity data on mRESVIA are not available for immunocompromised individuals. Individuals receiving immunosuppressant therapy or patients with immunodeficiency may have a diminished immune response to this vaccine.

Limitations of vaccine effectiveness

As with all vaccines, vaccination with mRESVIA may not protect all vaccine recipients.

Excipients with known effect

Sodium

This vaccine contains less than 1 mmol sodium (23 mg) per 0.5 ml dose, that is to say essentially “sodium-free”.

Interactions

No interaction studies with other medicinal products have been performed.

Concomitant administration of mRESVIA with other vaccines has not been studied.

Pregnancy, lactation

This vaccine is not indicated in women of childbearing potential (see section “Indication / uses”). It is not to be used in women who are or may be pregnant or breast-feeding.

Pregnancy

There are no or limited amount of data from the use of mRESVIA in pregnant women. Animal studies with mRESVIA do not indicate direct or indirect harmful effects with respect to pregnancy (see section “preclinical safety data”).

Lactation

It is unknown whether mRESVIA is excreted in human milk.

Fertility

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

Animal studies with mRESVIA do not indicate direct or indirect harmful effects with respect to female reproductive toxicity. Animal studies are insufficient to assess male reproductive toxicity (see section "preclinical safety data").

Effects on ability to drive and use machines

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

However, some of the effects mentioned under section "Undesirable effects" (e.g., fatigue, dizziness) may temporarily affect the ability to drive or use machines.

Undesirable effects

Summary of the safety profile

The most commonly reported adverse reactions were injection site pain (55.9%), fatigue (30.8%), headache (26.7%), myalgia (26.6%) and arthralgia (21.7%). The onset of most solicited local and systemic adverse reactions was within 1 to 2 days after injection and resolved within 1 to 2 days after onset. The majority of local and systemic solicited adverse reactions were mild in intensity.

Tabulated list of adverse reactions

The safety profile and the frequencies of adverse reactions presented below are based on data generated in a global placebo controlled phase 2/3 clinical study (EUDRA CT number 2021 005026 20) with a total of 18 245 participants aged ≥ 60 years who received one injection of 50 micrograms of mRESVIA. The clinical study was conducted in 22 countries in Central and Latin America, Africa, Asia Pacific, North America and Europe.

For information on the main characteristics of the patient population in the phase 2/3 clinical study, see section "Pharmacodynamic properties".

Adverse reactions reported are listed according to the following frequency convention:
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)

Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness (Table 1).

Table 1. Adverse reactions following administration of mRESVIA

MedDRA system organ class	Frequency	Adverse reaction(s)
Blood and lymphatic system disorders	Very common	Lymphadenopathy*
Immune system disorders	Uncommon	Hypersensitivity
Nervous system disorders	Very common	Headache
	Uncommon	Dizziness
	Rare	Peripheral facial nerve paralysis (e.g., Bell's palsy)†
Gastrointestinal disorders	Common	Nausea/vomiting
Skin and subcutaneous tissue disorders	Rare	Urticaria‡
Musculoskeletal and connective tissue disorders	Very common	Myalgia Arthralgia
General disorders and administration site conditions	Very common	Injection site pain Fatigue Chills
	Common	Pyrexia Injection site erythema Injection site swelling/induration
	Rare	Injection site pruritus

* Lymphadenopathy was collected as "Axillary (underarm) swelling or tenderness ipsilateral to the side of injection".
† One participant in the vaccine group had a serious adverse event of facial paralysis with onset on Day 5 assessed by the investigator as related to injection. Within the 42-day risk window following injection, Bell's palsy and/or facial paralysis was reported by 2 participants in the mRESVIA group and 2 participants in the placebo group. All 4 of these participants had risk factors for Bell's palsy.
‡ Urticaria has been observed with either acute onset (within a few days after vaccination) or delayed onset (up to approximately two weeks after vaccination) and may be acute or chronic (≥ 6 weeks) in duration.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is very important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions online via the ElViS portal (Electronic Vigilance System). You can obtain information about this at www.swissmedic.ch.

Overdose

No cases of overdose have been reported.
Overdose with mRESVIA is unlikely due to its single dose presentation (see section “Posology”).
In case of overdose, it is recommended that the patient be monitored for any signs or symptoms of adverse reactions or effects and appropriate symptomatic treatment instituted immediately.

