Claims

1. A pharmaceutical composition comprising a combination of 5-aminosalicylic acid or a prodrug thereof and one or more active substances selected from nicotinamide; a compound that converts in the body of an animal or human into nicotinamide; nicotinamide adenine dinucleotide (NAD); nicotinamide adenine dinucleotide phosphate (NADP); an intermediate in the biosynthesis of NAD or NADP.

2. The pharmaceutical composition of claim 1, for beneficially influencing the intestinal microbiota, wherein the pharmaceutical composition preferably releases one or both of the active substances for topical efficacy in the lower small intestine, more preferably in the terminal ileum, the colon or both.

3. The pharmaceutical composition of claim 2, comprising nicotinamide wherein the nicotinamide is released in the lower small intestine, preferably in the terminal ileum, the colon or both.

4. The pharmaceutical composition of claim 3, preferably comprising a combination of 5-aminosalicylic acid and nicotinamide for beneficially influencing the intestinal microbiota, wherein the pharmaceutical composition releases the active substances for topical efficacy in the terminal ileum, the colon or both.

5. The pharmaceutical composition according to any one of claims 1 to 4, for oral administration with delayed release of the active ingredients for specific local effectiveness in the lower small intestine, preferably in the terminal ileum and/or colon.

6. The pharmaceutical composition according to any one of claims 1 to 5, formulated for oral administration with controlled release of the active ingredients for specific local effectiveness in the lower small intestine, preferably in the terminal ileum and/or colon.

7. The pharmaceutical composition according to any one of claims 1 to 6, for the therapy or prophylaxis of inflammatory diseases of the small intestine and/or diseases of the large intestine and/or for the prophylaxis of colon carcinoma and/or for the therapy or prophylaxis of other diseases that result from changes in the in-

testinal microbiota and/or an impaired interaction between intestinal microbiota and intestines, preferably formulated for oral administration and more preferably with delayed or controlled release.

8. The pharmaceutical composition according to any one of claims 1 to 7, for the (neo-rectal) administration in the colon or pouch for the therapy of inflammatory diseases of the large intestine or pouchitis.

9. The pharmaceutical composition according to claim 8, formulated for (neo)rectal administration in the colon or pouch.

10. The pharmaceutical composition according to claim 7, characterized in that the oral application is performed with an active substance content of 1–3000 mg of nicotinamide and 1–3000 mg of 5-aminosalicylic acid per finished dosage form, preferably characterized in that the oral application is performed with an active substance content of 10–1000 mg of nicotinamide and 10–1500 mg of 5-aminosalicylic acid per finished dosage form.

11. The pharmaceutical composition according to claim 8, characterized in that the rectal application is performed for the local therapy of inflammations in the rectum or pouch.

12. The pharmaceutical composition according to any one of claims 8, 9, and 11, characterized in that the rectal application is performed with an active substance content of 10–5000 mg of nicotinamide and 10–5000 mg of 5-aminosalicylic acid per finished dosage form.

13. The pharmaceutical composition according to any one of claims 1 to 12,

(a) for the therapy or prophylaxis of an inflammatory bowel disease, preferably ulcerative colitis or Crohn's disease or pouchitis,

(b) for the therapy or prophylaxis of colon carcinoma, or

(c) for the therapy or prophylaxis of diseases of other body organs, which result from changes in the intestinal microbiota and/or an impaired interaction between intestinal microbiota and intestines.

14. The pharmaceutical composition of any one of claims 1 to 12, wherein the combination is administered in the same dosage form or in separate dosage forms or physically segregated in the same dosage form.

15. A treatment regimen comprising the pharmaceutical composition of any one of claims 1 to 14, wherein the active substances may be administered simultaneously or sequentially.

Claims

1. A pharmaceutical composition comprising a combination of 5-aminosalicylic acid or a prodrug thereof and one or more active substances selected from nicotinamide; a compound that converts in the body of an animal or human into nicotinamide; nicotinamide adenine dinucleotide (NAD); nicotinamide adenine dinucleotide phosphate (NADP); an intermediate in the biosynthesis of NAD or NADP.

2. The pharmaceutical composition of claim 1, for beneficially influencing the intestinal microbiota, wherein the pharmaceutical composition preferably releases one or both of the active substances for topical efficacy in the lower small intestine, more preferably in the terminal ileum, the colon or both.

3. The pharmaceutical composition of claim 2, comprising nicotinamide wherein the nicotinamide is released in the lower small intestine, preferably in the terminal ileum, the colon or both.

4. The pharmaceutical composition of claim 3, preferably comprising a combination of 5-aminosalicylic acid and nicotinamide for beneficially influencing the intestinal microbiota, wherein the pharmaceutical composition releases the active substances for topical efficacy in the terminal ileum, the colon or both.

5. The pharmaceutical composition according to any one of claims 1 to 4, for oral administration with delayed release of the active ingredients for specific local effectiveness in the lower small intestine, preferably in the terminal ileum and/or colon.

6. The pharmaceutical composition according to any one of claims 1 to 5, formulated for oral administration with controlled release of the active ingredients for specific local effectiveness in the lower small intestine, preferably in the terminal ileum and/or colon.

7. The pharmaceutical composition according to any one of claims 1 to 6, for use in the therapy or prophylaxis of inflammatory diseases of the small intestine and/or diseases of the large intestine and/or for the use in prophylaxis of colon carcinoma and/or for use in the therapy or prophylaxis of other diseases that result from changes in the intestinal microbiota and/or an impaired interaction between intes-

tinal microbiota and intestines, preferably formulated for oral administration and more preferably with delayed or controlled release.

8. The pharmaceutical composition according to any one of claims 1 to 7, for use in the (neo-rectal) administration in the colon or pouch for use in the therapy of inflammatory diseases of the large intestine or pouchitis.

9. The pharmaceutical composition according to claim 8, formulated for use in (neo)rectal administration in the colon or pouch.

10. The pharmaceutical composition according to claim 7, characterized in that the oral application is performed with an active substance content of 1–3000 mg of nicotinamide and 1–3000 mg of 5-aminosalicylic acid per finished dosage form, preferably characterized in that the oral application is performed with an active substance content of 10–1000 mg of nicotinamide and 10–1500 mg of 5-aminosalicylic acid per finished dosage form.

11. The pharmaceutical composition according to claim 8, characterized in that the rectal application is performed for the local therapy of inflammations in the rectum or pouch.

12. The pharmaceutical composition according to any one of claims 8, 9, and 11, characterized in that the rectal application is performed with an active substance content of 10–5000 mg of nicotinamide and 10–5000 mg of 5-aminosalicylic acid per finished dosage form.

13. The pharmaceutical composition according to any one of claims 1 to 12,

(a) for use in the therapy or prophylaxis of an inflammatory bowel disease, preferably ulcerative colitis or Crohn's disease or pouchitis,

(b) for use in the therapy or prophylaxis of colon carcinoma, or

(c) for use in the therapy or prophylaxis of diseases of other body organs, which result from changes in the intestinal microbiota and/or an impaired interaction between intestinal microbiota and intestines.

14. The pharmaceutical composition of any one of claims 1 to 12, wherein the combination is administered in the same dosage form or in separate dosage forms or physically segregated in the same dosage form.

15. A treatment regimen comprising the pharmaceutical composition of any one of claims 1 to 14, for use wherein the active substances may be administered simultaneously or sequentially.