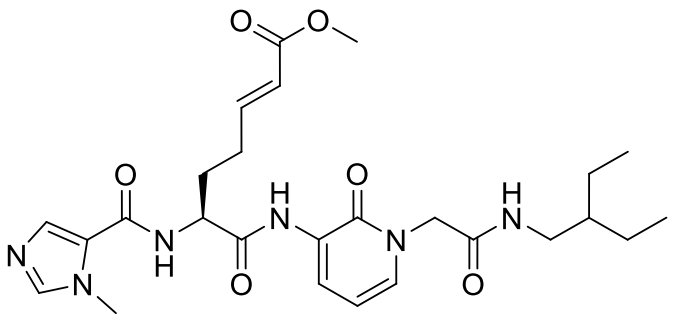
Claims

1. Use of a systemic formulation comprising (S,E)-methyl-7-(1-(2-(2-ethylbutylamino)-2-oxoethyl)-2-oxo-1,2-dihydro-pyridin-3-ylamino)-6-(1-methyl-1H-imidazole-5-carboxamido)-7-oxohept-2-enoate of formula (**I**):



(**I**)

,

or an enantiomer, a solvate, a hydrate or a pharmaceutically acceptable salt thereof for manufacture of a medicament for prophylaxis and/or treatment of coeliac disease, wherein the systemic formulation comprises 0.1 wt% to 80 wt% (S,E)-methyl-7-(1-(2-(2-ethylbutylamino)-2-oxoethyl)-2-oxo-1,2-dihydro-pyridin-3-ylamino)-6-(1-methyl-1H-imidazole-5-carboxamido)-7-oxohept-2-enoate, or an enantiomer, a solvate, a hydrate or a pharmaceutically acceptable salt thereof, 1 wt% to 75 wt% acidifier, and 0.1 wt% to 40 wt% polymeric precipitation inhibitor, wherein

the acidifier is adipic acid; and

the polymeric precipitation inhibitor is selected from the group consisting of L-hydroxypropyl cellulose, hydroxypropyl cellulose, a combination of L-hydroxypropyl cellulose and hydroxypropyl cellulose, polyethylene glycol, poly(ethylene oxide)-poly (propylene oxide)-poly (ethylene oxide), polyvinyl alcohol, polyvinylpyrrolidone, carboxymethyl cellulose, methylcellulose, hydroxyethylcellulose, hydroxypropylmethylcellulose, ethylcellulose, polyvinyl caprolactam–polyvinyl acetate–polyethylene glycol graft copolymer, and sodium carboxymethyl cellulose.

2. The use according to claim 1, wherein the systemic formulation is an oral formulation, especially an oral solid formulation.

3. The use according to claim 1 or 2, wherein the systemic formulation further comprises at least one binder.

4. The use according to claim 3, wherein the binder is selected from the group consisting of sugar, sucrose, polysaccharides, xanthan gum, guar gum, carrageenan, starches derived from wheat, corn, rice and potatoes, preagglutinated (modified) starch derived from wheat, corn, rice and potatoes, sodium starch glycolate, natural gums, acacia gum, gelatin, tragacanth, derivatives of sea weed, alginic acid, sodium alginate, ammonium calcium alginate, cellulose, cellulose derivatives, hydroxypropyl cellulose, L-hydroxypropyl cellulose, low-substituted hydroxypropyl cellulose, methyl cellulose, sodium carboxymethylcellulose, hydroxypropyl methylcellulose, polyvinylpyrrolidone, and povidone K25.

5. The use according to claim 3, wherein the polymeric precipitation inhibitor is polyvinyl alcohol, polyvinyl caprolactam–polyvinyl acetate–polyethylene glycol graft copolymer, L-hydroxypropyl cellulose, hydroxypropyl cellulose or a combination of L-hydroxypropyl cellulose and hydroxypropyl cellulose.

