

BELGIUM

Manufacturer: **SMITHKLINE BEECHAM PHARMACEUTICALS**
89 rue de l'Institut
B-1330 Rixensart

Telephone: 32 2 656 8754
Fax: 32 2 656 9034
Telex: 63251 SB BIO B

Type of vaccine: Rubella, RA 27/3 strain Freeze dried; for subcutaneous injection Min 1000 CCID 50 / dose (0.5 ml of reconstituted vaccine)

Proprietary name: Ervevax (Registered) RA 27/3

Available packaging: Vials of 1, 10 doses+ diluent; individually packed or in bulk packs of 25, 50, 100 units.

Delivery time: vials of 1 dose x 1:6 weeks-Vials of 1 dose x 25: 4 weeks: vials of 1 dose x100: 4 weeks-Vials of 10 doses x 50: 6 weeks

Recommended storage temperature: 2-8 deg C, avoid heat and light, may be frozen at -20 deg C

Shelf life: Freeze dried: 2 yrs. Reconstituted: 8 hrs. Vaccine @ 2-8 deg.

Stability: Freeze dried vaccine: 2 years at 2-8 deg C, 10 weeks at +20 deg C/+25 deg C, 4 weeks at 37 deg. C; 7 days at 45 Deg C

Other remarks: These data give an indication of the stability of the vaccine and are not storage recommendations

Vaccine exportation: Yes

Production capacity:

Stability at 8 ° C: 2 years

Stability at 37 ° C: 4 weeks

BULGARIA

Manufacturer: **MA - RESEARCH INSTITUTE OF INFECTIOUS
AND PARASITIC DISEASES**
Bl.'Vl. Zaimov' 26
1050 Sofia

Telephone: 43 - 471

Fax:

Telex:

Type of vaccine: Rubella Vaccine live Freeze dried

Proprietary name:

Available packaging:

Delivery time:

Recommended storage
temperature:

Shelf life:

Stability:

Other remarks:

Vaccine exportation:

Production capacity:

Stability at 8 ° C:

Stability at 37 ° C:

CROATIA

Manufacturer: **INSTITUTE OF IMMUNOLOGY**
Rockefellerova 2
41000 Zagreb

Telephone: 385 1 430 333
Fax: 385 1 277 278
Telex: 21864 VACC HR

Type of vaccine: Rubella Vaccine (RA 27/3 HDC) , live, freeze dried

Proprietary name: ZARUVAX

Available packaging: 1 box/50 vials/1 dose + diluent; 1 box/50 vials/5 doses + diluent; 1 box/50 vials /10 doses + diluent; 1 box/1 vial/1 dose + diluent

Delivery time: 3 months (smaller quantities could be delivered immediately)

Recommended storage temperature: 2 - 8 degrees C

Shelf life: 2 years

Stability: Satisfies WHO Requirements

Other remarks: One dose of 0.5 ml of reconstituted vaccine contains not less than 1000 TCID₅₀ of rubella virus.

Vaccine exportation: Yes

Production capacity: 150 000 vials/year

Stability at 8 ° C: Loss of potency (log 10) at expire date: 0.1

Stability at 37 ° C: Loss of potency (log 10) after 7 days: 0.50

FRANCE

Manufacturer: PASTEUR -MERIEUX VACCINS & SERA
17 rue Bourgelat
69002 Lyon

Telephone: 78 73 77 07
Fax: 310627 IM LYON
Telex:

Type of vaccine: Vaccin a virus vivant attenué contre la rubeole et vaccin diphtérique et tétanique de rappel

Proprietary name: D.T. BIS - RUDIVAX

Available packaging: Boîte de 1 flacon de 1 dose de vaccin lyophilisé Rudivax + 1 seringue contenant le D.T. Bis et servant de solvant

Delivery time: Entre 2 et 4 semaines en fonction de la quantité

Recommended storage temperature: Entre 2 et 8 degrés C

Shelf life: 18 mois

Stability: A condition de respecter les normes de conservation

Other remarks: RUDIVAX: La dose unitaire de vaccin rubéolique sous forme lyophilisée renferme au moins 1000 DICT50 de virus

