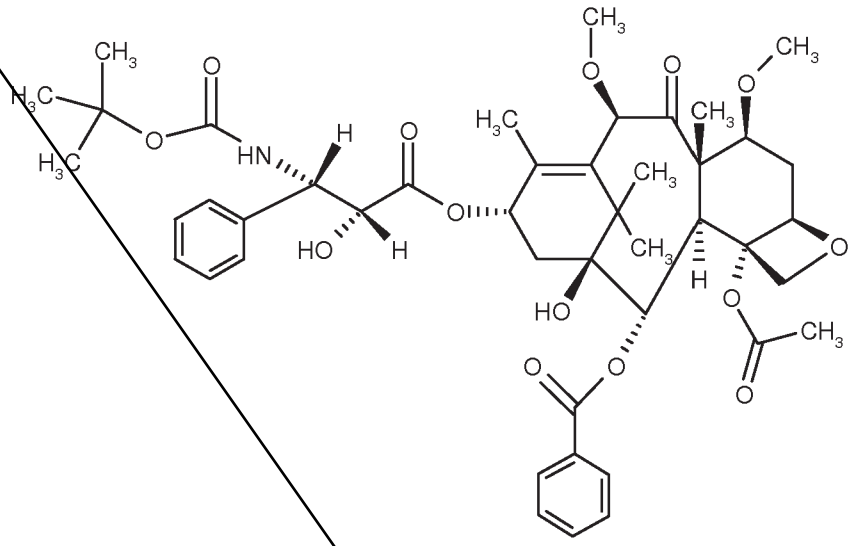
CLAIMS

1. Compound having the following formula (I):



(I)

which may be in base form or in the form of a hydrate or a solvate,

in combination with prednisone or prednisolone,

for its use for the treatment of castration resistant or hormone-refractory metastatic prostate cancer in patients not at risk of developing gastrointestinal disorders chosen from the group consisting of: gastrointestinal bleeding and perforation, gastritis, enterocolitis, neutropenic enterocolitis, colitis, intestinal obstruction, and ileus.

2. Compound for the use according to claim 1, wherein the patients do not display a prior history of neutropenia.

3. Compound for the use according to claim 1, wherein the patients do not have a concomitant non-steroidal anti-inflammatory drugs (NSAIDs), anti-platelet or anti-coagulants therapy.

4. Compound for the use according to claim 1, wherein the patients do not display a prior history of pelvic radiotherapy.

5. Compound for the use according to claim 1, wherein the patients do not display a prior history of gastrointestinal diseases, such as ulceration and gastrointestinal bleeding.

6. Compound for the use according to claim 1, wherein the patients are at least 50 years old, preferably 60-85 years old.

7. Compound for the use according to any one of claims 1 to 6, wherein the patients have been previously treated with docetaxel based regimen.

8. Compound for the use according to any one of claims 1 to 7, wherein the compound of formula (I) is in the form of an acetone solvate.

9. Compound for the use according to claim 8, in which the acetone solvate contains between 5% and 8%, and preferably between 5% and 7%, by weight of acetone.

10. Compound for the use according to any one of claims 1 to 9, wherein the compound of formula (I) is administered at a dose of between 15 and 25 mg/m^2, the prednisone or prednisolone being administered at a dose of 10 mg/day.

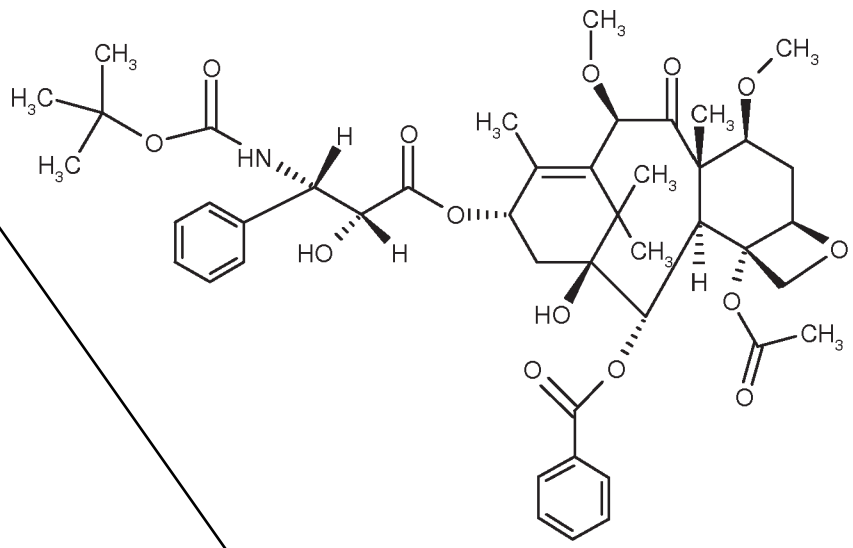
11. Compound for the use according to claim 10, wherein the compound of formula (I) is administered at a dose of 25 mg/m^2.

