over an intermittent period of about 4 to 6 months. This is a considerable drain on the patients, their families, the hospital resources and medical staff's time.

[0006] There is therefore a need for an improved formulation to deliver an active arsenic species useful in the treatment of a number of forms of cancer.

SUMMARY

[0006a] In one aspect of the present disclosure, there is provided a solid oral pharmaceutical composition comprising an alkali metal and/or an alkaline earth metal diarsenic (III) tetraoxide and a pharmaceutically acceptable excipient.

[0006b] In another aspect of the present disclosure, there is provided a pharmaceutical composition comprising a diarsenic tetraoxide of the formula $MHAs_2O_4$ wherein M is a metal of suitable valency of +1, and a pharmaceutically acceptable excipient.

[0006c] In a further aspect of the present disclosure, there is provided a use of a diarsenic tetraoxide in the manufacture of a medicament for treating a cancer in a patient, wherein the diarsenic tetraoxide is to be orally administered to the patient to thereby treat the cancer; wherein the medicament is the solid oral pharmaceutical composition as defined above or the pharmaceutical composition as defined above.

[0006d] In a another aspect of the present disclosure, there is provided the solid oral pharmaceutical composition as defined above or the pharmaceutical composition as defined above for use in the treatment of cancer in a patient.

[0006e] In a another aspect of the present disclosure, there is provided a use of diarsenic tetraoxide as disclosed herein, in the manufacture of a medicament for delivering a therapeutically effective amount of an arsenic ion

to a patient.

[0007] According to the present disclosure, there is provided a pharmaceutical composition comprising a diarsenic tetraoxide and a pharmaceutically acceptable excipient.

[0008] Suitably, the diarsenic tetraoxide is an alkali metal and/or an alkaline earth metal diarsenic tetraoxide.

[0009] In one embodiment, the diarsenic tetraoxide comprises an $HAs_2O_4^-$ ion.

[0010] In embodiments, the diarsenic tetraoxide is of the formula $MHAs_2O_4$ wherein M is a metal of suitable valency.

[0011] Therefore, in one embodiment, the present disclosure relates to a pharmaceutical composition comprising a diarsenic tetraoxide of the formula $MHAs_2O_4$ wherein M is a metal of suitable valency, and a pharmaceutically acceptable excipient.

[0012] In preferred embodiments, the diarsenic tetraoxide is of the formula $NaHAs_2O_4$.

[0013] Preferably, the diarsenic tetraoxide is present in solid form.

[0014] In one embodiment, the composition further comprises one or more of a drying agent, a disintegrant and a dispersant.

[0015] According to the present disclosure there is provided a method of treating a cancer in a patient including the step of orally administering a diarsenic tetraoxide to the patient to thereby treat the cancer.

[0016] The present disclosure also resides in a diarsenic tetraoxide for use in treating a cancer in a patient.

CLAIMS

1. A solid oral pharmaceutical composition comprising an alkali metal and/or an alkaline earth metal diarsenic (III) tetraoxide and a pharmaceutically acceptable excipient.

2. The solid oral pharmaceutical composition of claim 1 wherein the alkali metal and/or an alkaline earth metal diarsenic (III) tetraoxide is of the formula $MHAs_2O_4$ wherein M is a metal with a valency of +1.

3. The solid oral pharmaceutical composition of claim 1 wherein the alkali metal and/or an alkaline earth metal diarsenic (III) tetraoxide is of the formula $NaHAs_2O_4$.

4. The solid oral pharmaceutical composition of any one of the preceding claims further comprising one or more of a drying agent, a disintegrant and a dispersant.

5. The solid oral pharmaceutical composition of claim 4 wherein the drying agent, disintegrant or dispersant is a bicarbonate and/or a carbonate compound.

6. The solid oral pharmaceutical composition of claim 5 wherein the disintegrant or dispersant is selected from the group consisting of sodium bicarbonate, sodium carbonate, potassium carbonate, potassium bicarbonate, calcium carbonate, magnesium carbonate and magnesium bicarbonate, or a combination thereof.

7. The solid oral pharmaceutical composition of any one of the preceding claims wherein the composition is in the form of a tablet, granule or capsule.

8. A pharmaceutical composition comprising a diarsenic tetraoxide of the formula $MHAs_2O_4$ wherein M is a metal with a valency of +1, and a pharmaceutically acceptable excipient.

9. The pharmaceutical composition of claim 8 wherein the composition is in solid form.

10. The pharmaceutical composition of claim 8 or claim 9 further comprising one or more of a drying agent, a disintegrant and a dispersant.

11. The pharmaceutical composition of claim 10 wherein the drying agent, disintegrant or dispersant is a bicarbonate and/or a carbonate compound.

12. The pharmaceutical composition of claim 11 wherein the disintegrant or dispersant is selected from the group consisting of sodium bicarbonate, sodium carbonate, potassium carbonate, potassium bicarbonate, calcium carbonate, magnesium carbonate and magnesium bicarbonate, or a combination thereof.

13. The pharmaceutical composition of any one of claims 8 to 12 wherein the composition is in the form of a tablet, granule or capsule.

14. Use of a diarsenic tetraoxide in the manufacture of a medicament for treating a cancer in a patient, wherein the diarsenic tetraoxide is to be orally administered to the patient to thereby treat the cancer; wherein the medicament is the solid oral pharmaceutical composition of any one of claims 1 to 7 or the pharmaceutical composition of any one of claims 8 to 13.

15. The solid oral pharmaceutical composition of any one of claims 1 to 7 or the pharmaceutical composition of any one of claims 8 to 13 for use in the treatment of cancer in a patient.

16. The use of claim 14, or the solid oral pharmaceutical composition or the pharmaceutical composition of claim 15, wherein the cancer is selected from a haematological malignancy, a solid tumour and a lymphoma.

17. The use of claim 14, or the solid oral pharmaceutical composition or the pharmaceutical composition of claim 15, wherein when the cancer is selected from the group consisting of acute lymphoblastic leukaemia (ALL), acute lymphoblastic B-cell leukaemia, acute lymphoblastic T-cell leukaemia, acute myeloblastic leukaemia (AML), acute promyelocytic leukaemia (APL), acute monoblastic leukaemia, acute erythroleukemic leukaemia, acute megakaryoblastic leukaemia, acute myelomonocytic leukaemia, acute undifferentiated leukaemia, chronic myelocytic leukaemia, myelodysplastic syndrome (MDS) and chronic lymphocytic leukaemia.

18. The use or the solid oral pharmaceutical composition or the pharmaceutical composition of claim 17 wherein the cancer is acute promyelocytic leukaemia (APL).

19. The use or the solid oral pharmaceutical composition or the pharmaceutical composition of claim 18 wherein the cancer is multiple myeloma.

20. The use of claim 14, or the solid oral pharmaceutical composition or the pharmaceutical composition of claim 15 wherein the diarsenic tetraoxide is to be administered as part of a combination therapy.

21. Use of diarsenic tetraoxide as defined in any one of claims 1 to 3 and 8, in the manufacture of a medicament for delivering a therapeutically effective amount of an arsenic ion to a patient.