Properties/Effects

ATC code

J07BX05

Mechanism of action

mRESVIA is an mRNA-based vaccine encoding the membrane-anchored RSV-A F glycoprotein stabilised in the prefusion conformation through changes to the amino acid sequence. The RSV-A prefusion glycoprotein is antigenically cross-reactive to the RSV-B prefusion glycoprotein. The prefusion F glycoprotein is the target of neutralising antibodies that mediate protection against

RSV-associated respiratory tract disease.

mRESVIA stimulates production of RSV-A and RSV-B neutralising antibodies and induction of antigen-specific cellular immune responses.

Clinical efficacy mRESVIA

Study EUDRA CT number 2021-005026-20 is an ongoing phase 2/3 randomised, observer-blind, placebo controlled, case-driven pivotal study that was conducted in 22 countries. This study evaluated the safety and efficacy of a single dose of mRESVIA (50 micrograms) to prevent RSV-LRTD in adults ≥ 60 years with or without underlying medical conditions for up to a year after single vaccination with mRESVIA. Participants were randomised in a 1:1 ratio to mRESVIA or placebo. Randomisation was stratified by age and comorbidities increasing the risk of severe LRTD (see Table 2 and related footnotes).

The primary efficacy analysis population (referred to as the per-protocol efficacy set), included 35 088 participants who received either mRESVIA (n=17 572) or placebo (n=17 516). Most participants were White (63.5%); 12.2% of participants were Black or African American, 8.7% were Asian, and 15.2% reported ‘Other’. A total of 34.6% of participants were Hispanic or Latino. Treatment groups were balanced according to race and ethnicity. Risk factors were balanced between treatment groups.

There were approximately the same number of male and female participants (male 50.9%; female 49.1%). The median age of participants was 67.0 years (range: 60 to 96 years), with 63.5% of participants between 60-69 years, 30.9% of participants between 70 and 79 years and 5.5% of participants ≥ 80 years. There were no notable differences in demographics or pre-existing medical

conditions between participants who received mRESVIA and those who received placebo. A total of 6.9% had protocol-defined LRTD risk factors [congestive heart failure (CHF) and/or chronic obstructive pulmonary disease (COPD)] and 29.3% had one or more comorbidity of interest (see Table 2 and related footnotes). A total of 21.8% of the per protocol efficacy set scored “vulnerable” or “frail” according to Edmonton Frail Scale.

The primary efficacy endpoints were the prevention of a first episode of RSV-associated lower respiratory tract disease (RSV-LRTD) with ≥ 2 or ≥ 3 symptoms between 14 days and 12 months post injection. RSV-LRTD was defined by the following criteria: the participant must have had reverse transcription polymerase chain reaction(RT PCR) confirmed RSV infection and radiologic evidence of pneumonia or experienced new or worsening of at least 2 or more (or 3 or more) of the following symptoms, lasting for at least 24 hours: shortness of breath, cough and/or fever (≥ 37.8 °C), wheezing and/or rales and/or rhonchi, sputum production, tachypnoea (≥ 20 breaths per minute or increase of ≥ 2 breaths per minute from baseline measurement in those who have baseline tachypnoea), hypoxemia (new onset oxygen saturation ≤ 93% or increasing use of supplemental oxygen), pleuritic chest pain.

The primary efficacy endpoints have been met (lower bound of the alpha-adjusted confidence interval [CI] of the vaccine efficacy [VE] was > 20%), including VE of 83.7% (95.88% CI: 66.0%, 92.2%; p< 0.0001) against RSV-LRTD as defined by two or more symptoms. The other primary efficacy endpoint against RSV-LRTD defined by three or more symptoms was also met, with a VE of 82.4% (96.36% CI: 34.8%, 95.3%; p=0.0078). These analyses were performed after a median of 3.7 months of follow-up. An additional analysis of efficacy was performed after a median of 8.6 months of follow-up (range 15 to 530 days). A single dose of mRESVIA met the same criterion as defined in the primary analysis for the prevention of RSV-LRTD (lower bound of the 95% CI of the VE was > 20%). Vaccine efficacy in adults ≥ 60 years against RSV-LRTD with 2 or more signs/symptoms was 63.3% (95% CI: 48.7%, 73.7%; number of participants in mRESVIA group was n=47 / N=18 112 and in the placebo group was n=127 / N= 18 045) and against RSV-LRTD with 3 or more signs/symptoms was 63.0% (95% CI: 37.3%, 78.2%; number of participants in mRESVIA group was n=19 / N=18 112 and in the placebo group was n=51 / N=18 045).

