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(54) Title: PHARMACEUTICAL COMPOSITIONS FOR GLUCOCORTICOID REPLACEMENT THERAPY

(57) Abstract: The invention relates to glucocorticoid replacement therapy and provides pharmaceutical compositions and kits designed to deliver one or more glucocorticoids to a subject in need thereof in a manner that results in serum levels of the glucocorticoid that essentially mimic that of a healthy subject for a clinically relevant period of time. The pharmaceutical composition comprises one or more glucocorticoids, wherein a first part of one or more glucocorticoids is substantially immediately released and a second part of one or more glucocorticoids is released over an extended period of time of at least about 8 hours, and the amount of the one or more glucocorticoids of the first part, expressed as hydrocortisone equivalents, is in a range of from about 15 to about 50% of the total hydrocortisone equivalents. The invention also relates to a kit comprising a first and a second component, the first component designed to release one or more glucocorticoids substantially immediately and the second component is designed to release one or more glucocorticoids over an extended period of time of at least 8 hours. The invention also relates to a method for treating diseases requiring glucocorticoid treatment such as in subjects having a glucocorticoid deficiency disorder. In another aspect the invention relates to the use of a first and a second amount of one or more glucocorticoids for the preparation of a pharmaceutical composition or kit for the treatment of a glucocorticoid deficiency disorder.