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Front

For Pharmacode

VERORAB
PURIFIED INACTIVATED RABIES VACCINE, PREPARED ON VERO CELLS

COMPOSITION
After reconstitution, 1 dose (0.5 mL) contains:
Rabies virus*, WISTAR Rabies PM/WI38 1503-3M strain (inactivated) 3.25 IU**
* Produced in VERO cells
** Quantity measured according to the ELISA test against the international standard (corresponds to ≥ 2.5 IU in the NIH test)

List of excipients
Powder:
- Maltose
- 20% Human albumin solution
- Basal Medium Eagle (mixture of mineral salts including potassium, vitamins, dextrose and amino-acids including L-Phenylalanine)
- Water for injections
- Hydrochloric acid and sodium hydroxide for pH adjustment

Solvent:
- Sodium chloride
- Water for injections

PHARMACEUTICAL FORM
Powder and diluent for suspension for injection.
Before reconstitution, the powder is a white and homogeneous pellet. The solvent is a clear and colorless solution.

THERAPEUTIC INDICATIONS
This medicinal product is a vaccine.
Pre-exposure
This vaccine is recommended for the prevention of rabies in subjects at a high risk of exposure. All subjects at a permanent risk, such as diagnostic, research and production laboratory staff working on rabies virus, should be vaccinated. A serological test is recommended every 6 months. A booster injection should be administered when the antibody titre is below the level considered to guarantee protection: 0.5 IU/mL. The following categories should be vaccinated given the frequency of exposure to the risk:
- Veterinarians (and assistants), gamekeepers, hunters, forest rangers, slaughterhouse personnel, cavers, taxidermists.
- Subjects exposed enzootic areas: children, adults and travelers visiting these areas.

Post-exposure
- After confirmed or suspected exposure, vaccination must be started immediately at the risk of contamination with rabies. It must be performed in a rabies treatment centre. The treatment is adapted to the type of wound and the status of the animal.

POSOLOGY AND METHOD OF ADMINISTRATION
Posology
Once the vaccine is reconstituted with 0.5 mL of solvent, one intramuscular (IM) dose consists of 0.5 mL of reconstituted vaccine and one intradermal (ID) dose consists of 0.1 mL of reconstituted vaccine per injection site.
Pre-exposure prophylaxis
For pre-exposure immunization, individuals can be vaccinated according to the vaccination schedules presented in Table 1 and according to official local recommendations when available.

Table 1: Pre-exposure vaccination schedules

	D0	D7	D21 or D28
Conventional regimen IM route - 0.5 mL	1 dose	1 dose	1 dose

Booster injection 1 year later
Booster injections every 5 years

Post-exposure prophylaxis
Post-exposure prophylaxis includes local non-specific treatment of the wound, vaccination and, where appropriate, passive with rabies immunoglobulins.
Post-exposure prophylaxis should be initiated as soon as possible after suspected exposure to rabies. In all cases, proper wound care (careful washing of all bites and scratches with soap or detergent and copious amounts of water and/or virucidal agents) must be performed immediately or as soon as possible after exposure. It must be performed before administration of vaccine or rabies immunoglobulins, when they are indicated. Post-exposure prophylaxis should be adjusted to the exposure category, the condition of the animal (see Table 3) and the vaccination status of the patient, in accordance with official recommendations (see Table 2, WHO recommendations).
Post-exposure prophylaxis should be performed as soon as possible after exposure under medical supervision and only at rabies treatment center. If necessary, post-exposure prophylaxis can be supplemented by tetanus prophylaxis and antibiotic therapy to prevent the development of infections other than rabies.

Table 2: WHO Guide for post-exposure prophylaxis depending on severity of exposure (to be adapted according to local official recommendations).

Exposure category	Type of exposure to a domestic or wild animal suspected or confirmed to be rabid or animal not available for testing	Recommended post-exposure prophylaxis
I	Touching or feeding of animals Licks on intact skin (no exposure)	None, if reliable case history is available[a]
II	Nibbling of uncovered skin Minor scratches or abrasions without bleeding (exposure)	Administer vaccine immediately. Discontinue treatment if the animal is in good health after the 10 days observation period[b] or if the rabies test performed using appropriate laboratory method is negative. Treat as category III if bat exposure involved.
III	Single or multiple transdermal bites [c] or scratches, licks on broken skin or contamination of mucous membranes with saliva (licks), exposure to bats (severe exposure).	Administer the vaccine immediately and rabies immunoglobulin, preferably as soon as possible after initiation of post-exposure prophylaxis. Rabies immunoglobulins can be injected up to 7 days after the first dose of vaccine is administered. Discontinue treatment if animal is in good health after the 10-day observation period[b] or if the rabies test performed using appropriate laboratory methods is negative.

a. If the animal is an apparently healthy dog or cat living in a low-risk area and placed under veterinary observation, treatment may be postponed (see Table 3).
b. This observation period applies only applies to cats and dogs. With the exception of endangered or threatened species, domestic animals and wild animals suspected to have rabies should be euthanised and their tissues examined using appropriate laboratory methods (see Table 3).
c. Bites, particularly to the head, neck, face, hands and genitals are classified as Category III exposure due to the extensive innervation of these parts of the body

Table 3: Course of action after exposure depending on the condition of the animal (WHO recommendations to be adapted according to local recommendations)

Circumstances	Course of action regarding		Comments
	The animal	The patient	
Animal unavailable **Suspect or non-suspect circumstances**		To be taken to a rabies centre for treatment.	Treatment [(b)] is always completed.
Dead animal **Suspect or non-suspect circumstances**	Send the brain to an approved laboratory for analysis.	To be taken to a rabies centre for treatment.	Treatment [(b)] is discontinued if the tests are negative or, otherwise, continued.
Live animal **Non-suspect circumstances**	Place under veterinary supervision [(a)].	Postpone rabies treatment.	Treatment [(b)] is continued according to the results of veterinary supervision of the animal.
Live animal **Suspect circumstances**	Place under veterinary supervision [(a)].	To be taken to a rabies centre for treatment.	Treatment [(b)] is discontinued if veterinary supervision invalidates initial doubts, or, otherwise, continued.

a) In France, veterinary supervision includes 3 certificates, drawn up at D0, D7, and D14, declaring the absence of signs of rabies. According to WHO recommendations, the minimum observation period under veterinary supervision for dogs and cats is 10 days.
(b) Treatment is recommended depending on the seriousness of the wound: see Table 2.

