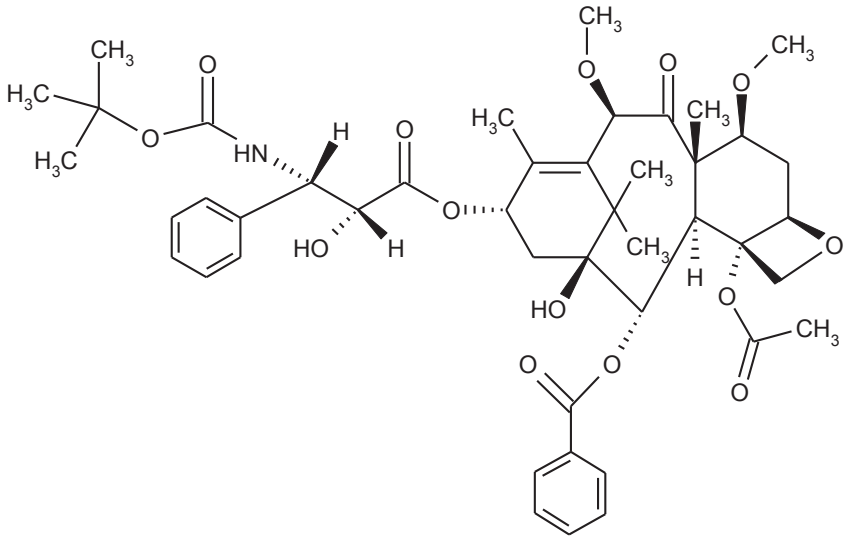
CLAIMS

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.