Summary of the invention

The present ~~invention~~ disclosure relates to a nalmefene for use in the reduction of alcohol consumption in a patient with alcohol dependence, wherein said use comprises the following steps;

a) identifying a patient with alcohol dependence i) who has a high DRL, and ii) who maintains a high DRL after an observation period following initial assessment, and

b) administering a therapeutically effective amount of nalmefene to the patient identified in step a), wherein said nalmefene is to be administered as-needed, such as on each day the patient perceives a risk of drinking alcohol, preferably 1-2 hours prior to the anticipated time of drinking.

In one aspect, there is disclosed a use of a therapeutically effective amount of nalmefene in the preparation of a medicament for reduction of alcohol consumption in a patient with alcohol dependence, wherein; a) said patient with alcohol dependence is one i) who has a high DRL, and ii) who maintains a high DRL after an observation period following initial assessment, and b) wherein said medicament is to be administered as-needed, such as on each day the patient perceives a risk of drinking alcohol, preferably 1-2 hours prior to the anticipated time of drinking.

Brief description of drawings

Figures 1-12 show the change from baseline in monthly Heavy Drinking days (HDDs) and Total Alcohol Consumption (TAC) (g/day) per study. Results are shown for the Total study population, Patients with a high DRL at baseline, Total study population excluding Early Reducers (ERs) and Patients with a high DRL at baseline and randomization

Figures 1a-12a show the change from baseline in monthly HDDs. X-axis: time (months); Y –axis: change in HDD.

Figures 1b-12b show the change from baseline in monthly TAC (g/day). X-axis: time (months); Y-axis: change in TAC (g/day).

(---□--- = placebo, —■— = nalmefene, *=P-value<0.05). "B" denotes baseline, "R" denotes randomization.

Figure 1a: Study 12014A, total study population, change in monthly HDD.

Figure 1b: Study 12014A, total study population, change in monthly TAC.

Figure 2a: Study 12014A, high DRL at baseline, change in monthly HDD.

Figure 2b: Study 12014A, high DRL at baseline, change in monthly TAC.

Figure 3a: Study 12014A, total study population excluding ERs, change in monthly HDD.

Figure 3b: Study 12014A, total study population excluding ERs, change in monthly TAC.

CLAIMS

1. Use of a therapeutically effective amount of Nalmefene in the preparation of a medicament for ~~use in~~ reduction of alcohol consumption in a patient with alcohol dependence, wherein ~~said use comprises the following steps~~;

   a) ~~identifying a~~said patient with alcohol dependence is one i) who has a high DRL, and ii) who maintains a high DRL after an observation period following initial assessment, and

   b) wherein said medicament ~~administering a therapeutically effective amount of nalmefene to the patient identified in step a), wherein said nalmefene~~ is to be administered as-needed, such as on each day the patient perceives a risk of drinking alcohol, preferably 1-2 hours prior to the anticipated time of drinking.

2. ~~Nalmefene~~ The use according to claim 1, wherein said observation period following initial assessment is 1-2 weeks, such as about 2 weeks.

3. ~~Nalmefene~~ The use according to any of claims 1-2, wherein the patient identified in step a) has a DRL corresponding to consumption >60 g/day of pure alcohol for men and >40 g/day for women.

4. ~~Nalmefene~~ The use according to any of claims 1-3, wherein said high DRL in identified in step a) i) has been assessed by calculating mean daily alcohol consumption in g/day over a period preceding assessment, wherein said period is 1 week or longer, such as 2 weeks or longer, such as 3 weeks or longer, such as 4 weeks or longer, such as 1 month or longer such as 2 months or longer, such as 3 months or longer, such as 4 months or longer, such as 5 months or longer, such as 6 months or longer, such as about 1 year.

5. ~~Nalmefene~~ The use according to any of claims 1-4, wherein said maintained DRL in step a) ii) is assessed by calculating mean daily alcohol consumption in g/day over said observation period.

6. ~~Nalmefene~~ The use according to any of claims 1-5, wherein said patient is subject to counseling focused on enhanced treatment adherence and reduced alcohol consumption.

7. ~~Nalmefene~~ The use according to claim 6, wherein said counseling is performed according to the BRENDA model.

8. ~~Nalmefene~~ The use according to any of claims 1-7, wherein said ~~nalmefene~~ medicament is to be used for a treatment period of 6 -12 months, such as 6 months.

9. ~~Nalmefene~~ The use according to any of claims 1-8, wherein said patient is 12 years or older, such as 14 years or older, such as 16 years or older, such as 18 years or older.

10. ~~Nalmefene~~ The use according to any of claims 1-9, wherein the medicament comprises ~~amount of~~ nalmefene in an amount of ~~is~~ 10-20 mg, such as 10 mg, 11 mg, 12 mg, 13 mg, 14 mg, 15 mg, 16 mg, 17 mg, 18 mg, 19 mg or 20 mg.

11. ~~Nalmefene~~ The use according to any of claims 1-10, wherein said nalmefene is administered in the form of a pharmaceutically acceptable acid addition salt.

12. ~~Nalmefene~~ The use according to claim 11, wherein said nalmefene is administered in the form of the hydrochloride dihydrate.

13. ~~Nalmefene~~ The use according to any of claims 1-12, wherein said nalmefene is administered in an oral dose form such as tablets or capsules.

14. The ~~method~~ use according to any of claims 1-13, wherein said nalmefene is administered in combination with a further active ingredient.