Post-exposure prophylaxis of previously non-immunised subjects
Individuals not previously immunized can be vaccinated according to one of the vaccination schedules presented in Table 4:

Table 4: Post-exposure vaccination schedules in previously non-immunized subjects

	D0	D3	D7	D14	D21	D28
Essen regimen IM route - 0.5 mL	1 dose	1 dose	1 dose	1 dose		1 dose
Zagreb regimen IM route - 0.5 mL	2 doses[a]		1 dose		1 dose	
Updated Thai Red Cross regimen ID route - 0.1 mL	2 doses[b]	2 doses[b]	2 doses[b]			2 doses[b]
One week, four-site regimen ID route - 0.1 mL	4 doses[c]	4 doses[c]	4 doses[c]			

a – one injection in each of the two deltoids (for adults and children) or anterolateral thigh sites (infants and toddlers)
b – to be injected in 2 distinct sites, if possible contralaterally.
c – to be injected in 4 distinct sites

Immunogenicity and safety data in children < 2 years old are limited (see section on clinical studies).
Whatever the regimen used, vaccination must not be discontinued unless the contact animal is declared free from rabies after veterinary supervision (see Table 3).
Rabies immunoglobulins should be administered concomitantly with the vaccine, in case of category III exposure (WHO classification, see Table 2). If possible, the vaccine should be administered contralaterally to the immunoglobulin administration sites.

Refer to the Summary of Characteristics of the rabies immunoglobulins used.

In enzootic areas, the severity of certain exposures due to the severity of the lesions and/or location (proximity of the central nervous system), a late consultation or immune deficiency of the subject may justify, depending on the case, 2 injections on D0.

Post-exposure prophylaxis of previously immunized subjects
In accordance with official recommendations, this applies to subjects who have already received pre-exposure prophylaxis or post-exposure prophylaxis or who discontinued post-exposure prophylaxis after receiving at least two doses of vaccine prepared in cell culture.
These individuals should receive one dose of vaccine intramuscularly (vaccine dose 0.5 mL) or intradermally (vaccine dose 0.1 mL) on each of days 0 and 3.
Rabies immunoglobulin is not indicated for previously immunized individuals.

Paediatric population
Children should receive the same doses as adults.

Method of administration
Precautions to be taken before handling or administering the medicinal product.
The vaccine is administered via the intramuscular route, in the anterolateral region of the thigh muscle in infants and young children and in the deltoid muscle in older children and adults.
It can also be administered by intradermal (ID) route preferably on upper arm or forearm. Do not inject in the buttocks region.
Do not inject via the intravascular route.
For instructions on reconstitution of the medicinal product before administration, see Special Precautions for Disposal and other Handling

CONTRAINDICATIONS
Pre-exposure prophylaxis
Hypersensitivity to the active substance(s) or to any of the excipients listed, to polymyxin B, to streptomycin, to neomycin or to any antibiotic of the same class to a previous administration or to any vaccine containing the same components.
Vaccination should be postponed in case of febrile or acute diseases.

Post-exposure prophylaxis
Given the always-fatal outcome of the declared rabies infection, there are no contraindications to post-exposure vaccination.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE
Special warnings
As with all vaccines, VERORAB may not protect 100% of people vaccinated.
Use with caution in people with known allergies to polymyxin B, to streptomycin, to neomycin (present as traces in the vaccine) or to any antibiotic of the same class.

Precautions for use
- Injection-schedule recommendations should be followed scrupulously. The need for serological tests (to assess seroconversion in subjects) should be determined in accordance with official recommendations.
- When the vaccine is administered in subjects with known immunodeficiency, due to an immunosuppressive disease or a concomitant immunosuppressive treatment (including corticosteroids), blood tests must be performed 2 to 4 weeks after vaccination to ensure that a protective immunising response was obtained. In case of post-exposure vaccination, a complete vaccination regimen must be administered. Rabies immunoglobulins should also be administered concomitantly with the vaccine in the event of any category II or III exposure (see section POSOLOGY AND METHOD OF ADMINISTRATION).
- Do not inject via the intravascular route: make sure the needle does not penetrate a blood vessel.
- As with all injectable vaccines, appropriate medical treatment and supervision must be readily available in case of a rare anaphylactic reaction after vaccine administration, particularly in case of post-exposure in subjects with a known hypersensitivity to polymyxin B, to streptomycin, to neomycin or to any antibiotic of the same class.
- As with all injectable vaccines, VERORAB should be administered with caution in subjects with thrombocytopenia or coagulation disorders as intramuscular injection may induce bleeding in these subjects.
- Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions can occur following, or even before, any vaccination as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance and paraesthesia. It is important that procedures are in place to avoid injury from faints.

Paediatric population
The potential risk of apnoea and the need for respiratory monitoring for 48-72 h should be considered when administering the primary immunization series to very premature infants (born ≤ 28 weeks of gestation) and particularly for those with a previous history of respiratory immaturity. As the benefit of vaccination is high in this group of infants, - vaccination should not be withheld or delayed. If there is any doubt, do not hesitate to consult your doctor or your pharmacist. Keep out of the reach of children.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION
Immunosuppressive treatments, including long-term systemic corticosteroid therapy, may interfere with the production of antibodies and lead to vaccination failure. It is therefore recommended to perform a serological test 2 to 4 weeks after the last injection (see section POSOLOGY AND METHOD OF ADMINISTRATION).
Verorab may be administered concomitantly with a Vi polysaccharide typhoid vaccine during the same vaccination visit, using two different injection sites.
Rabies immunoglobulins and vaccine must never be combined in the same syringe or administered at the same site.
Given that rabies immunoglobulins interfere with the development of the immune response to the rabies vaccine, the recommendations for administration of rabies immunoglobulins should be strictly followed.

FERTILITY, PREGNANCY AND LACTATION
Pregnancy
The vaccine has not been the subject of animal teratogenicity studies.
Pre-exposure vaccination.
In the absence of sufficient human data, it is recommended to postpone

VERORAB
PURIFIED INACTIVATED RABIES VACCINE, PREPARED ON VERO CELLS

NAMA PRODUK OBAT DAN SEDIAAN FARMASI
VERORAB, *Purified inactivated rabies vaccine, Prepared on vero cell*
Suspensi serbuk dan pelarut untuk injeksi. Sebelum rekonstitusi, serbuk berwarna putih dan homogen. Pelarut berupa larutan bening dan tidak berwarna.

