## Zeyzelf (rivastigmine) Twice Weekly Transdermal Patches Abbreviated Prescribing Information. Please refer to the Zeyzelf <u>Summary of Product Characteristics (SmPC)</u> for full details.

Presentations: Transdermal patches each releasing either 4.6mg or 9.5mg of rivastigmine per 24 hours. Indication: Symptomatic treatment of mild to moderately severe Alzheimer's dementia. Dosage and administration: Zeyzelf twice weekly transdermal patches should be applied twice weekly on fixed days (after four and three days, respectively). Dosage: Initial dose: Treatment is started with 4.6mg/24h. Maintenance dose: After a minimum of four weeks of treatment and if well tolerated according to the treating physician, the dose of 4.6mg/24h should be increased to 9.5mg/24h, the daily recommended effective dose, which should be continued for as long as the patient continues to demonstrate therapeutic benefit. Switching from capsules or oral solution to transdermal patches: Refer to SmPC. Special populations: Patients with body weight below 50 kg: Particular caution should be exercised in titrating patients with body weight below 50 kg above the recommended effective dose of 9.5mg/24h. Hepatic impairment: In mild to moderate hepatic impairment dosing recommendations to titrate according to individual tolerability should be closely followed. Renal impairment: No dose adjustment is necessary for patients with renal impairment. Method of administration: Zeyzelf twice weekly is for transdermal use. Transdermal patches should be applied twice weekly on fixed days (after four and three days, respectively) Patients and caregivers should be instructed on important administration instructions: Refer to SmPC. Common Adverse Reactions: Application site skin reactions (usually mild to moderate application site erythema) are the most frequent adverse reactions observed with the use of rivastigmine transdermal patch. The next most common adverse reactions are gastrointestinal in nature including nausea and vomiting. Please consult the full SmPC for other adverse reactions. Contraindications: Hypersensitivity to the active substance rivastigmine, to other carbamate derivatives or to any other excipients. Previous history of application site reactions suggestive of allergic contact dermatitis with rivastigmine patch. Warnings and Precautions: Zeyzelf twice weekly transdermal patches are multiday patches. Care should be exercised and application of more than one patch at the same time should be avoided. The incidence and severity of adverse reactions generally increase with increasing doses, particularly at dose changes. If treatment is interrupted for more than three days, it should be re-initiated with 4.6mg/24h. Misuse of the medicinal product and dosing errors resulting in overdose: Misuse of the medicinal product and dosing errors with rivastigmine transdermal patch have resulted in serious adverse reactions; some cases have required hospitalisation, and rarely led to death. Patients and their caregivers must be instructed on important administration instructions for rivastigmine transdermal patch. Gastrointestinal disorders: Gastrointestinal disorders such as nausea, vomiting and diarrhoea are dose related, and may occur when initiating treatment and/or increasing the dose. Skin application site reactions: Skin application site reactions may occur with rivastigmine patch and are usually mild or moderate in intensity. Patients and caregivers should be instructed accordingly. Other warnings and precautions: Rivastigmine may exacerbate or induce extrapyramidal symptoms. Contact with the eyes should be avoided after handling Zeyzelf twice weekly transdermal patches. Hands should be washed with soap and water after removing the patch. In case of contact with eyes or if the eyes become red after handling the patch, rinse immediately with plenty of water and seek medical advice if symptoms do not resolve. Interactions: Refer to the SmPC for full details. Effects on ability to drive and use machines: Alzheimer's disease may cause gradual impairment of driving performance or compromise the ability to use machines. Marketing Authorisation Number and Basic NHS Price: Zeyzelf twice weekly 4.6mg/24h transdermal patch PLGB 50827/0023 (8 patches: £35.09); Zeyzelf twice weekly 9.5mg/24h transdermal patch PLGB 50827/0024 (8 patches: £35.09). Marketing Authorisation Holder: Luye Pharma Ltd. 40 Occam Road, Guildford, GU2 7YG, United Kingdom. Legal Category: POM. Further information: Luye Pharma Ltd., 40 Occam Road, Guildford, GU2 7YG. info@luyepharma.co.uk Date of preparation: April 2024. Item number: UK-ZEY-32

> Adverse events should be reported. Reporting forms and information can be found at: https://yellowcard.mhra.gov.uk/ Adverse events should also be reported to Luye Pharma Ltd at