RABIPUR®

Prescribing Information RABIPUR® powder and solvent for solution for injection in pre-filled syringe. Rabies vaccine (inactivated) **Composition:** After reconstitution a vial (1ml) contains: rabies virus (inactivated, strain Flury LEP) ≥ 2.5 IU, prepared in purified chick embryo cells (PCEC). Contains residues of chicken protein (e.g. ovalbumin) and human serum albumin and may contain traces of neomycin, chlortetracycline and amphotericin B. **Other ingredients:** trometamol, sodium chloride, disodium edetate, potassium L-glutamate, polygeline, sucrose, water for injection. **Indication:** Active immunization against rabies in individuals of all ages, before possible contact with the rabies virus (pre-exposure prophylaxis) or for the treatment of people who presumably or actually had contact with the rabies virus (post-exposure prophylaxis). **Dosage:** For intramuscular administration only. The recommended dose for both primary immunization and boosters is 1.0 ml. Pre-exposure prophylaxis conventional regimen: 1 dose on days 0, 7 and 21 (or 28). Pre-exposure prophylaxis rapid regimen (should only be considered for adults aged 18-65 years not able to complete the conventional pre-exposure prophylaxis regimen within 21 or 28 days before protection is required): 1 dose on days 0, 3 and 7. Booster doses are generally recommended every 2-5 years. Timing for booster after vaccination with rapid regimen has not yet been established. Serological testing for the presence of antibody ≥ 0.5 IU/ml to assess the need for booster doses should be conducted in accordance with official recommendations. Post-exposure prophylaxis should commence as soon as possible after exposure and might also require administration of rabies immunoglobulin depending on the type of exposure and previous vaccination. Post-exposure prophylaxis of previously unvaccinated individuals: Essen regimen (1 dose on days 0, 3, 7, 14, 28), or Zagreb regimen (2 doses on day 0 and 1 dose on days 7 and 21), or Reduced Essen regimen (1 dose on days 0, 3, 7, 14). The Reduced Essen may be used as an alternative for healthy, immunocompetent individuals provided they receive wound care plus rabies immunoglobulin in category III as well as in category II exposures. In immunocompromised individuals the Essen regimen can be administered or the Alternative to Essen regimen (2 doses on day 0 and 1 dose on days 3, 7, 14, and 28). Post-exposure prophylaxis in previously vaccinated individuals: 2 doses on days 0 and 3. **Contraindications:** Pre-exposure prophylaxis: Known severe allergic reaction to any ingredient of the vaccine. Vaccination should be postponed in individuals with a severe febrile illness. Post-exposure Prophylaxis: In view of the almost invariably fatal outcome of rabies, there is no contraindication to post-exposure prophylaxis. **Warnings and precautions:** In case of acute diseases requiring treatment, do not vaccinate until at least 2 weeks after recovery. The vaccination should only be administered by personnel with the capability and facilities to manage anaphylaxis. Rabies vaccine should not be injected intragluteally or subcutaneously as this may not reliably provide an adequate immune response. Do not inject intravascularly. Procedures should be in place to avoid injury from fainting. **Interactions:** As immunosuppressive agents can interfere with the development of an adequate response, it is recommended that serological responses should be monitored in such subjects, and additional doses administered as necessary. If rabies immunoglobulin is indicated in addition to Rabipur vaccine, then it must be administered at an anatomical site distant to the vaccination. Available clinical data support concomitant administration of Rabipur with inactivated Japanese encephalitis (JE) vaccine and conjugated MenACWY meningococcal vaccine in adult subjects. From day 57 after vaccination a faster decline in immune response was observed in individuals vaccinated concomitantly with JE vaccine according to the rapid PrEP schedule compared with the concomitant conventional PrEP schedule and the rabies only conventional PrEP schedule. **Fertility, pregnancy and lactation:** Rabipur may be administered to pregnant or breast-feeding women when post-exposure prophylaxis is required. The vaccine may also be used for pre-exposure prophylaxis during pregnancy or for breast-feeding women if it is considered that the potential benefit outweighs any possible risk. Non-clinical reproductive and developmental toxicity studies have not been performed. **Effect on ability to drive and use machines:** RABIPUR® has none or negligible influence. **Undesirable effects: Very common**: Headache, dizziness, rash, injection site reactions, malaise, fatigue, asthenia, fever.

Common: Lymphadenopathy, decreased appetite, nausea, vomiting, diarrhoea, abdominal pain / discomfort, urticaria, myalgia, arthralgia. **Rare:** Hypersensitivity, paraesthesia, hyperhidrosis, chills.

Other side effects, of which the frequency cannot be estimated from the available information, have been reported after Rabipur administration, and some of these were serious. These included: Anaphylaxis including anaphylactic shock, encephalitis, Guillain-Barré syndrome, presyncope, syncope, vertigo, and angioedema. **Nature and contents of container:** 1 vial of freeze-dried vaccine, 1 disposable pre-filled syringe of Sterile Diluent for reconstitution (1 ml). 1 small needle for injection and 1 long needle for reconstitution. **Basic cost**: £48.19 per dose. **Legal Category:** POM **Marketing authorisation holder**: Bavarian Nordic A/S, Philip Heymans Allé 3, 2900 Hellerup, Denmark
Marketing authorisation number: PL 40365/0004

For full prescribing information and details of other side effects please refer to the Summary of Product Characteristics which can be found at: www.medicines.org.uk/emc

Full prescribing information is available on request from: Medical Information, Bavarian Nordic A/S, Philip Heymans Allé 3, 2900 Hellerup, Denmark,
Email: medical.information_eu@bavarian-nordic.com

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Adverse events should be reported.
Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
Adverse events should also be reported to the Valneva UK Ltd Medical Information department on Tel: 01506 446608 or via email: mailto: vaccinesafety@valneva.com