KOMPOSISI
Setelah rekonstitusi, 1 dosis (0,5 mL) mengandung:
Rabies virus*, WISTAR Rabies PM/WI38 1503-3M strain (inactivated) 3.25 IU**
* Produced in VERO cells
** Quantity measured according to the ELISA test against the international standard (corresponds to ≥ 2.5 IU in the NIH test)

Komponen zat tambahan
Serbuk:
- Maltosa
- 20% larutan albumin manusia
- Basal Medium Eagle (campuran garam mineral termasuk potasium, vitamin, dekstrosa dan asam amino termasuk L-Phenylalanine)
- Air untuk injeksi
- Asam hidroklorida dan natrium hidroksida untuk pengatur pH

Pelarut:
- Natrium klorida
- Air untuk injeksi

INDIKASI
Pra-paparan
Vaksin dianjurkan untuk pencegahan pada individu yang berisiko tinggi tertular rabies. Semua individu yang mempunyai risiko yang permanen di antaranya, pegawai laboratorium (bagian produksi, penelitian & diagnosa) yang besar kemungkinan terkontaminasi virus rabies, seharusnya mendapat vaksin rabies.
Test serologi dianjurkan setiap 6 bulan sekali. Dosis penguat diberikan ketika titer antibodi di bawah level perlindungan maksimum: 0,5 IU/mL.
Kategori berikut yang harus divaksin rabies mengingat frekuensi dari risiko terpapar:
- Dokter hewan (dan asisten), penjaga perburuan, pemburu, penjaga hutan, tukang jagal, *cavers*, orang yang menguliti binatang.
- Individu di area endemis rabies: anak-anak, dewasa, dan wisatawan yang berkunjung ke daerah endemis rabies.

Pasca-paparan
Setelah yakin atau dicurigai terpapar, vaksinasi harus segera dimulai pada risiko terkecil untuk terkontaminasi rabies. Harus dilakukan di pusat perawatan rabies.

POSOLOGI DAN CARA PEMBERIAN
Posologi
Setelah vaksin dilarutkan dengan 0,5 mL pelarut, satu dosis intramuskular (IM) terdiri dari 0,5 mL vaksin yang dilarutkan dan satu dosis intradermal (ID) terdiri dari 0,1 mL vaksin yang dilarutkan per tempat suntikan.

Profilaksis Pra-paparan
Untuk imunisasi pra-paparan, individu dapat divaksinasi sesuai dengan jadwal vaksinasi yang disajikan pada Tabel 1 dan menurut rekomendasi resmi setempat bila tersedia.

Tabel 1: Jadwal Vaksinasi Pra-paparan

	H0	H7	H21 atau H28
Regimen konvensional Rute IM - 0,5 mL	1 dosis	1 dosis	1 dosis

Dosis penguat 1 suntikan satu tahun
kemudian dosis penguat setiap 5 tahun,

Profilaksis Pasca-paparan
Profilaksis pasca-paparan termasuk pengobatan lokal non-spesifik pada luka, vaksinasi dan, bila perlu, imunisasi pasif dengan immunoglobulin rabies.
Pencegahan pasca-paparan harus dimulai sesegera mungkin setelah diduga terpapar rabies. Pada semua kasus, perawatan luka yang tepat (cuci hati-hati dari semua gigitan dan goresan dengan sabun atau deterjen dan banyak air dan/atau dengan agen pembunuh virus) harus dilakukan segera atau sesegera mungkin setelah terpapar. Hal ini harus dilakukan sebelum pemberian vaksin atau imunoglobulin rabies, jika diindikasikan. Profilaksis pasca paparan harus disesuaikan dengan kategori paparan, kondisi hewan (lihat Tabel 3) dan status vaksinasi pasien, sesuai dengan rekomendasi resmi (lihat Tabel 2, rekomendasi WHO).

Vaksinasi untuk pencegahan pasca-paparan harus diberikan sesegera mungkin di bawah pengawasan dokter dan dilakukan di pusat perawatan rabies

Jika diperlukan, Profilaksis pasca-paparan dapat ditambahkan dengan profilaksis tetanus dan terapi antibiotik untuk mencegah perkembangan infeksi selain rabies.

Tabel 2: Panduan WHO tentang profilaksis pasca-paparan, tergantung pada tipe kontak dan tingkat keparahan (untuk diadaptasi sesuai dengan rekomendasi resmi setempat).

Kategori paparan	Kategori paparan terhadap hewan domestik atau liar yang dicurigai atau dikonfirmasi sebagai rabies atau hewan yang tidak tersedia untuk pengujian	Profilaksis pasca paparan yang direkomendasikan
I	Menyentuh atau memberi makan hewan. jilatan pada kulit yang sehat. (tidak ada paparan)	Tidak perlu tindakan bila riwayat penyakit tersedia[a]
II	Gigitan pada kulit yang tak terlindungi. Cakaran kecil atau lecet tanpa pendarahan. (terpapar)	Berikan vaksin segera. Hentikan pengobatan jika hewan dalam keadaan sehat setelah periode pengamatan 10 hari atau jika uji rabies yang dilakukan dengan metode laboratorium yang sesuai negatif. Perlakukan sebagai kategori III jika terkena paparan kelelawar.
III	Satu atau lebih gigitan[c] atau cakaran yang menembus kulit. jilatan pada kulit yang rusak, kontaminasi selaput lendir dengan air liur hewan (misalnya jilatan), Paparan kelelawar (terpapar parah).	Segera berikan imunoglobulin dan Vaksin Anti Rabies (VAR), sebaiknya sesegera mungkin setelah memulai pencegahan pasca-paparan. Imunoglobulin rabies dapat disuntikkan hingga 7 hari setelah dosis pertama vaksin diberikan. Hentikan pengobatan jika hewan dalam keadaan sehat setelah periode pengamatan 10 hari atau jika uji rabies yang dilakukan dengan metode laboratorium yang sesuai negatif.

(a) Jika hewan tersebut adalah anjing atau kucing yang tampaknya sehat yang tinggal di daerah berisiko rendah dan ditempatkan di bawah pengawasan dokter hewan, pengobatan dapat ditunda (lihat Tabel 3).