6. The use according to any one of the claims 1 to 5, wherein the (S,E)-methyl-7-(1-(2-(2-ethylbutylamino)-2-oxoethyl)-2-oxo-1,2-dihydro-pyridin-3-ylamino)-6-(1-methyl-1H-imidazole-5-carboxamido)-7-oxo-hept-2-enoate is in form of particles having a particle size distribution which is defined by d(0.95) ≤ 25 µm.

7. The use according to any one of the claims 1 to 6, wherein the systemic formulation comprises 0.1 wt% to 80 wt% (S,E)-methyl-7-(1-(2-(2-ethylbutylamino)-2-oxoethyl)-2-oxo-1,2-dihydro-pyridin-3-ylamino)-6-(1-methyl-1H-imidazole-5-carboxamido)-7-oxohept-2-enoate, 1 wt% to 75 wt% acidifier, 0.1 wt% to 40 wt% polymeric precipitation inhibitor, 0 wt% to 30 wt% binder, 0.1 wt% to 35 wt% disintegrant, and 0.1 wt% to 10 wt% lubricant/glidant.

8. The use according to claim 7, wherein the polymeric precipitation inhibitor is polyvinyl alcohol, polyvinyl caprolactam–polyvinyl acetate–polyethylene glycol graft copolymer, L-hydroxypropyl cellulose, hydroxypropyl cellulose or a combination of L-hydroxypropyl cellulose and hydroxypropyl cellulose.

9. The use according to claim 1, wherein the systemic formulation comprises 4.5 wt% to 55 wt% adipic acid, and 3.5 wt% to 30.5 wt% L-hydroxypropyl cellulose and/or hydroxypropyl cellulose or a combination of L-hydroxypropyl cellulose and hydroxypropyl cellulose.

10. The use according to any one of the claims 1 to 9, wherein the systemic formulation comprises 0.1 wt% to 80 wt% (S,E)-methyl-7-(1-(2-(2-ethylbutylamino)-2-oxoethyl)-2-oxo-1,2-dihydro-pyridin-3-ylamino)-6-(1-methyl-1H-imidazole-5-carboxamido)-7-oxohept-2-enoate, 4.5 wt% to 55 wt% adipic acid, 3.5 wt% to 30 wt% L-hydroxypropyl cellulose, 0 wt% to 30 wt% mannitol, 2 wt% to 35 wt% sodium croscarmellose, and 1 wt% to 9 wt% talc or silicon dioxide.

11. The use according to any one of the claims 1 to 10, wherein the systemic formulation is a tablet, coated tablet, capsule, powder, or granules.

12. The use according to claim 11, wherein the systemic formulation is a capsule comprising 2.5 wt% to 30.5 wt% (S,E)-methyl-7-(1-(2-(2-ethylbutylamino)-2-oxoethyl)-2-oxo-1,2-dihydro-pyridin-3-ylamino)-6-(1-methyl-1H-imidazole-5-carboxamido)-7-oxohept-2-enoate, 4.5 wt% to 55 wt% adipic acid, 3.5 wt% to 30 wt%. L-hydroxypropyl cellulose, 2 wt% to 35 wt% sodium croscarmellose, and 1 wt% to 9 wt% talc.

13. The use according to claim 11, wherein the systemic formulation is a tablet comprising 0.1 wt% to 30 wt% (S,E)-methyl-7-(1-(2-(2-ethylbutylamino)-2-oxoethyl)-2-oxo-1,2-dihydro-pyridin-3-ylamino)-6-(1-methyl-1H-imidazole-5-carboxamido)-7-oxohept-2-enoate, 35 wt% to 50 wt% microcrystalline cellulose, 5 wt% to 50 wt% adipic acid, 3.5 wt% to 30 wt% L-hydroxypropyl cellulose, 0.01 wt% to 30 wt% mannitol, 3.7 wt% to 15 wt% sodium croscarmellose, and 0.5 wt% to 4.00 wt% silicon dioxide.