swissmedic

*Date:* 25 February 2026
Swissmedic, Swiss Agency for Therapeutic Products

# *Swiss Public Assessment Report*
## *Extension of therapeutic indication*

# 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:** | extension of therapeutic indication approved on 6 February 2026 |

**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) and information regarding procedure

**Extension(s) of the therapeutic indication(s)**
The applicant requested the addition of a new therapeutic indication or modification of an approved indication in accordance with Article 23 TPO.

**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 (RSV) in adults 18 through 59 years of age who are at increased risk for LRTD caused by RSV

### 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 (RSV) in adults 18 through 59 years of age who are at increased risk for LRTD caused by RSV

### 2.2.3 Requested dosage

**Summary of the requested standard dosage:**
No change to the dosage recommendation was requested with the application for extension of indication.

### 2.2.4 Approved dosage

(See appendix)

## 2.3 Regulatory history (milestones)

| | |
|---|---|
| Application | 10 October 2025 |
| Formal control completed | 17 October 2025 |
| Final decision | 6 February 2026 |
| Decision | approval |

Based on Art. 13 TPA 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 EMA. This SwissPAR relates to the assessment report mResvia (EMADOC-1700519818-2305287; Procedure No. EMA/VR/0000248175, published on 24 July 2025) issued by EMA.

## 3 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 EMA (see section 2.3 Regulatory history (milestones).

## 4 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.

# 5 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 0.017 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 (RSV) in:

- adults 60 years of age and older;
- adults 18 through 59 years of age who are at increased risk for LRTD caused by RSV.

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**

Use with other vaccine

mRESVIA can be administered concomitantly with:

- seasonal influenza vaccines, either standard dose or high dose unadjuvanted
- COVID-19 mRNA vaccine

**Pregnancy, lactation**

*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”). As a precautionary measure, it is preferable to avoid the use of mRESVIA during pregnancy.

*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 safety profile and the frequencies of adverse reactions presented below are based on data generated in two clinical studies: Study 1 in adults ≥ 60 years of age (n=18 245) and Study 2 in adults 18 through 59 years of age (n=502).

*Individuals 60 years of age and older*
In Study 1, which enrolled individuals 60 years of age and older, the most commonly reported adverse reactions were injection site pain (55.9%), fatigue (30.8%), headache (26.7%), myalgia (25.6%) 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.

*Individuals 18 through 59 years of age at increased risk for LRTD caused by RSV*
In Study 2, which enrolled individuals 18 through 59 years of age, the most commonly reported adverse reactions were injection site pain (73.9%), fatigue (36.9%), headache (33.3%), myalgia

(28.9%) and arthralgia (22.7%). Most solicited local and systemic adverse reactions had onset within 1 to 2 days after injection, and a median duration of 2 days.

Tabulated list of adverse reactions

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** | Very common | Nausea/vomiting[‡] |
| **Skin and subcutaneous tissue disorders** | Rare | Urticaria[§] |
| **Musculoskeletal and connective tissue disorders** | Very common | Myalgia<br>Arthralgia |
| **General disorders and administration site conditions** | Very common | Injection site pain<br>Fatigue<br>Chills |
| | Common | Pyrexia<br>Injection site erythema<br>Injection site swelling/induration |

| MedDRA system organ class | Frequency | Adverse reaction(s) |
|---|---|---|
| | Rare | Injection site pruritus |

* Lymphadenopathy was collected as “Axillary (underarm) swelling or tenderness ipsilateral to the side of injection”.
† In study 1, 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. In Study 2, one participant who had multiple confounding underlying medical conditions and received a lower dose of the investigational vaccine had an SAE of Bell’s palsy on Day 43 that was assessed by the investigator as related to injection.
‡ Reported as common in individuals 60 years of age and older (Study 1).
§ 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 1 – in individuals 60 years of age and older*

Study 1 (EUDRA CT number 2021-005026-20) is an ongoing phase 2/3 randomised, observer-blind, placebo controlled, pivotal study conducted in 22 countries in Central and Latin America, Africa, Asia Pacific, North America and Europe. The study evaluated the safety and efficacy of a single dose of mRESVIA for the prevention of RSV-LRTD in adults ≥ 60 years with or without underlying medical conditions.

The primary efficacy analysis population (per-protocol efficacy set) included 35 088 participants who received either mRESVIA (n=17 572) or placebo (n=17 516). Among all participants, 50.9% were male, 63.5% were White,12.2% were Black or African American, 8.7% were Asian, and 34.6% were Hispanic or Latino.

The median age was 67 years (range: 60-96), with 63.5% aged 60-69, 30.9% aged 70-79 and 5.5% aged ≥ 80 years. 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. A total of 21.8% scored “vulnerable” or “frail” according to Edmonton Frail Scale.

The primary efficacy endpoints were the prevention of a first episode of RSV-LRTD with ≥ 2 or ≥ 3 symptoms, occurring between 14 days and 12 months post injection. RSV-LRTD was defined as reverse transcription polymerase chain reaction (RT PCR) confirmed RSV infection and radiologic evidence of pneumonia or experienced new or worsening of ≥ 2 of predefined symptoms ≥ 24 hours including shortness of breath, cough and/or fever, wheezing, sputum production, tachypnoea, hypoxemia and pleuritic chest pain.