(b) Periode observasi ini hanya berlaku untuk kucing dan anjing. Kecuali spesies yang hampir punah atau terancam punah, hewan peliharaan dan hewan liar yang diduga rabies harus di-eutanasia dan jaringannya diperiksa menggunakan metode laboratorium yang sesuai (lihat Tabel 3)

(c) Gigitan, terutama pada kepala, leher, wajah, tangan dan alat kelamin diklasifikasikan sebagai paparan Kategori III karena persarafan yang luas dari bagian-bagian tubuh ini.

Tabel 3 : Tindakan setelah terpapar tergantung pada kondisi hewan (Rekomendasi WHO untuk diadaptasi sesuai dengan rekomendasi lokal)

Kondisi	Tindakan		Keterangan
	Hewan	Pasien	
Tidak ada hewan **yang dicurigai atau tidak dicurigai**		Pengobatan oleh pusat perawatan rabies	Pengobatan [(b)] harus sampai tuntas
Hewan mati **Dicurigai atau tidak dicurigai**	Kirim otak hewan ke laboratorium terpercaya untuk dianalisa	Pengobatan oleh pusat perawatan rabies	Pengobatan [(b)] dihentikan jika hasil analisanya negatif, kalau tidak, dilanjutkan
Hewan hidup **Keadaan tidak dicurigai**	Di bawah pengawasan dokter hewan [(a)].	Keputusan untuk menunda pengobatan rabies	Pengobatan [(b)] diteruskan tergantung hasil pengawasan dokter hewan
Hewan hidup **Keadaan yang dicurigai**	Di bawah pengawasan dokter hewan [(a)].	Pengobatan oleh pusat perawatan rabies	Pengobatan [(b)] dihentikan jika dokter hewan membatalkan keraguan awal, jika tidak, dapat dilanjutkan

(a) Di Prancis, Pengawasan Dokter hewan mencakup 3 sertifikat yang disusun berdasarkan H0, H7, dan H14, untuk menyatakan tidak adanya tanda-tanda rabies. Menurut rekomendasi WHO, periode observasi minimum di bawah pengawasan dokter hewan untuk anjing dan kucing adalah 10 hari.
(b) Dianjurkan perawatan tergantung pada keseriusan luka: lihat Tabel 2.

Profilaksis pasca-paparan dari subjek yang tidak diimunisasi
Individu yang sebelumnya tidak diimunisasi dapat divaksinasi berdasarkan salah satu dari jadwal imunisasi yang terdapat pada Tabel 4:

Tabel 4: Jadwal vaksinasi pasca-paparan pada subjek individu yang sebelumnya belum diimunisasi

	H0	H3	H7	H14	H21	H28
Regimen Essen Rute IM - 0,5 mL	1 dosis	1 dosis	1 dosis	1 dosis		1 dosis
Regimen Zagreb IM route - 0,5 mL	2 dosis[a]		1 dosis		1 dosis	
Regimen Updated Thai Red Cross Rute ID - 0,1 mL	2 dosis[b]	2 dosis[b]	2 dosis[b]			2 dosis[b]
Regimen Satu minggu, 4 tempat Rute ID - 0,1 mL	4 dosis[c]	4 dosis[c]	4 dosis[c]			

a – satu suntikan di masing-masing dari dua deltoid (untuk orang dewasa dan anak-anak) atau area paha anterolateral (bayi dan balita)
b – disuntikkan di 2 tempat yang berbeda, jika memungkinkan secara kontralateral.
c – disuntikkan di 4 tempat berbeda

Data imunogenisitas dan keselamatan pada anak-anak <2 tahun adalah terbatas (lihat bagian studi klinis).
Apapun regimen yang digunakan, vaksinasi tidak boleh dihentikan kecuali hewan kontak dinyatakan bebas dari rabies setelah pengawasan dokter hewan (lihat Tabel 3).

Imunoglobulin rabies harus diberikan bersamaan dengan vaksin, dalam kasus paparan kategori III (klasifikasi WHO, lihat Tabel 1). Jika memungkinkan, vaksin harus diberikan secara kontralateral dengan tempat pemberian imunoglobulin.
Lihat Ringkasan Karakteristik imunoglobulin rabies yang digunakan.
Di area enzootic, tingkat keparahan paparan tertentu dikarenakan beratnya luka dan atau lokasinya (kedekatan dengan sistem saraf pusat), terlambat konsultasi atau imunodefisiensi, diberikan 2 suntikan VAR (vaksin anti rabies) pada H0

Profilaksis pasca-paparan dari subjek yang sebelumnya telah diimunisasi
Sesuai dengan rekomendasi resmi, hal ini berlaku untuk subjek yang telah menerima profilaksis pra-paparan atau profilaksis pasca-paparan atau yang menghentikan profilaksis pasca-paparan setelah menerima setidaknya dua dosis vaksin yang disiapkan dalam kultur sel.
Individu ini harus menerima satu dosis vaksin secara intramuskular (dosis vaksin 0,5 mL) atau secara intradermal (dosis vaksin 0,1 mL) pada setiap hari ke 0 dan 3.
Imunoglobulin rabies tidak diindikasikan untuk individu yang sebelumnya diimunisasi.

Populasi pediatrik
Anak-anak harus menerima dosis yang sama seperti orang dewasa.

Cara & Rute Pemberian
Tindakan pencegahan harus diambil sebelum menangani atau memberikan produk obat.
Vaksin diberikan dengan cara intramuskular di daerah anterolateral otot paha pada bayi dan anak-anak dan di otot deltoid remaja dan orang dewasa.
Penyuntikan juga dapat dilakukan secara intradermal (ID) diutamakan pada daerah lengan bagian atas atau lengan bagian depan.
Jangan menyuntikkan di daerah bokong.
Jangan menyuntikkan melalui rute intravaskular.
Untuk petunjuk tentang rekonstitusi produk obat sebelum pemberian, lihat Perhatian Khusus Untuk Pembuangan Dan Penanganan Lainnya.