12. Compound for the use according to claim 10, wherein the compound of formula (I) is administered at a dose of 20 mg/m^2.

13. Compound for the use according to any one of claims 1 to 12, wherein the administration of the compound of formula (I) is repeated as a new cycle every 3 weeks.

14. Compound for the use according to claim 13, wherein the median number of cycles is 6.

15. Compound having the following formula (I):



(I)

which may be in base form or in the form of a hydrate or a solvate,

in combination with prednisone or prednisolone,

for its use for the treatment of castration resistant or hormone-refractory metastatic prostate cancer,

the compound of formula (I) being administered at a dose of between 15 and 25 mg/m^2, and the prednisone or prednisolone being administered at a dose of 10 mg/day, the administration of said compound being repeated as a new cycle every 3 weeks,

wherein, if the patient experiences gastrointestinal disorders during this administration cycle, then the administration of the compound is delayed and continued once the gastrointestinal disorders are resolved or completely stopped,

said gastrointestinal disorders being chosen from the group consisting of: gastrointestinal bleeding and perforation, gastritis, enterocolitis, neutropenic enterocolitis, colitis, intestinal obstruction, and ileus.

16. An article of manufacture comprising:

a) a packaging material;

b) prednisone or prednisolone;

c) the compound of formula (I) in the form of an acetone solvate; and

d) a label or package insert contained within the packaging material indicating that gastrointestinal disorders can occur, said gastrointestinal disorders being chosen from the group consisting of: gastrointestinal

bleeding and perforation, gastritis, enterocolitis, neutropenic enterocolitis, colitis, intestinal obstruction, and ileus.

17. The article of manufacture of claim 16, comprising a label or package insert contained within the packaging material indicating that:

i) the compound of formula (I) in the form of an acetone solvate is contraindicated in patients with a prior history of gastrointestinal disorders, said gastrointestinal disorders being chosen from the group consisting of: gastrointestinal bleeding and perforation, gastritis, enterocolitis, neutropenic enterocolitis, colitis, intestinal obstruction, and ileus, and

ii) if any abdominal pain and tenderness, fever, persistent constipation, and/or diarrhoea, with or without neutropenia, is detected during the treatment with the compound of formula (I) in the form of an acetone solvate, then the treatment should be discontinued.

18. A package comprising the compound of formula (I) of claim 1 and a label, said label comprising one or more messages that:

(a) the compound of formula (I) should not be prescribed to a patient who has been diagnosed with gastrointestinal disorders;

(b) the compound of formula (I) should not be prescribed to a patient who has a prior history of gastrointestinal disorders; and

(c) the compound of formula (I) is contraindicated in patients with a prior history of gastrointestinal disorders; and

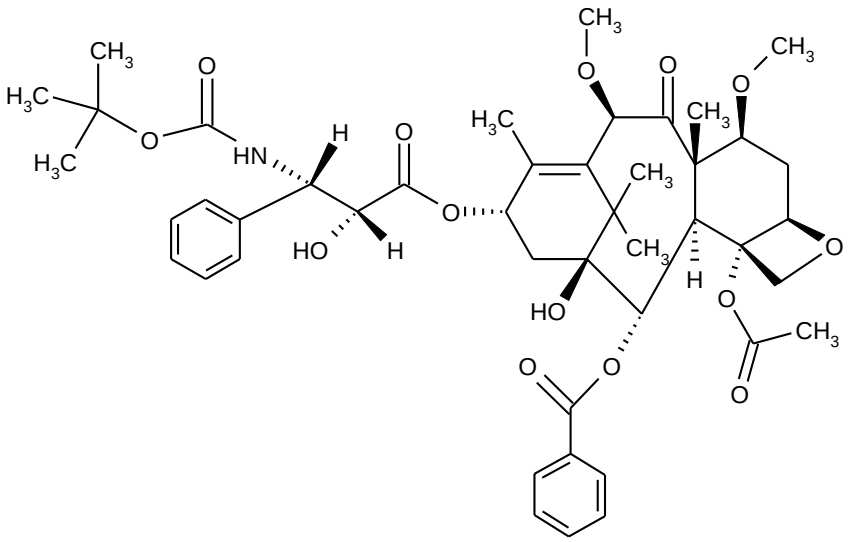
(d) if any abdominal pain and tenderness, fever, persistent constipation, and/or diarrhoea, with or without neutropenia, is detected during the treatment with the compound of formula (I) in the form of an acetone solvate, then the treatment should be discontinued,

said gastrointestinal disorders being chosen from the group consisting of: gastrointestinal bleeding and perforation, gastritis, enterocolitis, neutropenic enterocolitis, colitis, intestinal obstruction, and ileus.

