

IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

PA0544/002/001

Case No: 2032529

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Sanofi Pasteur MSD Ltd

Block A, Second Floor, Cookstown Court, Old Belgard Road, Tallaght, Dublin 24, Ireland

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Rubavax Powder and Solvent for Solution for Injection, Rubella Vaccine, Live

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **25/01/2007** until **12/07/2009**.

Signed on behalf of the Irish Medicines Board this

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rubavax
Powder and Solvent for Solution for Injection
Rubella Vaccine, Live

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.5 millilitre dose contains:

Active ingredients:
Live attenuated Rubella virus (Wistar RA 27/3M strain) containing 1000 TCID₅₀

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder and solvent for solution for injection.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For active immunisation against rubella.

4.2 Posology and method of administration

Administer by intramuscular or deep subcutaneous injection.

Adults, children and the elderly

Single dose of 0.5 millilitre of the reconstituted vaccine. Rubavax is intended for administration to girls of 10-14 years and non-pregnant women of child bearing age who are sero-negative.

Infants less than 12 months of age

Not recommended.

4.3 Contraindications

Rubavax must not be administered to any women who are pregnant or suspected to be pregnant. Following its administration, pregnancy must be avoided for at least three months.

Rubavax should not be given in the presence of acute infectious disease, or currently evolving acute or chronic disease.

It is contra-indicated in states of altered immunity including malignancy, leukaemia, lymphoma or in those receiving corticosteroids, cytotoxic drugs or irradiation.

The vaccine contains traces of neomycin and should not be given to those known to be hypersensitive to this antibiotic.

Rubavax must not be given to those who previously have had severe reactions to rubella vaccine.

4.4 Special warnings and precautions for use

Immunisation should be deferred for at least 3 months following a blood or plasma transfusion or the administration of human immunoglobulin. If the vaccine is given within 3 months of human immunoglobulin, revaccination should be considered. Other live vaccines may be given simultaneously at different sites or with an interval of three weeks between vaccines.

Although anaphylaxis is extremely rare, remedial facilities such as a solution of 1:1000 Epinephrine (adrenaline) should always be available during immunisation.

Avoid contamination with bactericides.

4.5 Interaction with other medicinal products and other forms of interaction

The vaccine is rapidly inactivated by ether, alcohol and detergents and therefore care must be taken with any skin cleaning technique to avoid contact with these substances.

4.6 Pregnancy and lactation

The vaccine must never be given to a pregnant woman. Pregnancy must be avoided for at least three months following vaccination.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Adverse reactions are usually mild and transient: slight fever, malaise, sore throat, erythema, induration or pain at the site of injection. Regional lymphadenopathy, rubella-like rash, pharyngitis, arthralgia, and arthritis have been reported. Transient joint symptoms are more common in women than young girls. Neurological symptoms, thrombocytopaenia and allergic reactions (urticarial rash, oedema) have been reported rarely following the administration of rubella vaccine.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not applicable.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Neomycin sulphate
Human Albumin
Solvent: Water for injections

6.2 Incompatibilities

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

6.3 Shelf Life

24 months between +2°C and +8°C.
Use immediately after reconstitution.

6.4 Special precautions for storage

Store between +2°C and +8°C.
Do not freeze.
Protect from light.

6.5 Nature and contents of container

Lyophilised vaccine: - single dose type I glass (Ph.Eur.) vial with elastomer stopper and flip-off overcap.
Solvent: - 1 millilitre disposable syringe Type I glass (Ph.Eur.) with elastomer needle-shield.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

The vaccine should be reconstituted with the supplied solvent prior to administration. Dispose of residues safely in accordance with local regulations.

7 MARKETING AUTHORISATION HOLDER

Sanofi Pasteur MSD
Block A, Second Floor
Cookstown Court
Old Belgard Road,
Tallaght,
Dublin 24.

8 MARKETING AUTHORISATION NUMBER

PA 544/2/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13 July 1989

Date of last renewal: 13 July 2004

10 DATE OF REVISION OF THE TEXT

January 2007