KONTRAINDIKASI
Produk ini tidak boleh digunakan pada kasus berikut ini:

Pra-paparan (sebelum terpapar)
Vaksinasi harus ditunda jika terjadi demam atau penyakit akut lainnya.
Reaksi alergi terhadap zat aktif atau salah satu komponen vaksin yang termasuk dalam komposisi, polymyxin B, streptomisin, neomisin atau antibiotik kelompok yang sama, reaksi alergi terhadap pemberian vaksin ini sebelumnya atau vaksin lain yang mengandung komponen yang sama.

Pasca-paparan (setelah terpapar)
Mengingat infeksi rabies yang berakibat fatal atau kematian, maka tidak ada kontraindikasi terhadap pemberian vaksin pasca-paparan.
Jika terdapat keraguan, segera konsultasi dengan Dokter atau Apoteker.

FERTILTAS, KEHAMILAN dan MENYUSUI
Kehamilan
Belum dilakukan pengujian vaksin pada studi teratogenisitas hewan.

Pra-paparan (sebelum terpapar)
Dengan tidak adanya data pada manusia yang memadai, direkomendasikan untuk menunda vaksinasi sebelum terpapar. Untuk vaksinasi pada individu yang mempunyai risiko tinggi terkontaminasi, pertimbangan risiko dan manfaat harus selalu dilakukan sebelum pemberian suntikan.

Pasca-paparan (setelah terpapar)
Mengingat penyakit ini dapat mengakibatkan kematian, kehamilan bukan merupakan kontraindikasi.

Menyusui
Vaksin ini dapat digunakan selama menyusui dan direkomendasikan untuk selalu meminta saran dokter dan apoteker sebelum menggunakan vaksin ini.

Fertilitas (Kesuburan)
Verorab belum dievaluasi dalam studi kesuburan.

PENGARUH DALAM MENGENDARAI DAN MENGGUNAKAN MESIN
Pusing pasca vaksinasi sering dilaporkan, Ini dapat mempengaruhi kemampuan mengemudi atau menggunakan mesin untuk sementara waktu.

PERINGATAN DAN TINDAK PENCEGAHAN
Peringatan
Seperti pada semua vaksin, VERORAB mungkin tidak melindungi 100% individu yang divaksinasi.
Hati-hati bila digunakan pada individu yang diketahui mempunyai riwayat alergi terhadap neomycin, polymyxin B, streptomycin atau antibiotik lain dari kelompok yang sama (vaksin mengandung bahan tersebut).

Tindakan Pencegahan
- Rekomendasi jadwal penyuntikan harus diikuti dengan teliti.
- Kebutuhan untuk melakukan tes darah untuk memeriksa antibodi (dalam menilai perubahan hasil tes antibodi dari negatif ke positid pada individu) harus ditentukan sesuai dengan rekomendasi resmi.
- Ketika vaksin diberikan pada individu yang diketahui mengalami gangguan kekebalan tubuh, karena penyakit penurunan kekebalan tubuh atau pengobatan untuk menekan sistem kekebalan tubuh yang terjadi bersamaan (termasuk kortikosteroid), tes darah harus

DISETUJUI BPOM: 14 AGUSTUS 2025
ID REG: EREG100022VR12500184

Reverse

dilakukan 2 hingga 4 minggu setelah vaksinasi untuk memastikan bahwa respons imunisasi protektif diperoleh. Dalam kasus vaksinasi pasca pajanan, program vaksinasi lengkap harus diberikan. Imunoglobulin (sejenis protein yang diproduksi oleh sel darah putih) rabies juga harus diberikan bersamaan dengan vaksin jika terjadi paparan kategori II atau III (lihat bagian POSOLOGI DAN CARA PEMBERIAN).

- Seperti semua vaksin suntik, perawatan dan pengawasan medis yang tepat harus tersedia jika terjadi reaksi alergi parah yang jarang terjadi setelah pemberian vaksin, khususnya dalam kasus pasca paparan pada individu yang diketahui memiliki reaksi alergi terhadap polimiksin B, terhadap streptomisin, terhadap neomisin, atau terhadap antibiotik apa pun dari kelas yang sama.
- Seperti halnya pada semua vaksin, VERORAB harus diberikan dengan hati-hati pada individu dengan jumlah trombosit rendah atau gangguan pembekuan darah karena pemberian secara suntikan ke otot dapat menginduksi perdarahan pada individu ini.
- Reaksi terkait kecemasan, termasuk reaksi pingsan, pernapasan cepat atau reaksi terkait stres dapat terjadi setelah, atau bahkan sebelum, vaksinasi sebagai respons terkait dengan kondisi psikologis terhadap jarum suntik. Hal ini dapat disertai dengan beberapa tanda masalah saraf seperti gangguan penglihatan sementara dan kebas. Penting bahwa ada prosedur untuk menghindari cedera karena pingsan.

Populasi Anak

- Potensi risiko henti napas dan kebutuhan untuk pemantauan pernapasan selama 48-72 jam harus dipertimbangkan ketika memberikan imunisasi primer untuk bayi yang sangat prematur (lahir ≤ 28 minggu kehamilan) dan terutama bagi mereka yang memiliki riwayat sistem pernapasan yang belum sempurna. Karena manfaat vaksinasi dalam kelompok bayi ini adalah besar vaksinasi tidak boleh ditunda.
- Bila ada keraguan, harap berkonsultasi dengan dokter atau apoteker. Jauhkan dari jangkauan anak- anak.

INTERAKSI

Perawatan untuk menekan sistem kekebalan tubuh, termasuk terapi kortikosteroid sistemik jangka panjang, dapat mengganggu pembentukan antibodi dan menyebabkan kegagalan vaksinasi Oleh karena itu dianjurkan untuk melakukan tes darah untuk memeriksa antibodi 2 sampai 4 minggu setelah penyuntikan terakhir (lihat bagian POSOLOGI DAN CARA PEMBERIAN).

Verorab dapat diberikan bersamaan dengan vaksin tipus polisakarida Vi selama kunjungan vaksinasi yang sama, menggunakan dua tempat suntikan yang berbeda.
Imunoglobulin dan vaksin rabies tidak boleh digabungkan dalam jarum suntik yang sama atau diberikan di tempat yang sama.
Mengingat imunoglobulin rabies mengganggu perkembangan respon imun terhadap vaksin rabies, rekomendasi pemberian imunoglobulin rabies harus dipatuhi dengan ketat.

