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Novartis Alzheimer's patch gets FDA nod

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Singapore: The US FDA expanded the approved indication for Novartis' rivastigmine transdermal system. Novartis Exelon Patch 13.3mg/24h can now be used to treat people with severe Alzheimer's disease (AD) and has become the first and only transdermal therapy approved to treat patients with mild, moderate and severe AD.

The approval of was based on the pivotal ACTION (Activities of daily living and cognition in patients with severe dementia of the alzheimer's type) study. In this randomized, double-blind study, Exelon Patch 13.3 mg/24h demonstrated statistically significant improvement in overall cognition and function in severe AD patients versus the 4.6 mg/24h dose at week 24, as assessed by measures of cognition and daily function (SIB and ADCS-ADL-SIV), respectively. These data support the efficacy of Exelon Patch 13.3 mg/24h in this advanced population of patients suffering from AD.

The most commonly observed adverse reactions included application site erythema (redness or rash), fall, insomnia, vomiting, diarrhea, weight loss and nausea. These reactions were observed in a higher percentage of patients in the Exelon Patch 13.3 mg/24h dose than in the Exelon Patch 4.6 mg/24h dose.

Dr Andre Wyss, president, Novartis Pharmaceuticals, said that, "This approval is a significant milestone in the treatment of Alzheimer's disease. It exemplifies Novartis' continuing commitment to the Alzheimer's community. With this expanded indication, Exelon Patch can now address a wider range of Alzheimer's patients, including the large population of people in the severe stage of the disease."