At the time of the additional analysis (median follow up 8.6 months, range 0.5-17.7 months), point estimates of VE in the subgroup analyses by age, comorbidity and frailty were generally consistent with VE of overall population based on the PPE Set (Table 2).

Table 2. Additional analysis of vaccine efficacy (VE) of mRESVIA to prevent first episode of RSV-LRTD (with 2 or more symptoms) 14 days post-injection up to 12 months post-injection by subgroups (per-protocol efficacy set)

Subgroup	mRESVIA Cases, n/N*	Placebo Cases, n/N*	VE, % (95% CI)
Overall	47/18 112	127/18 045	63.3 (48.7, 73.7)
Age group			
60 to 69 years	31/11 219	77/11 170	60.1 (39.5, 73.7)
70 to 79 years	10/5 464	45/5 439	78.0 (56.3, 88.9)
≥ 80 years	6/1 429	5/1 436	NA†
Comorbidities‡			
None (0)	31/12 751	76/12 796	59.5 (38.5, 73.4)
One or more (≥ 1)	16/5 361	51/5 249	69.3 (46.1, 82.5)
Frailty status			
Fit (0-3)	37/13 417	104/13 274	65.0 (49.0, 75.9)
Vulnerable/Frailty (≥ 4)	9/3 817	17/3 884	46.5 (-20.0, 76.2)

* Based on the number of participants in each subgroup.
† NA = not applicable due to low number of total cases accrued in this subgroup.
‡ Comorbidities included in this analysis were chronic cardiopulmonary conditions, including CHF, COPD, asthma and chronic respiratory conditions as well as diabetes, advanced liver, and advanced kidney disease.

As shortness of breath is associated with more severe RSV disease, an exploratory analysis was conducted. A total of 54 cases of RSV-LRTD with shortness of breath occurred: 43 in placebo recipients and 11 in mRESVIA recipients.

Pharmacokinetics

Absorption

Not applicable.

Distribution

Not applicable.

Metabolism

Not applicable.

Elimination

Not applicable.

Kinetics in specific patient groups

Renal impairment

No clinical studies have been conducted to investigate the effect of renal impairment.

Hepatic impairment

No clinical studies have been conducted to investigate the effect of hepatic impairment.

Preclinical data

Non-clinical data reveal no special hazards for humans based on conventional studies of repeat toxicity, genotoxicity and developmental and reproductive toxicity.

General toxicity

General toxicity studies were conducted in rats (intramuscularly with mRESVIA receiving up to two doses that exceeded the human dose, once every 3 weeks or intramuscularly receiving up to 4 dose administrations of related vaccine drug products once every 2 weeks). Transient and reversible injection site oedema and erythema and transient and reversible changes in laboratory tests (including increases in eosinophils, activated partial thromboplastin time, and fibrinogen) were observed. Results suggests the toxicity potential to humans is low.

Genotoxicity/carcinogenicity

In vitro and in vivo genotoxicity studies were conducted to evaluate the novel lipid component SM 102 of the vaccine. Results suggests the genotoxicity potential to humans is very low. Carcinogenicity studies were not performed.

Developmental and reproductive toxicity

In a combined developmental and reproductive toxicity study, mRESVIA was administered to female rats 4 times intramuscularly at 96 micrograms/dose (twice prior to mating [28 and 14 days prior] and twice after mating [on gestation days 1 and 13]). Anti-RSV antibodies were present in maternal animals from prior to mating to the end of the study on lactation day 21, as well as in foetuses and offspring, and maternal milk. There were no vaccine-related adverse effects on female fertility, pregnancy, embryo foetal or offspring development or postnatal development.

Other information

Incompatibilities

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

Shelf life

Do not use this medicine after the expiry date ("EXP") stated on the pack.

Special precautions for storage

Store in a freezer between -40°C to -15°C.
Keep the pre-filled syringes in the original carton in order to protect from light.
Keep out of the reach of children.