Vaccine exportation:

Production capacity:

Stability at 8 ° C:

Stability at 37 ° C:

FRANCE

Manufacturer: **PASTEUR -MERIEUX VACCINS & SERA**
17 rue Bourgelat
69002 Lyon

Telephone: 78 73 77 07
Fax: 310627 IM LYON
Telex:

Type of vaccine: Vaccin a virus vivant attenué contre la rubeole,
souche Wistar RA 27/3, cultivé sur diploïdes
humaines

Proprietary name: RUDIVAX

Available packaging: 4 options. See 'Other remarks' *

Delivery time: Entre 2 et 4 semaines en fonction de la quantité

Recommended storage
temperature: Entre 2 - 8 degrés C

Shelf life: 2 ans

Stability: A condition de respecter les normes de
conservation

Other remarks: La dose unitaire de vaccin sous forme lyophilisée
renferme: au moins 1000 DICT 50 de virus vivant
attenué de la

Vaccine exportation:

Production capacity:

Stability at 8 ° C:

Stability at 37 ° C:

INDIA

Manufacturer: **SERUM INSTITUTE OF INDIA LTD.**
212/2, Hadapsar
Pune - 411028

Telephone: 91 212 672016
Fax: 91 212 672040
Telex: 145 7317 SERA IN/145 7216 SEAL IN

Type of vaccine: Rubella Vaccine live B.P. RUC/VAC (LIVE)

Proprietary name: R-VAC (Lyophilised)

Available packaging: 0.5 ml single dose vial supplied with sterile diluent

Delivery time: Ex-Stock

Recommended storage temperature: 2 - 8 degrees C

Shelf life: 2 years

Stability: Stable under recommended storage conditions

Other remarks:

Vaccine exportation: No

Production capacity: 2 million doses

Stability at 8 ° C: 30 months

Stability at 37 ° C: 14 days

ITALY

Manufacturer: **BIOCINE; Director of Regulatory Compliance**
Via Fiorentina, 1
53100 Siena

Telephone: (0577) 243111
Fax: 0577 243 074
Telex: 573479 BIOCIN I

Type of vaccine: Rubella Virus Vaccine, Live, Attenuated Freeze dried preparation

Proprietary name: GUNEVAX®

Available packaging: 0.5 ml vial (1 dose) + 0.5 ml amp. of diluent; 5 ml vial (10 doses) + 5 ml amp. of diluent

Delivery time: 6 - 8 weeks

Recommended storage temperature: 2 - 8 degrees C

Shelf life: 2 years

Stability: Stable under recommended storage conditions

Other remarks:

Vaccine exportation: yes

Production capacity: highly flexible, depending on requirements

Stability at 8 ° C: 2 years

Stability at 37 ° C: 7 days

JAPAN

Manufacturer: **THE CHEMO-SERO-THERAPEUTIC RESEARCH
INST. General Manager of Human Vaccine
Department
668 Okubo, Shimizu
Kumamoto 860**

Telephone: 81 96 345 6500
Fax: 81 96 344 9269
Telex: KUMAMOTO KAKETSUKEN CSTI J

Type of vaccine: Freeze-dried Live Attenuated Rubella Vaccine

Proprietary name: Rubella Vaccine Kaketsuken

Available packaging: 1 dose / vial; 1x vial of diluent; 5 x single dose vial;
5x vial of diluent

Delivery time: 150 days when bulk materials in store, depends on
quantities

Recommended storage
temperature: 5 degrees C or lower away from light, avoid
freezing of diluent to prevent breakage of the vial.