EFEK SAMPING

Ringkasan Profil Keamanan

Lebih dari 13,000 subjek, termasuk sekitar 1,000 anak-anak dan remaja di bawah usia 18 tahun, telah menerima setidaknya satu dosis Verorab dalam studi klinis.

Efek samping umumnya intensitasnya sedang dan terjadi dalam 3 hari setelah vaksinasi. Sebagian besar reaksi hilang secara spontan dalam 1 hingga 3 hari setelah timbulnya reaksi.
Efek samping yang paling umum terjadi pada semua kelompok umur (kecuali pada bayi/anak kecil berusia di bawah 24 bulan) adalah sakit kepala, lemas, nyeri otot, dan nyeri di tempat suntikan.

Daftar Tabulasi Efek yang tidak diinginkan:

Efek yang tidak diinginkan dilaporkan selama studi klinis dan setelah penggunaan komersial. Dalam setiap kelas organ sistem, reaksi yang tidak diinginkan diberi peringkat berdasarkan frekuensi menggunakan ketentuan berikut:

- sangat umum: ≥ 1/10
- umum: ≥ 1/100 dan <1/10
- tidak umum: ≥ 1/1000 dan <1/100
- jarang: ≥ 1/10000 dan <1/1000
- sangat jarang: <1/10000
- Tidak diketahui (tidak dapat diperkirakani dari data yang tersedia)

Efek Samping	Dewasa ≥ 18 tahun	Populasi Anak dibawah 18 tahun
	Frekuensi	Frekuensi
Gangguan darah dan jaringan getah bening		
Pembesaran kelenjar getah bening	Umum	Umum
Gangguan sistem kekebalan		
Reaksi alergi (seperti ruam, biduran, gatal)	Tidak Umum	Tidak Umum
Reaksi alergi parah dan bengkak yang disebabkan oleh reaksi alergi	Tidak diketahui	Tidak diketahui
Gangguan Metabolisme dan Nutrisi		
Penurunan Nafsu Makan	Tidak Umum	Tidak Umum
Gangguan Sistem Saraf		
Sakit Kepala	Sangat Umum	Sangat Umum
Pusing/Vertigo	Tidak Umum	-
Mudah menangis (pada bayi/anak kecil)	-	Sangat Umum
Tidur berlebihan (pada bayi/anak kecil)	-	Sangat Umum
Kesulitan tidur (pada bayi/anak kecil)	-	Umum
Gangguan pendengaran dan keseimbangan		
Kehilangan pendengaran tiba-tiba, yang mungkin bertahan	Tidak diketahui	Tidak diketahui
Gangguan pernapasan dan di area dada		
Sesak napas	Jarang	-
Gangguan Saluran Pencernaan		
Mual	Tidak Umum	-
Sakit perut	Tidak Umum	Tidak Umum
Diare	Tidak Umum	-
Muntah	-	Tidak Umum
Gangguan pada otot dan tulang		
Nyeri otot	Sangat Umum	Sangat Umum
Nyeri sendi	Tidak Umum	-
Gangguan umum di tempat yang disuntikkan		
Nyeri di tempat suntikan (Penggunaan secara suntikan ke otot)	Sangat Umum	Sangat Umum
Nyeri di tempat suntikan (Pengunaan secara suntikan ke bawah kulit)	Sangat Umum	Sangat Umum
Kemerahan pada kulit di tempat suntikan (Penggunaan secara suntikan ke otot)	Umum	Umum
Kemerahan pada kulit di tempat suntikan Pengunaan secara suntikan ke bawah kulit)	Sangat Umum	Sangat Umum
Gatal di tempat suntikan (Penggunaan secara suntikan ke otot)	Umum	-
Gatal di tempat suntikan (Pengunaan secara suntikan ke bawah kulit)	Umum	Tidak Umum
Pembengkakan di tempat suntikan (Penggunaan secara suntikan ke otot)	Umum	Umum
Pembengkakan di tempat suntikan (Pengunaan secara suntikan ke bawah kulit)	Umum	Sangat Umum
Benjolan keras di tempat suntikan (Penggunaan secara suntikan ke otot)	Umum	-
Bengkak darah di tempat suntukan (Pengunaan secara suntikan ke bawah kulit)	Tidak umum	
Rasa lemas	Sangat Umum	Sangat Umum
Gejala seperti influenza	Umum	
Demam	Umum	Umum
Kondisi kurang energi	Tidak umum	-
Menggigil	Tidak umum	Tidak umum
Tangisan yang tidak bisa ditenangkan (pada bayi/anak)	-	Sangat Umum

Pelaporan efek samping

Jika Anda mengalami efek samping apapun, bicarakan dengan dokter atau apoteker. Efek samping ini termasuk efek samping apapun yang mungkin muncul yang tidak tercantum pada leaflet ini. Anda juga dapat melaporkan efek samping secara langsung ke Industri Farmasi dengan kontak berikut farmakovigilans@kalventis.com. Dengan melaporkan efek samping Anda dapat membantu memberikan informasi tentang keamanan obat ini.

DISETUJUI BPOM: 14 AGUSTUS 2025

OVERDOSIS

Tidak ada kasus overdosis yang dilaporkan

TANGGAL KEDALUWARSA

3 tahun
Jangan gunakan setelah tanggal kedaluwarsa
Setelah rekonstitusi, vaksin harus segera diberikan

PENYIMPANAN

Simpan antara +2°C dan +8°C (dalam lemari es). Jangan dibekukan.
Simpan dalam kemasan asli, terlindung dari cahaya.

PERHATIAN KHUSUS UNTUK PEMBUANGAN DAN PENANGANAN LAINNYA

Instruksi penanganan:

- Lepaskan tutup botol serbuk liofilisasi.
- Pasang batang pendorong ke dalam spuit, jika disediakan secara terpisah.
- Suntikkan pelarut ke dalam botol serbuk liofilisasi.
- Kocok vial dengan lembut sampai diperoleh suspensi homogen dari serbuk.
- Vaksin yang dilarutkan harus jernih, homogen, dan bebas dari partikel.
- Lepas dan buang spuit yang sudah digunakan untuk pemberian vaksin.
- Gunakan spuit baru dengan jarum suntik baru untuk mengambil vaksin yang telah dilarutkan.
- Ganti jarum yang digunakan untuk mengambil vaksin dengan jarum baru untuk injeksi intramuskular dan intradermal.
- Panjang jarum yang digunakan untuk pemberian vaksin harus disesuaikan dengan pasien.