19. The package of claim 18, wherein the compound of formula (I) is in the form of an acetone solvate.

CLAIMS

1. Use of a compound having the following formula (I):



(I)

which may be in base form or in the form of a hydrate or a solvate,

in combination with prednisone or prednisolone,

in the manufacture of a medicament for the treatment of castration resistant or hormone-refractory metastatic prostate cancer in patients, wherein the patients are not at risk of developing gastrointestinal disorders chosen from the group consisting of: gastrointestinal bleeding and perforation, gastritis, neutropenic enterocolitis, colitis, intestinal obstruction, and ileus.

2. The use according to claim 1, wherein the patients do not display a prior history of neutropenia.

3. The use according to claim 1, wherein the patients do not have a concomitant non-steroidal anti-inflammatory drugs (NSAIDs), anti-platelet or anti-coagulants therapy.

4. The use according to claim 1, wherein the patients do not display a prior history of pelvic radiotherapy.

5. The use according to claim 1, wherein the patients do not display a prior history of gastrointestinal diseases, such as ulceration and gastrointestinal bleeding.

6. The use according to claim 1, wherein the patients are at least 50 years old, preferably 60-85 years old.

7. The use according to any one of claims 1 to 6, wherein the patients have been previously treated with docetaxel based regimen.

8. The use according to any one of claims 1 to 7, wherein the compound of formula (I) is in the form of an acetone solvate.

9. The use according to claim 8, in which the acetone solvate contains between 5% and 8%, and preferably between 5% and 7%, by weight of acetone.

10. The use according to any one of claims 1 to 9, wherein the compound of formula (I) is administered at a dose of between 15 and 25 mg/m^2, the prednisone or prednisolone being administered at a dose of 10 mg/day.

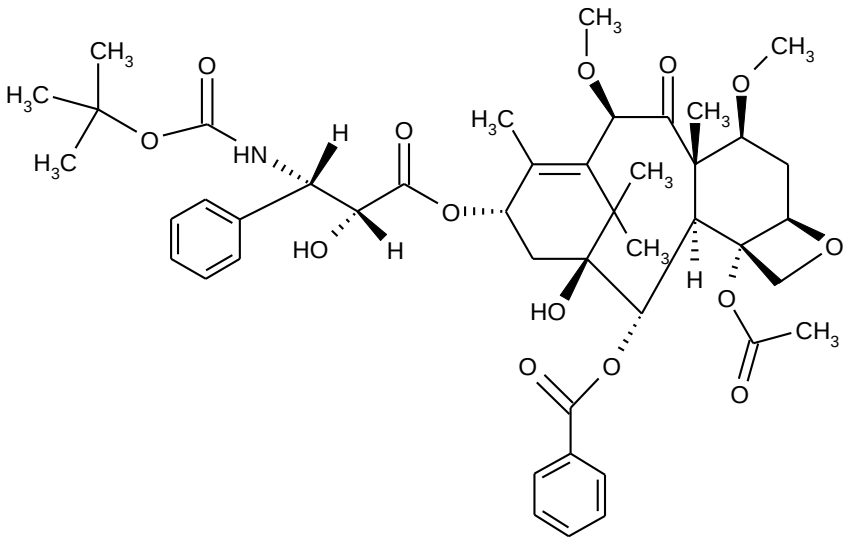
11. The use according to claim 10, wherein the compound of formula (I) is administered at a dose of 25 mg/m^2.

12. The use according to claim 10, wherein the compound of formula (I) is administered at a dose of 20 mg/m^2.

13. The use according to any one of claims 1 to 12, wherein the administration of the compound of formula (I) is repeated as a new cycle every 3 weeks.

14. The use according to claim 13, wherein the median number of cycles is 6.

15. The use of a compound having the following formula (I):



(I)

which may be in base form or in the form of a hydrate or a solvate,

in combination with prednisone or prednisolone,

in the manufacture of a medicament for the treatment of castration resistant or hormone-refractory metastatic prostate cancer,

the compound of formula (I) being administered at a dose of between 15 and 25 mg/m^2, and the prednisone or prednisolone being administered at a dose of 10 mg/day, the administration of said compound being repeated as a new cycle every 3 weeks,

wherein, if the patient experiences gastrointestinal disorders during this administration cycle, then the administration of the compound is delayed and continued once the gastrointestinal disorders are resolved or completely stopped,

said gastrointestinal disorders being chosen from the group consisting of: gastrointestinal bleeding and perforation, gastritis, neutropenic enterocolitis, colitis, intestinal obstruction, and ileus.