[0009]

A pharmaceutical composition according to an example of the present disclosure is characterized by containing edaravone as an active ingredient, the pharmaceutical composition being administered to a subject orally or intragastrically with any one first time interval selected from the group consisting of 1) to 3) below:

1) in a case where the subject has consumed a high-fat meal, 8 hours or longer after the consumption;

2) in a case where the subject has consumed a standard meal, 4 hours or longer after the consumption; and

3) in a case where the subject has consumed a light meal, 2 hours or longer after the consumption.

[0010]

A method of administering an edaravone-containing pharmaceutical composition according to an example of the present disclosure is characterized by administering a pharmaceutical composition containing edaravone as an active ingredient to a subject orally or intragastrically with any one first time interval selected from the group consisting of 1) to 3) below:

1) in a case where the subject has consumed a high-fat meal, 8 hours or longer after the consumption;

2) in a case where the subject has consumed a standard meal, 4 hours or longer after the

consumption; and

3) in a case where the subject has consumed a light meal, 2 hours or longer after the consumption.

[0010a] In another aspect, there is provided the use of an edaravone-containing pharmaceutical composition which contains edaravone as an active ingredient, in the manufacture of a medicament for treating amyotrophic lateral sclerosis, wherein the pharmaceutical composition is to be administered to a subject orally or intragastrically with any one first time interval selected from the group consisting of 1) to 3):

1) in a case where the subject has consumed a high-fat meal, at least 8 hours but less than 10 hours after the consumption;

2) in a case where the subject has consumed a standard meal, at least 4 hours but less than 10 hours after the consumption; and

3) in a case where the subject has consumed a light meal, at least 2 hours but less than 10 hours after the consumption,

wherein:

the high-fat meal is a meal with total calories of 3,347,200 J (800 kilocalories) to 4,184,000 J (1000 kilocalories);

the standard meal is a meal with total calories of 1,673,600 J (400 kilocalories) to 2,092,000 J (500 kilocalories); and

the light meal is a meal with total calories of 1,046,000 J (250 kilocalories) or less.

[0011]

The present inventors have found the present disclosure through the circumstances described below. These descriptions, however, do not particularly limit the present disclosure.

[0012]

Food-drug interactions can have a significant effect on safety and efficacy of drugs. For example, administration of a drug together with a meal may increase systemic absorption of the drug and change pharmacokinetics, and may result in improvement in efficacy and increase in the incidence of side effects. Alternatively, administration of a drug together with a meal may reduce systemic absorption of the drug and reduce efficacy.

[0013]

On the other hand, Wu et al. reported, for drugs exhibiting high solubility and high permeability and classified as BCS Class 1, meal consumption has little effect on pharmacokinetics, such as bioavailability, when the drugs are administered orally (Non-Patent Document 1).

[0014]

The present inventors found that a volume of water required for dissolving 1 g of edaravone is 500 mL (Drug Interview Form of Radicut (Revised in June 2017 (Revision 20)), which

Claims

[Claim 1]

Use of an edaravone-containing pharmaceutical composition which contains edaravone as an active ingredient, in the manufacture of a medicament for treating amyotrophic lateral sclerosis, wherein the pharmaceutical composition is to be administered to a subject orally or intragastrically with any one first time interval selected from the group consisting of 1) to 3):

1) in a case where the subject has consumed a high-fat meal, at least 8 hours but less than 10 hours after the consumption;

2) in a case where the subject has consumed a standard meal, at least 4 hours but less than 10 hours after the consumption; and

3) in a case where the subject has consumed a light meal, at least 2 hours but less than 10 hours after the consumption,

wherein:

the high-fat meal is a meal with total calories of 3,347,200 J (800 kilocalories) to 4,184,000 J (1000 kilocalories);

the standard meal is a meal with total calories of 1,673,600 J (400 kilocalories) to 2,092,000 J (500 kilocalories); and

the light meal is a meal with total calories of 1,046,000 J (250 kilocalories) or less.

[Claim 2]

The use according to claim 1, wherein a second time interval from administration of the

pharmaceutical composition to next meal consumption is 30 minutes or longer.

[Claim 3]

The use according to claim 1 or 2, wherein a second time interval from administration of the pharmaceutical composition to next meal consumption is 1 hour or longer.

[Claim 4]

The use according to any one of claims 1 to 3, wherein the pharmaceutical composition is to be administered orally.

[Claim 5]

The use according to any one of claims 1 to 3, wherein the pharmaceutical composition is to be administered intragastrically.

[Claim 6]

The use according to claim 5, wherein the intragastric administration is to be administration via a tube.

[Claim 7]

The use according to claim 6, wherein the tube is a percutaneous endoscopic gastrostomy tube (PEG tube).

[Claim 8]

The use according to claim 6, wherein the tube is a nasopharyngeal gastric tube (NG tube).

[Claim 9]

The use according to any one of claims 1 to 8, wherein

administration of the pharmaceutical composition includes intermittent administration or daily administration; and

the pharmaceutical composition is to be administered with the first time interval during an administration period of the intermittent administration or daily administration.

[Claim 10]

The use according to any one of claims 1 to 9, wherein the pharmaceutical composition is to be administered at a dose per administration of from 90 to 120 mg of edaravone.

[Claim 11]

The use according to any one of claims 1 to 9, wherein the pharmaceutical composition is to be administered at a dose per administration of from 90 to 105 mg of edaravone.

[Claim 12]

The use according to any one of claims 1 to 11, wherein the pharmaceutical composition is to be administered at a daily administration frequency of once, and a dose per administration of 105 mg of edaravone.