Setiap produk obat atau bahan limbah yang tidak digunakan harus dibuang sesuai dengan peraturan setempat.

HARUS DENGAN RESEP DOKTER.

Pada proses pembuatannya bersinggungan dengan bahan bersumber babi

Reg.No. : DKI2259703944A1
Untuk informasi lebih lanjut: PT Kalventis Sinergi Farma
Jl. Jend. A. Yani, Pulomas-Jakarta,
Phone : (021) 5089 5000

Diproduksi oleh: Sanofi Winthrop Industrie, Marcy L'Etoile - France
Didaftarkan oleh: PT Kalventis Sinergi Farma, Jakarta - Indonesia

Based on BPOM Approval dated 19 December 2024

sanofi

pre-exposure vaccination.
For the vaccination of subjects at a high risk of contamination, the benefit/risk ratio must be assessed before administering the injection.

Post-exposure prophylaxis
In post-exposure vaccination, due to the severity of the disease, pregnancy is not a contraindication.

Lactation
This vaccine can be used during lactation.

Fertility
Verorab has not been evaluated in fertility studies.

EFFECT ON ABILITY TO DRIVE AND USE MACHINES
Post-vaccination dizziness was frequently reported. It can temporarily affect the ability to drive or use machines.

UNDESIRABLE EFFECTS

Summary of the safety profile

Over 13,000 subjects, including approximately 1,000 children and adolescents under the age of 18, have received at least one dose of Verorab in clinical studies.
Adverse reactions were generally moderate in intensity and occurred within 3 days of vaccination. Most reactions resolved spontaneously within 1 to 3 days of their onset.
The most common adverse effects in all age groups (except in infants/young children aged under 24 months) were headache, malaise, myalgia and pain at the injection site. Injection site reactions (pain, erythema and swelling) were more common after an ID injection than an IM injection. Pain was the most common injection site reaction for both administration routes.

Tabulated list of adverse reactions

The adverse reactions listed below were reported during clinical studies and worldwide post-marketing surveillance. Within each system organ class, adverse reactions are ranked under headings of frequency using the following convention:

- very common (≥ 1/10);
- common (≥ 1/100 and <1/10);
- uncommon (≥ 1/1,000 and <1/100);
- rare (≥ 1/10,000 and <1/1,000);
- very rare (<1/10,000);
- not known (cannot be estimated from the available data).

Adverse reactions	Adults ≥ 18 years	Paediatric population under 18 years old
	Frequency	Frequency
Blood and lymphatic system disorders		
Lymphadenopathy	Common	Common
Immune system disorders		
Allergic reactions (e.g., rash, urticaria, pruritus)	Uncommon	Uncommon
Anaphylactic reactions and angioedema	Not known	Not known
Metabolism and nutrition disorders		
Decreased appetite	Uncommon	Uncommon
Nervous system disorders		
Headache	Very common	Very common
Dizziness/vertigo	Uncommon	-
Irritability (in infants/young children)	-	Very common
Somnolence (in infants/young children)	-	Very common
Insomnia (in infants/young children)	-	Common
Ear and labyrinth disorders		
Sudden hearing loss, which may persist	Not known	Not known
Respiratory, thoracic and mediastinal disorders		
Dyspnoea	Rare	-
Gastrointestinal disorders		
Nausea	Uncommon	-
Abdominal pain	Uncommon	Uncommon
Diarrhoea	Uncommon	-
Vomiting	-	Uncommon
Musculoskeletal and connective tissue disorders		
Myalgia	Very common	Very common
Arthralgia	Uncommon	-
General disorders and administration site conditions		
Injection site pain (IM use)	Very common	Very common
Injection site pain (ID use)	Very common	Very common
Injection site erythema (IM use)	Common	Common
Injection site erythema (ID use)	Very common	Very common
Injection site pruritus (IM use)	Common	-
Injection site pruritus (ID use)	Common	Uncommon
Injection site swelling (IM use)	Common	Common
Injection site swelling (ID use)	Common	Very common
Injection site induration (IM use)	Common	-
Injection site haematoma (ID use)	Uncommon	
Malaise	Very common	Very common
Influenza-like syndrome	Common	
Fever	Common	Common
Asthenia	Uncommon	-
Chills	Uncommon	Uncommon
Inconsolable crying (in infants/young children)	-	Very common

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Healthcare professionals are asked to report any suspected adverse reaction via farmakovigilans@kalventis.com and Pusat Farmakovigilans/MESO Nasional Direktorat Pengawasan Keamanan, Mutu, dan Ekspor Impor Obat, Narkotika, Psikotropika, Prekursor dan Zat Adiktif Badan Pengawas Obat dan Makanan. Jl. Percetakan Negara No. 23, Jakarta Pusat, 10560
Email: pv-center@pom.go.id
Phone: +62-21-4244691 Ext.1079
Website: https://e-meso.pom.go.id/.

OVERDOSE

No cases of overdose were reported.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Pharmacotherapeutic group: Rabies vaccines, ATC code: J07BG01.

Mechanism of action

Protection after vaccination is provided by the induction of anti-rabies neutralising antibodies.
Clinical studies have been conducted to assess the immunogenicity of the vaccine in post-exposure and pre-exposure prophylaxis. Rabies virus neutralising antibody levels of ≥ 0.5 IU/mL are considered to be protective by the WHO.