Shelf life: 1 year from the following day of state validation

Stability: 18 months at 5 degrees C; 6 months at 20 degrees

Other remarks:

Vaccine exportation: No

Production capacity: 1 million doses/year

Stability at 8 ° C: Not performed

Stability at 37 ° C: 10 weeks

JAPAN

Manufacturer: **THE KITASATO INSTITUTE**
5-9-1 Shirogane, Minato-ku
Tokyo 108

Telephone: 03 3444 6161

Fax: 03 3444 6316

Telex: 242 3738 KUL IB

Type of vaccine: Rubella Vaccine, live attenuated, freeze dried

Proprietary name:

Available packaging:

Delivery time:

Recommended storage
temperature:

Shelf life:

Stability:

Other remarks:

Vaccine exportation:

Production capacity:

Stability at 8 ° C:

Stability at 37 ° C:

JAPAN

Manufacturer: **THE RESEARCH FOUNDATION FOR
MICROBIAL DISEASES OF OSAKA UNIVERSITY**
3-1 Yamada-Oka, Suita
Osaka

Telephone: 06 (877) 5121
Fax: 06 876 1984
Telex: BIKEN-ZAIDAN SUITA JAPAN

Type of vaccine: Live Attenuated Rubella Vaccine freeze dried

Proprietary name: Rubella Virus Vaccine 'BIKEN' Live Attenuated

Available packaging: 1 dose / vial x 5

Delivery time: depends on quantities

Recommended storage temperature: 5 degrees C or lower

Shelf life: 1 year

Stability:

Other remarks:

Vaccine exportation: No

Production capacity: Not less than 7,000,000 doses/year

Stability at 8 ° C: Titer loss at 5°C for 24 months: -0.1(log)

Stability at 37 ° C: Titer loss at 37°C for 7 days:<-0.2 (log)

SWITZERLAND

Manufacturer:	SWISS SERUM AND VACCINE INSTITUTE BERNE P.O. Box 2707 <u>CH-3001 Berne</u>
	Telephone: 41 31 980 6 111 Fax: 41 31 980 6 775 Telex: 912 618
Type of vaccine:	Live vaccine for active immunization against rubella (Wistar RA 27/3 strain)
Proprietary name:	Rubeaten Berna
Available packaging:	Vial of lyophilized vaccine + solvent - containing syringe 1 vaccination. Vial of lyophilized vaccine + solvent 1, 10 x 1 vaccination, 50 x 1 vaccination, 10 vaccinations; 50 x 10 vaccinations
Delivery time:	A few days to several weeks
Recommended storage temperature:	2 - 8 degrees C
Shelf life:	2 years
Stability:	Stable under recommended storage conditions
Other remarks:	Since Rubeaten Berna contains no avian proteins, nor antibiotics, this vaccine is also suitable for people who are sensitized to such components
Vaccine exportation:	Yes
Production capacity:	upon demand
Stability at 8 ° C:	2 years
Stability at 37 ° C:	

SWITZERLAND

Manufacturer: **SWISS SERUM AND VACCINE INSTITUTE
BERNE
P.O. Box 2707
CH-3001 Berne**

Telephone: 41 31 980 6 111
Fax: 41 31 980 6 775
Telex: 912 618

Type of vaccine: Human Rubella Immunoglobulin Liquid

Proprietary name: Rubeuman Berna

Available packaging: Vial of 5 ml = 30, 000 I.U.

Delivery time: A few days to several weeks

Recommended storage temperature: 2 - 8 degrees C

Shelf life: 3 years

Stability: Stable under recommended storage conditions

Other remarks:

Vaccine exportation: Yes

Production capacity: upon demand

Stability at 8 ° C: 3 years

Stability at 37 ° C:

UNITED KINGDOM

Manufacturer: **EVANS MEDICAL LTD**
Biological Drive
Speke, Liverpool L24

Telephone: 01-658-2211
Fax: WELLAB 23937
Telex: WELLAB BECKENHAM

Type of vaccine: Rubella Vaccine, Live BP. Wistar RA 27/3 Strain,
(Human Diploid) Freeze-dried

Proprietary name: ALMEVAX

Available packaging: 1 dose, 10 dose, 50 dose + diluent

Delivery time: Subject to requirement

Recommended storage temperature: 2 - 8 degrees C

Shelf life: 2 years

Stability: Stable under recommended storage conditions

Other remarks:

Vaccine exportation:

Production capacity:

Stability at 8 ° C:

Stability at 37 ° C:

