United Kingdom (UK) Prescribing Information: RABIPUR® Please refer to the Summary of Product Characteristics (SmPC) before prescribing

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 those who presumably or actually had contact with the rabies virus (post-exposure prophylaxis).

Dosage: The recommended dose for both primary immunization and boosters is 1ml.

Method of Administration: For intramuscular administration only. For adults and children ≥ 2 years of age, administer into the deltoid muscle. In children < 2 years, the anterolateral area of the thigh is recommended.

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. In immunocompetent individuals, 1 dose on day 0 and day 7 can be used (one week schedule). In *immunocompromised individuals*, the conventional regimen should be followed. The rapid regimen and the one-week schedule may be used if accompanied by serological testing 2-4 weeks post first dose (please see SmPC).

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 may 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, defined in the SmPC. 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:* 1 dose on days 0 and 3.

*For the 2 doses at day 0 please refer to SmPC for recommended injection sites.

Paediatric individuals should receive the same dose as adults (1 ml) for all indications.

Contraindications: *Pre-exposure prophylaxis*: Known severe allergic reaction to any ingredient of the vaccine (e.g. severe egg allergy). Vaccination should be postponed in individuals with a severe febrile illness. *Post-exposure Prophylaxis*: There is no contraindication to post-exposure prophylaxis, including those with severe egg allergies, as risk of death from Rabies outweighs the risk of hypersensitivity.

Warnings and precautions: In case of acute diseases requiring treatment, do not vaccinate for pre-exposure prophylaxis until at least 2 weeks after recovery. Anaphylactic reactions including anaphylactic shock have occurred following vaccination. The vaccination should only be administered by personnel with the capability and facilities to manage anaphylaxis. The 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: Immunosuppressive agents can interfere with the development of an adequate response to the vaccine, please monitor serological response and provide additional doses if necessary. Other products should not be mixed in the same syringe as the vaccine. If rabies immunoglobulin is indicated in addition to Rabipur, it must be administered at an anatomical site distant to the vaccination site. Available clinical data support concomitant administration of Rabipur with inactivated Japanese encephalitis (JE) vaccine and conjugated

MenACWY meningococcal vaccine in adults, please see SmPC for data. Limited data are available in paediatrics. Concomitant vaccines should be administered at separate injection sites and preferably contralateral limbs.

Fertility, pregnancy and lactation: The vaccine may 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. No cases of harm attributable to the vaccine have been observed during pregnancy. It is not known if Rabipur enters breast milk, but no risk to the infant has been identified. Rabipur may be administered to pregnant or breast-feeding women when *post-exposure prophylaxis* is required.

Non-clinical reproductive and developmental toxicity studies have not been performed.

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.

Serous adverse events have been reported: Anaphylaxis including anaphylactic shock, hypersensitivity, encephalitis, Guillain-Barré syndrome, syncope, angioedema and vaccination failure.

Nature and contents of container: 1 vial of freeze-dried vaccine, 1 disposable pre-filled syringe of Sterile Diluent for reconstitution (1 ml). 2 identical needles, one for reconstitution and one for administration.

Basic cost: £48.19 per dose.

Legal Category: POM

Marketing authorisation holder: Bavarian Nordic A/S, Philip Heymans Alle 3, 2900 Hellerup, Denmark

Marketing authorisation number: PL 40365/0004

Please refer to the Summary of Product Characteristics prior to prescribing: www.medicines.org.uk/emc

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Bavarian Nordic: drug.safety@bavarian-nordic.com