



PROTOCOL 1042-0112

INCLUSION CRITERIA

VISIT 1 - SCREENING

SITE NUMBER

01

SUBJECT INITIALS

JAC

BIRTH
DATE620618
year month day

FORM: I/E

INCLUSION CRITERIA: *If any answer to questions 1-11 is NO, the subject must be excluded from the clinical investigation.*

YES NO

1. Subject is a pre-menopausal female between 18 and 55 years of age (inclusive). ☒ YES ☐ NO
2. Subject is medically stable and in good health as determined by medical history, physical examination, vital signs, 12-lead ECG, and laboratory evaluation. ☒ YES ☐ NO
3. Subject has had a neurologic examination that is considered to be within normal limits, and Subject is without a defined neurologic disorder other than migraine headaches. ☒ YES ☐ NO
4. Subject is either practicing effective birth control (using the same method for the past 3 months), or is surgically sterilized; if a hysterectomy has been performed, Subject's ovaries remain intact. ☒ YES ☐ NO
5. Subject has had a negative urine pregnancy test, and is currently not lactating. (Note: a negative serum pregnancy test is also required, and results must be obtained prior to randomization.) ☒ YES ☐ NO
6. Subject has a measured supine diastolic blood pressure (after being supine for 5 minutes) of less than 95 mm Hg, but greater than or equal to 65 mm Hg. ☒ YES ☐ NO
7. Subject's body weight is within 15 % of normal for sex, height, and body frame, as specified by the Metropolitan Life Insurance table *Ideal Body Weight Nomogram* (see Protocol, Appendix 11.9). ☒ YES ☐ NO
8. Subject is able to communicate effectively with the study personnel, and is able to follow protocol procedures. ☒ YES ☐ NO
9. Subject is properly informed of the nature and risks of the clinical investigation, and has given informed consent in writing prior to entering the clinical investigation. ☒ YES ☐ NO
10. Subject is able to devote the necessary time to comply with all of the visit schedules for this study, to complete all tests related to safety and efficacy, and participate for the full term of the clinical investigation. ☒ YES ☐ NO
11. Subject is asymptomatic at Screening, but has a 6-month or greater history of 1-8 moderate to severe migraine headaches per month, with or without an aura, as defined by the International Headache Society diagnostic criteria (see Protocol, Appendix 11.2). ☒ YES ☐ NO

Complete the following calculation, excluding the number of mild migraines:

Average number of each migraine type per month

00
mild

01	+	02	=	03
moderate		severe		total



PROTOCOL 1042-0112

EXCLUSION CRITERIA

VISIT 1 - SCREENING

SITE NUMBER

SUBJECT INITIALS

BIRTH DATE

01
JAC
06 06 18
year month day

FORM: I/E

EXCLUSION CRITERIA: *If any answer to questions 1-14 is YES, the subject must be excluded from the clinical investigation.*

YES NO

- | | | |
|---|--------------------------|-------------------------------------|
| 1. Subject requires the use of valproate, dihydroergotamine, or ergot preparations as a prophylactic agent (see Protocol for acceptable migraine prophylactic therapies). | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 2. Subject is known to abuse drugs for the treatment of migraine headaches (i.e., Subject takes medication for acute migraine headache on more than 10 days per month). | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 3. Subject presents with frequent chronic tension-type headaches (≥ 15 days/month) or is not able to distinguish between tension-type headaches and migraine attacks. | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 4. Subject has a history of renal dysfunction, cardiovascular disease, or pulmonary disease. | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 5. Subject is a known or suspected alcohol abuser or illicit drug user (at present or at any time within the past year); or Subject has had a positive urine drug screen. | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 6. Subject has a history of liver disease, the diagnosis of cirrhosis by liver biopsy, or three of the following clinical signs of cirrhosis:
• spider angiomata • palpable spleen or ascites • abnormal collateral veins on the abdomen
• palmar erythema • firm, non-tender liver (with a nodular or irregular edge) | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 7. Subject has previously tested positive for hepatitis, or has a history of hepatitis. | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 8. Subject has either a history of a positive blood test for HIV, a history of risk factors associated with HIV infection, or is suspected of having an HIV infection. | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 9. Subject is pregnant or lactating, or is of childbearing potential and fails to use adequate contraception or is judged to be unreliable in her use of contraception. | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 10. Subject anticipates undergoing the implantation of a contraceptive device under the skin (e.g., Norplant), or a contraceptive injection (e.g., Depo-Provera) within 1 week prior to investigational product administration. | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 11. Subject has exhibited AST, ALT, gGGT, Alkaline Phosphatase, or LDH values that are outside of the clinical laboratory reference range, and that are considered clinically significant by the Investigator. | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 12. Subject has donated blood within 1 month prior to investigational product administration. | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 13. Subject has used an investigational drug within the past month. | <input type="checkbox"/> | <input checked="" type="checkbox"/> |
| 14. Subject has previously participated in this clinical investigation. | <input type="checkbox"/> | <input checked="" type="checkbox"/> |

