

Title (en)  
NALOXONE MONOPREPARATION AND MULTI-LAYER TABLET

Title (de)  
NALOXON-MONOPRÄPARAT UND MEHRSCHICHTTABLETTE

Title (fr)  
MONOPRÉPARATION DE NALOXONE ET COMPRIMÉ MULTICOUCHE

Publication  
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Application  
**EP 15817094 A 20151207**

Priority

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Abstract (en)  
[origin: WO2016091805A2] The present invention relates to a solid, oral pharmaceutical composition comprising naloxone, or a pharmaceutically acceptable salt thereof as the active ingredient, the composition having a delayed release of said active ingredient. The composition can comprise a matrix containing glycerol di-behenic acid esters as matrix formers, with a mass ratio of naloxone to matrix former(s) of between 1:1 and 1:10, whereby the active ingredient naloxone has a delayed release. According to the invention, in order to provide a composition suitable for a dosage covering at least twelve hours for treating opioid-induced obstipation, the composition has an in-vitro release rate of the active ingredient, measured using a vane stirrer method according to Eur. Ph. at 75 U/min in 500 ml of 0.1 N hydrochloric acid at 37 °C, of 0 % to 75 % in 2 h, 3 % to 95 % in 4 h, 20 % to 100 % in 10 h, 30 % to 100 % in 16 h, 50 % to 100 % in 24 h and more than 80 % in 36 h, said composition having an IC<sub>50</sub>/C<sub>max</sub> value of at least 40. Preferably, the composition comprises a value for t<sub>max</sub> (naloxone) / t<sub>max</sub> (naloxone-3-glucuronoid) of at least 5. In an alternative embodiment, the composition can take the form of a multi-layer tablet.

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