

CLAIMS:

1. Melflufen (melphalan flufenamide; L-Melphalanyl-4-fluoro-L-phenylalanine ethyl ester), or a salt thereof, for use in the treatment or prophylaxis of multiple myeloma, wherein a dosage of melflufen (excluding the mass of any salt) is
5 administered as a parenteral dosage at an infusion rate of 1.0 to 1.8 mg/min.
2. The compound for use as claimed in claim 1, wherein the infusion rate is 1.2 to 1.4 mg/min, preferably 1.3 mg/min.
3. The compound for use as claimed in claim 1 or 2, wherein the maximum total dosage of melflufen is 45 mg.
- 10 4. The compound for use as claimed in any one of claims 1 to 3, wherein the dosage of melflufen is 35 to 45 mg.
5. The compound for use as claimed in any one of claims 1 to 4, wherein the dosage is administered over 25 to 35 minutes.
6. Melflufen (melphalan flufenamide; L-Melphalanyl-4-fluoro-L-phenylalanine
15 ethyl ester), or a salt thereof, for use in the treatment or prophylaxis of multiple myeloma, wherein a dosage of melflufen (excluding the mass of any salt) of 35 to 45 mg is administered as a parenteral dosage over 25 - 35 minutes.
7. Melflufen hydrochloride, for use in the treatment or prophylaxis of multiple myeloma, wherein a dosage of melflufen hydrochloride (including the mass of the
20 salt) of 37.6 to 48.3 mg is administered as a parenteral dosage over 25 - 35 minutes.
8. The compound for use as claimed in any one of claims 1 to 7, wherein the dosage of melflufen (excluding the mass of the salt) is 37.5 to 42.5 mg, preferably 40
25 mg.
9. The compound for use as claimed in any one of claims 1 to 8, wherein the dosage of melflufen is administered over around 30 minutes.
10. The compound for use as claimed in any one of claims 1 to 9, wherein the dosage of melflufen is administered as an intravenous infusion.

11. The compound for use as claimed in any one of claims 1 to 10, in which the multiple myeloma is relapsed, refractory and/or relapsed refractory multiple myeloma, for example refractory to at least one drug from a class of drugs selected
5 from protease inhibitors (PIs), immunomodulatory drugs (IMiDs) or alkylators; for example at refractory to least one alkylator; and/or, for example, refractory to at least pomalidomide and/or daratumumab.

12. The compound for use as claimed in in any one of claims 1 to 11, in which the
10 multiple myeloma is relapsed and/or relapsed refractory to at least lenalidomide; and more especially to at least lenalidomide and 2, 3 or 4 other drugs including at least one protease inhibitors (PIs) and immunomodulatory drugs (IMiDs).

13. The compound for use as claimed in any one of claims 1 to 12, in which said
15 melflufen is administered simultaneously, sequentially or separately with one or more further therapeutic agent(s).

14. The compound for use as claimed in claim 13, in which said further
therapeutic agent is dexamethasone.

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15. The compound for use as claimed in any one of claims 1 to 14, wherein the dosage of melflufen is administered as a pharmaceutical solution having a volume of 200 to 500 ml, preferably 350 ml.

25 16. The compound for use as claimed in any one of claims 1 to 15, wherein the dosage of melflufen is administered as a pharmaceutical solution comprising a physiologically acceptable solution, for example a glucose solution.

17. The compound for use as claimed in any one of claims 1 to 16, wherein the
30 dosage of melflufen is administered as a pharmaceutical solution and wherein the concentration of melflufen, or a salt thereof, in the pharmaceutical solution is 1.2 mg/mL or less, for example 0.2 to 1.2 mg/mL.

18. The compound for use as claimed in any one of claims 1 to 17, wherein the dosage of melflufen is prepared from a lyophilized pharmaceutical preparation comprising melflufen, or a salt thereof, and optionally sucrose.
- 5 19. The compound for use as claimed in any one of claims 1 to 18, wherein the dosage of melflufen, or a salt thereof, is taken on day 1 of a cycle of 21 days or a cycle of 28 days.
20. The compound for use as claimed in claims 19, wherein the cycle is repeated
10 from 1 to 9 times, preferably from 2 to 7 times, for example 4 times.
21. The compound for use as claimed in claims 19 or 20, wherein dexamethasone (for example 40 mg of dexamethasone) is administered on day 1 in a cycle; and optionally also administered on days 8 and 15 of a 21 day cycle, or
15 optionally also administered on days 8, 15 and 22 of a 28 day cycle.
22. A method for the treatment or prophylaxis of multiple myeloma comprising administering melflufen, or a salt thereof, to a patient, wherein a dosage of melflufen (excluding the mass of any salt) is administered as a parenteral dosage at an
20 infusion rate of 1.0 to 1.8 mg/min.
23. A method for the treatment or prophylaxis of multiple myeloma comprising administering melflufen, or a salt thereof, to a patient, wherein a dosage of melflufen of 35 to 45 mg is administered by parenteral infusion over around 25 - 35 minutes.
24. Melflufen, or a salt thereof, for the manufacture of a medicament for the
25 treatment or prophylaxis of multiple myeloma, wherein a dosage of melflufen (excluding the mass of any salt) is administered as a parenteral dosage at an infusion rate of 1.0 to 1.8 mg/min
25. Melflufen, or a salt thereof, for the manufacture of a medicament for the treatment or prophylaxis of multiple myeloma, wherein a dosage of melflufen of 35 to
30 45 mg is administered by parenteral infusion over 25 - 35 minutes.

26. Melflufen (melphalan flufenamide; L-Melphalanyl-4-fluoro-L-phenylalanine ethyl ester), or a salt thereof, for use in the treatment or prophylaxis of a cancer, for example a solid cancer, wherein a dosage of melflufen is administered as a parenteral dosage at an infusion rate less than 0.8 mg/min (for example 0.3 to 1.0 mg/min or for example 0.3 to 0.8 mg/min).

27. Melflufen (melphalan flufenamide; L-Melphalanyl-4-fluoro-L-phenylalanine ethyl ester), or a salt thereof, and one or more further chemotherapeutic agent(s), for use in the treatment or prophylaxis of a cancer, for example a solid cancer, wherein a dosage of melflufen is administered as a parenteral dosage at an infusion rate less than 0.8 mg/min (for example 0.3 to 0.8 mg/min).