

Title (en)
STABLE LIQUID SUSPENSION COMPOSITION OF FLUDROCORTISONE

Title (de)
STABILE FLÜSSIGE SUSPENSIONSZUSAMMENSETZUNG FÜR FLUDROCORTISON

Title (fr)
COMPOSITION DE SUSPENSION LIQUIDE STABLE DE FLUDROCORTISONE

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Application
EP 19713218 A 20190303

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Abstract (en)
[origin: GB2571937A] A stable liquid suspension comprising fludrocortisone or a salt thereof is provided, wherein the fludrocortisone is present in the range from about 0.001mg/ml to 1mg/ml, and wherein the liquid suspension further comprises a vehicle for fludrocortisone or salts thereof, a suspending agent, an antifoaming agent, at least one preservative and one or more inactive excipients. Preferably the vehicle for fludrocortisone is selected from polyethylene glycol, glycerol and propylene glycol. Preferably the suspending agent is selected from xanthan gum, guar gum, tragacanth gum, veegum, hydroxypropyl methylcellulose, Avicel® RC-591 (microcrystalline cellulose/sodium carboxymethyl cellulose), Carbopol® (carboxyvinyl polymer) and polyvinyl pyrrolidone. The antifoaming agent is preferably selected from polydimethylsiloxane, simethicone, other silicones, stearates, alcohols and glycols. The preservative is preferably selected from methyl parahydroxybenzoate (methyl paraben), ethyl parahydroxybenzoate (ethyl paraben) propyl parahydroxybenzoate (propyl paraben), butyl parahydroxybenzoate (butyl paraben), isobutyl parahydroxybenzoate (isobutyl paraben), isopropyl parahydroxybenzoate (isopropyl paraben) benzyl parahydroxybenzoate (benzyl paraben), sodium benzoate, benzoic acid, potassium sorbate and combinations thereof. Preferably the liquid suspension comprises (a) 0.001mg/ml to 1mg/ml fludrocortisone, (b) 0.01 to 5% w/v glycerol, (c) 0.1 to 10% w/v hydroxypropyl methylcellulose, (d) 0.005 to 1% w/v simethicone, (e) methyl paraben and ethyl paraben, (f) one or more inactive excipients.

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Cited by
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