Pre-exposure prophylaxis

In clinical trials assessing a 3-dose vaccine regimen (D0, D7, D28 [or D21]) in both adults and children, all subjects achieved an adequate immune response, with serum neutralising antibody titres ≥ 0.5 IU/mL by D14 after the end of the primary vaccine regimen.
A ten-year follow-up in 49 patients who received a 3-dose regimen (D0, D7 and D28) followed by a booster dose at 1 year demonstrated a persistent immune response, with neutralising antibody titres maintained for 10 years in 96.9% of vaccinated subjects.
The 1-week pre-exposure schedule by IM use (one 0.5 mL dose at D0 and one 0.5 mL dose at D7) was assessed in one study (VAJ00001) in 75 subjects (including 35 children aged 2 to 17 years).
At D21, 98.6% vaccinated subjects reached a serum antibody titre ≥ 0.5 IU/mL.
One year later, following a simulated post-exposure prophylaxis (PEP) with two 0.5 mL doses injected 3 days apart (at D0 and D3) by IM use, a high and rapid anamnestic response was demonstrated in all subjects from D7 (7 days after the 1st PEP dose).
In 5 other additional studies conducted with Verorab in a total of 392 subjects assessing the conventional three-dose regimen (at D0, D7, D21 or D28) by IM use, all subjects reached a serum antibody titre ≥ 0.5 IU/mL. After the two doses (at D0 and D7), just before the third dose at D21 or D28.
The 1-week pre-exposure schedule by intradermal use (two 0.1 mL doses at D0 and two 0.1 mL doses at D7) was assessed in one study in 75 subjects (including 36 children aged 2 to 17 years).
At D21, 97.2% subjects reached a serum antibody titre ≥ 0.5 IU/mL.
One year later, following a simulated PEP with two 0.1 mL doses injected 3 days apart (at D0 and D3) by ID use, a high and rapid anamnestic response was demonstrated in all subjects from D7. Except one subject who remained seronegative at every time points despite completing all study vaccinations.
In another additional study conducted in 430 subjects who received one 0.1 mL dose of Verorab at D0 and one 0.1 mL dose at D7 by ID use, 99.1% subjects reached a serum antibody titre ≥ 0.5 IU/mL at D21

Post-exposure prophylaxis

In clinical trials assessing the 5-dose Essen regimen (D0, D3, D7, D14 and D28) and the 4-dose Zagreb regimen (2 doses on D0, then 1 dose on D7 and 1 dose on D21) in both children and adults, Verorab elicited neutralising antibody titres ≥ 0.5 IU/mL in almost all vaccinated subjects by D14 and in all subjects by D28.
During a phase-3 study including 600 exposed subjects aged from 11 months to 50 years, 2 intradermal PEP regimens were tested: 1 regimen in 4 sites in 1 week (4 doses on D0, 4 doses on D3 and 4 doses on D7) with or without equine rabies immunoglobulins (ERIG) on D0, and the new Thailand Red Cross regimen (2 doses on D0, 2 doses on D3, 2 doses on D7 and 2 doses on D28) with equine rabies immunoglobulins (ERIG) on D0. The Institute Pasteur of Cambodia (IPC) regimen (2 doses on D0, D3 and D7) was also included in the Thailand Red Cross regimen up to D28. Almost all vaccinated subjects (98.8%) reached rabies neutralising antibody levels ≥ 0.5 IU/mL by D14. Five years later and before the simulated PPE was received, the protective level of rabies neutralising antibodies was maintained in more than 84% of subjects who received a 4-site 1-week regimen with or without ERIG, and in 64.1% (95% CI: 55.1; 72.3) of subjects who received the new Thailand Red Cross regimen with ERIG. Eleven days after the simulated PPE with a 4-dose ID regimen performed in one visit, all the vaccinated subjects reached rabies neutralising antibody levels ≥ 0.5 IU/mL on D14 (geometric mean antibody titre [GMT] between 138 and 193 IU/mL).
The administration of human rabies immunoglobulin (HRIG) or equine rabies immunoglobulin (ERIG) concomitantly with the rabies vaccine may cause slightly lower mean neutralising antibody titres due to immune interference.
The efficacy of Verorab was assessed in 44 adult subjects bitten by animals with rabies in a phase-4 clinical trial. The subjects received the vaccine according to the 5-dose Essen regimen (D0, D3, D7, D14 and D28 by IM use) and immunoglobulins, if applicable. All subjects were alive 3 years after the post-exposure prophylaxis.

Paediatric population

There are no clinically significant differences in the immunogenicity of the vaccine in the paediatric population compared to adults.
In the study (VAJ00001) assessing the 1-week pre-exposure schedule by intradermal use (two 0.1 mL doses of Verorab at D0 and two 0.1 mL doses at D7) or by IM use (one 0.5 mL dose of Verorab at D0 and one 0.5 mL dose at D7) in 71 children aged 2 to 17 years, all children reached a serum antibody titre ≥ 0.5 IU/mL at D21.
One year later, following a simulated PEP with two doses injected 3 days apart (at D0 and D3) by IM or ID use, a high and rapid anamnestic response was demonstrated in all subjects from D7.

Pharmacokinetic properties

No pharmacokinetic studies were performed.

Preclinical safety data

Toxicity studies in animals (acute, subacute and chronic toxicity) do not indicate any toxic effects or target organ toxicity.

SHELF LIFE

3 years
Do not use later than the date of expiry
After reconstitution, the vaccine must be administered immediately.

SPECIAL PRECAUTIONS FOR STORAGE

Keep between +2°C and +8°C (in a refrigerator).
Do not freeze. Store in the original outer package, protected from light.

SPECIAL PRECAUTIONS FOR DISPOSAL AND OTHER HANDLING

Handling instructions:

- Remove the cap of the vial of lyophilised powder.
- Screw the plunger rod into the syringe, if provided separately.
- Inject the solvent into the vial of lyophilised powder.
- Shake the vial gently until homogeneous suspension of the powder is obtained.
- The reconstituted vaccine should be limpid, homogeneous, and free from particles.
- Remove and discard the syringe that was used for vaccine reconstitution.
- Use a new syringe with a new needle to withdraw the reconstituted vaccine.
- Replace the needle used to withdraw the vaccine by a new needle for intramuscular or intradermal injection.
- The length of the needle used for vaccine administration should be adapted to the patient.

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

PACKAGES:

Box, 1 Vial–1 syringe of diluent @ 0.5 mL NaCl 0.4%,
Reg.No. : DKI2259703944A1

Manufactured by: Sanofi Winthrop Industrie, Marcy L'Etoile - France
Registered by: PT Kalventis Sinergi Farma, Jakarta - Indonesia

Pada proses pembuatannya bersinggungan dengan bahan bersumber babi

HARUS DENGAN RESEP DOKTER

Based on BPOM Approval dated 19 December 2024

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ID REG: EREG100022VR12500184

REVISION HISTORY		
Date	Item Code	Description of Change
21 Mar 2025	KSF/XXXXXX (V1)	• New Launch (Alfa Project Vaccines For BPOM Submission) • CC Number : CC-1765 (Change labeling of Verorab due to change drug product's manufacturer name and removal of releaser)