[0006] However, many of these treatments are recommended for acute conditions and do not address or provide for a long-term reduction in cardiovascular events in patients with clinically stable atherosclerotic vascular disease.

[0007] It is against this background that the present invention has been developed.

[0008] The present invention seeks to overcome, or at least ameliorate, one or more of the deficiencies of the prior art mentioned above, or to provide the consumer with a useful or commercial choice.

SUMMARY

[0009] In one aspect, there is provided use of a therapeutically effective amount of a composition comprising 0.5 to ~~about~~ 0.6 total mg of colchicineor a salt thereof , in the manufacture of a medicament for ~~treating and/or preventing~~reducing the risk of a cardiovascular event in a subject with atherosclerotic vascular disease, wherein the cardiovascular event is acute coronary syndrome, out-of-hospital cardiac arrest, or noncardioembolic ischemic stroke, and wherein the medicament is ~~formulated for use~~to be administered once per day.

[0009a] In another aspect, there is provided use of a therapeutically effective amount of a composition comprising 0.5 to ~~no more than about~~ 0.6 total mg of colchicineor a salt thereof , in the manufacture of a medicament for treating and/or preventing cholesterol crystal-induced inflammation within atherosclerotic plaques in a subject having, or having a previous history of, atherosclerotic vascular disease, wherein the medicament is to be administered ~~formulated for use~~ once per day.

[0009b] In yet another aspect, there is provided use of a therapeutically effective amount of a composition comprising ~~no more than about~~0.5 to 0.6 total mg of colchicine or a salt thereof or any combination thereof, in the manufacture of a medicament for reducing the risk of ~~treating and/or preventing~~ a cardiovascular event in patients with atherosclerotic vascular disease, wherein the cardiovascular event is acute coronary syndrome, out-of-hospital cardiac arrest, or noncardioembolic ischemic stroke.

[0009c] In a further aspect, there is provided use of a therapeutically effective amount of a composition comprising 0.5 to ~~no more than about~~ 0.6 total mg of colchicineor a salt thereof , or any combination thereof, in the manufacture of a medicament for reducing the risk of ~~treating and/or preventing~~ a cardiovascular event in a patient undergoing co-administration of a second agent for the treatment and/or prevention of an atherosclerotic vascular disease, wherein the cardiovascular event is acute coronary syndrome, out-of-hospital cardiac arrest, or noncardioembolic ischemic stroke, and wherein the medicament is ~~formulated for use~~to be administered once per day.

CLAIMS

1. Use of a therapeutically effective amount of a composition comprising ~~about~~ 0.5 to 0.6 total mg of colchicine or a salt thereof, in the manufacture of a medicament for reducing the risk of ~~treating and/or preventing~~ a cardiovascular event in a subject with atherosclerotic vascular disease, wherein the cardiovascular event is acute coronary syndrome, out-of-hospital cardiac arrest, or noncardioembolic ischemic stroke, and wherein the medicament is ~~formulated for use~~ to be administered once per day.

2. The use of claim 1, wherein the treatment and/or prevention of the cardiovascular event further comprises a second agent to be co-administered for the treatment and/or prevention of the cardiovascular event in the subject.

3. Use of a therapeutically effective amount of a composition comprising 0.5 to ~~no more than about~~ 0.6 total mg of colchicine or a salt thereof, in the manufacture of a medicament for treating and/or preventing cholesterol crystal-induced inflammation within atherosclerotic plaques in a subject having, or having a previous history of, atherosclerotic vascular disease, wherein the medicament is to be administered ~~formulated for use~~ once per day.

4. The use of claim 3, wherein the composition reduces or prevents cholesterol crystal induced inflammation within atherosclerotic plaques.

5. Use of a therapeutically effective amount of a composition comprising 0.5 to ~~no more than about~~ 0.6 total mg of colchicine or a salt thereof, or any combination thereof, in the manufacture of a medicament for reducing the risk of ~~treating and/or preventing~~ a cardiovascular event in patients with atherosclerotic vascular disease, wherein the cardiovascular event is acute coronary syndrome, out-of-hospital cardiac arrest, or noncardioembolic ischemic stroke.

6. The use of claim 5, wherein the atherosclerotic vascular disease is a coronary disease.

7. The use of claim 6, wherein the coronary disease is a clinically stable coronary disease.

8. The use of any one of claims 1 to 7, wherein the composition is to be administered orally, topically, parenterally, intraorbitally, ophthalmically, intraventricularly, intracranially, intracapsularly, intraspinally, intracisternally, intraperitoneally, buccally, rectally, vaginally, intranasally, or by aerosol administration, and/or inhalation spray, or via an implanted reservoir.

9. The use of any one of claims 1 to 8, wherein the composition is to be administered in the form of a tablet, capsule, liquid dose, gel, or powder.

10. Use of a therapeutically effective amount of a composition comprising 0.5 to ~~no more than about~~ 0.6 total mg of colchicine or a salt thereof, or any combination thereof, in the manufacture of a medicament for ~~treating and/or preventing~~reducing the risk of a cardiovascular event in a patient undergoing co-administration of a second agent for the treatment and/or prevention of an atherosclerotic vascular disease, wherein the cardiovascular event is acute coronary syndrome, out-of-hospital cardiac arrest, or noncardioembolic ischemic stroke, and wherein the medicament is to be administered ~~formulated for use~~ once per day.

11. The use of claim 10, wherein the second agent is a statin.

12. The use of claim 11, wherein the statin is selected from the group consisting of atorvastatin, rosuvastatin, simvastatin, fluvastatin, lovastatin, pitavastatin~~, rosuvastatin~~ and pravastatin, or a salt thereof.

13. The use of claim 10, wherein the second agent is an anti-platelet agent.

14. The use of claim 13, wherein the anti-platelet agent is selected from the group consisting of irreversible cyclooxygenase inhibitors; adenosine diphosphate (ADP) receptor inhibitors; phosphodiesterase inhibitors; glycoprotein IIB/IIIA inhibitors; adenosine reuptake inhibitors; thromboxane inhibitors; and Thromboxane receptor antagonists.

15. The use of any one of claims 1 to 14, wherein the composition comprises a pharmaceutically acceptable carrier, diluent, or excipient.