Storage conditions after thawing

Within the shelf life of 1 year at -40°C to -15°C, stability data indicate that the vaccine is stable for 30 days when stored at 2 °C to 8 °C and protected from light. At the end of 30 days, the vaccine should be used immediately or discarded.
Once thawed, the vaccine should not be refrozen.
Upon moving the vaccine to 2 °C to 8 °C storage, the outer carton should be marked with the new expiry date at 2 °C to 8 °C.
If the vaccine is received at 2 °C to 8 °C, it should be stored at 2 °C to 8 °C. The expiry date on the outer carton should have been marked with the new expiry date at 2 °C to 8 °C.
The pre-filled syringes may be stored at 8 °C to 25 °C for up to 24 hours after removal from refrigerated conditions. Within this period of time, pre-filled syringes may be handled in ambient light conditions. Do not refrigerate after being stored at 8 °C to 25 °C. Discard the syringe if not used within this time.
Transportation of thawed pre-filled syringes in the outer carton in liquid state at 2 °C to 8 °C
If transport at -40 °C to -15 °C is not feasible, available data support transportation of one or more thawed pre-filled syringes in liquid state at 2 °C to 8 °C (within the 30 days shelf life).
Once thawed and transported in liquid state at 2 °C to 8 °C, pre-filled syringes should not be refrozen and should be stored at 2 °C to 8 °C until use.

Instructions for handling

This medicinal product should be administered by a trained healthcare professional using aseptic techniques to ensure sterility.
Handling instructions for mRESVIA before use
The vaccine is ready to use once thawed.
Do not dilute the product.
Do not shake the pre-filled syringe before use.
The pre-filled syringe is for single use only.
Do not use if the pre-filled syringe has been dropped or damaged or the security seal on the carton has been broken.

mRESVIA is shipped and supplied either as a frozen or thawed pre-filled syringe (see section “Special Precautions for storage”). If the vaccine is frozen, it must be completely thawed before use. Thaw each pre-filled syringe before use, either in the refrigerator or at room temperature, following the instructions in Table 3.
Prior to immediate use, single blisters may be removed from a carton of 1 or 10 pre-filled syringes and thawed either in the refrigerator or at room temperature. The remaining blisters must continue to be stored in their original carton in the freezer or refrigerator.

Table 3. Thawing conditions and times based on pack size and temperature before use

Pack size	**Thaw instructions and durations**				
	Thaw in refrigerator	**Thaw duration (minutes)**		**Thaw at room temperature**	**Thaw duration (minutes)**
Carton or blister of 1 pre-filled syringe	2 °C to 8 °C	60	**or**	15 °C to 25 °C	45
Carton of 10 pre-filled syringes	2 °C to 8 °C	155		15 °C to 25 °C	140

- After thawing, the vaccine cannot be refrozen.
- If the vaccine has been thawed or stored in the refrigerator (2 °C to 8 °C), let each pre-filled syringe stand at 8 °C to 25 °C for between 10 to 20 minutes after removing from the refrigerator before administering.
- If the vaccine has been thawed at room temperature (15 °C to 25 °C), the pre-filled syringe is ready to administer. Syringes should not be returned to the refrigerator after being thawed at room temperature.
- The pre-filled syringes may be stored at 8 °C to 25 °C for a total of 24 hours after removal from refrigerated conditions. Within this period of time, pre-filled syringes may be handled in ambient light conditions. Discard the syringe if not used within this time.

Administration

- Remove a pre-filled syringe from the blister.
- The vaccine should be inspected visually for particulate matter and discolouration prior to administration. mRESVIA is a white to off-white dispersion. Do not administer if vaccine is discoloured or contains other particulate matter.
- With tip cap upright, remove tip cap by twisting counter-clockwise until tip cap releases. Remove tip cap in a slow, steady motion. Avoid pulling tip cap while twisting.

- The vaccine should be administered immediately after uncapping.
- Needles are not provided in the pack.
- Use a sterile needle of the appropriate size for intramuscular injection (21 gauge or thinner needles).
- Attach the needle by twisting in a clockwise direction until the needle fits securely on the pre filled syringe.
- Administer the entire dose intramuscularly.
- Discard the pre-filled syringe after use.

Disposal

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

Authorisation number

69995 (Swissmedic) mRESVIA dispersion for injection in pre-filled syringe

Packs

Pack-sizes:

1 pre-filled syringe per carton. The pre-filled syringe contains one dose of 0.5 ml [B].

10 pre-filled syringes per carton. Each pre-filled syringe contains one dose of 0.5 ml [B].

mRESVIA is supplied in a pre-filled syringe (polymeric barrel) with plunger stopper and a rubber tip cap (without needle).

Marketing authorisation holder

Moderna Switzerland GmbH, Basel

Date of revision of the text

April 2025