The primary efficacy endpoints were 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%) against RSV-LRTD as defined by ≥ 2 symptoms. The other primary efficacy endpoint against RSV-LRTD defined by ≥ 3 symptoms was also met, with a VE of 82.4% (96.36% CI: 34.8%, 95.3%). 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 (range: 0.5 to 17.7 months) of follow-up. A single dose of mRESVIA met the same criterion as defined in the primary analysis for the prevention of RSV-LRTD with ≥ 2 symptoms (see Table 2). The vaccine efficacy against RSV-LRTD with ≥ 3 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, 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.

*Study 2 – in individuals 18 through 59 years of age at increased risk for LRTD caused by RSV*

Study 2 is a phase 3 randomised, double-blind trial to evaluate the immunogenicity and safety of mRESVIA in individuals 18 through 59 years of age at increased risk for LRTD caused by RSV. The clinical study was conducted in the US, Canada and United Kingdom.

Eligible participants enrolled in the study had at least one of the conditions that increased their risk for developing RSV-LRTD. Of the 494 participants in the Per-Protocol (PP) Set, diabetes mellitus (DM) was reported in 59.7%, persistent asthma in 38.1%, coronary artery disease (CAD) in 20.9%, chronic obstructive pulmonary disease (COPD) in 10.1%, congestive heart failure (CHF) in 8.9%, and chronic respiratory disease other than COPD or asthma in approximately 2.4%. Additionally, 63.6% of participants had a BMI of 30 kg/m² or higher, indicating a significant prevalence of obesity within the study population.

The median age was 53 years (range: 19-59). Most participants were White (80.2%), 53.6% were female and 27.5% of participants were Hispanic or Latino.

Efficacy of mRESVIA in this population was inferred by comparison of RSV neutralising antibody (nAb) levels at Day 29 post-vaccination to those in a subset of Study 1 participants ≥ 60 years of age. Non-inferiority was demonstrated for the nAb geometric mean titres (GMTs) for RSV A and RSV B [Study 2 PP/Study 1 Per-Protocol Immunogenicity (PPI) subset; lower bound of the 2-sided 95% CI of the geometric mean ratio (GMR) > 0.667].

**Table 3: Day 29 nAb GMT and GMR (nAb against RSV-A and RSV-B) from Study 2 (individuals 18 through 59 years of age at increased risk for LRTD caused by RSV) and Study 1 (individuals 60 years of age and older)**

| | mRESVIA Study 2 - (PP set) (N=494) | | | mRESVIA Study 1 - (PPI set) (N=1 515) | | | Study 2 versus Study 1 | |
|---|---|---|---|---|---|---|---|---|
| **nAb titre (IU/mL)** | **N1** | **Model-based GMT[a]** | **95% CI** | **N1** | **Model-based GMT[a]** | **95% CI** | **Adjusted GMR** | **95% CI** |
| RSV-A | 492 | 23 245 | 21 326, 25 336 | 1 513 | 19 988 | 19 038, 20 985 | 1.163 | 1.053, 1.285 |
| RSV-B | 489 | 7 831 | 7 242, 8 467 | 1 511 | 6 901 | 6 603, 7 213 | 1.135 | 1.037, 1.242 |

CI=confidence interval; GMT=geometric mean titre; GMR=geometric mean ratio; LRTD=lower respiratory tract disease; nAb=neutralising antibody; PP=Per-Protocol; PPI=Per-Protocol Immunogenicity; RSV-A=respiratory syncytial virus subtype A; RSV-B= respiratory syncytial virus subtype B.
N1 = Number of participants with non-missing antibody data at baseline (Day 1) and Day 29.
[a] The model-based GMT is estimated on Analysis of covariance (ANCOVA) model.

**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, 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 then be stored at 2 °C to 8 °C. The use by date corresponding to these storage conditions would be marked on a label on the carton. Please note in that case the expiration date (“EXP”) printed on the outer carton and on the pre-filled syringe for storage between -40°C to -15°C is not pasted over.
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 4.
Prior to immediate use, single blisters or pre-filled syringes 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 or syringes must continue to be stored in their original carton in the freezer or refrigerator.

**Table 4. Thawing conditions and times based on pack size and temperature before use**

| **Pack size** | **Thaw instructions and durations** | | | | |
|---|---|---|---|---|---|
| | **Thaw temperature (in refrigerator)** | **Thaw duration** | | **Thaw temperature (at room temperature)** | **Thaw duration** |
| 1 pre-filled syringe in carton | 2 °C to 8 °C | 100 min | **or** | 15 °C to 25 °C | 40 min |
| 10 pre-filled syringes in carton | 2 °C to 8 °C | 160 min | | 15 °C to 25 °C | 80 min |
| 1 pre-filled syringe (removed from carton) | 2 °C to 8 °C | 100 min | | 15 °C to 25 °C | 40 min |

- After thawing, the vaccine cannot be refrozen.
- If the vaccine has been thawed, the pre-filled syringe is ready to administer. Syringes should not be returned to the refrigerator after 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 or tray.
- 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.
- Canulas are not provided in the pack.
- Use a sterile canula of the appropriate size for intramuscular injection (21 gauge or thinner canulas).
- Attach the canula by twisting in a clockwise direction until the canula 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 canula).

**Marketing authorisation holder**

Moderna Switzerland GmbH, Basel

**Date of revision of the text**

February 2026