INFORMED CONSENT OBTAINED:

1997 03 10
year month day

PRINCIPAL INVESTIGATOR'S SIGNATURE

1997 03 13
year month day

CORNING SciCor, Inc.

Marietta Henry, M.D., Director
8211 SciCor Drive • Indianapolis, IN 46214-2985
800.327.7270



LABORATORY REPORT
ACCESSION NO. C570812

Page 1 of 3

INVESTIGATOR: (L3713)

Jerome Goldstein, M.D.
c/o Earnest V. De Guzman
San Francisco Headache Clin.
909 Hyde St
San Francisco, CA 94109

PROTOCOL: 1042-0112

INVESTIGATOR: 01

SUBJECT NUMBER: 010125/116/97

PATIENT INITIALS: JAC

VISIT: SCRIN

Screening

SPONSOR REPORT TO:

Herbert Swarz, M.D.
c/o Nancy Westergaard
CoCensys, Inc.
213 Technology Drive
Irvine, CA 92718

COLLECTION TIME: 15:30 DATE: 10-Mar-97

DATE RECEIVED IN LABORATORY: 11-Mar-97

DATE REPORTED BY LABORATORY: 11-Mar-97

SEX: F BIRTHDATE: 18-Jun-62 AGE: 34

Clinical Significance	*Comments
No	Yes

CHEMISTRY

Total Bili	0.5	0.2-1.2 mg/dL
Alk Phos	65	31-110 U/L
ALT (SGPT)	25	6-34 U/L
AST (SGOT)	20	9-34 U/L
Urea Nitr	9	4-24 mg/dL
Creatinine	0.7	0.4-1.1 mg/dL
Glucose	124	H 70-115 mg/dL
Calcium	9.0	8.4-10.3 mg/dL
Phosphorus	3.2	2.2-5.1 mg/dL
Total Prot	7.0	6.1-8.4 g/dL
Albumin	4.0	3.3-4.9 g/dL
Cholest	231	140-261 mg/dL
Triglycer	173	44-213 mg/dL
LDH	189	53-234 U/L
Sodium	143	132-147 mEq/L
Potassium	3.8	3.4-5.4 mEq/L
Chloride	112	94-112 mEq/L
Bicarb	20.8	17.0-30.6 mEq/L

[] []

*If Clinically significant, please comment.

Investigator's Signature:

Date

3/13/97

d="delta" significant change (+ or -) from patient's baseline

H(High) or L(Low)=Values above or below SciCor reference range

T=Telephoned P="Panic" EX=Exclusion-as specified by the sponsor

L3713

(INV)

****TESTING COMPLETE**** PROTOCOL: 1042-0112 INVESTIGATOR: 01
VISIT: SCRIN

110 2323 403

CORNING SciCor, Inc.

Marietta Henry, M.D., Director
8211 SciCor Drive • Indianapolis, IN 46214-2985
800.327.7270



LABORATORY REPORT
ACCESSION NO. C570812

Page 2 of 3

INVESTIGATOR: (L3713)

Jerome Goldstein, M.D.
c/o Earnest V. De Guzman
San Francisco Headache Clin.
909 Hyde St
San Francisco, CA 94109

PROTOCOL: 1042-0112

INVESTIGATOR: 01

SUBJECT NUMBER: 0101 *5/16/97*

PATIENT INITIALS: JAC

VISIT: SCRIN

Screening

SPONSOR REPORT TO:

Herbert Swarz, M.D.
c/o Nancy Westergaard
CoCensys, Inc.
213 Technology Drive
Irvine, CA 92718

COLLECTION TIME: 15:30 DATE: 10-Mar-97

DATE RECEIVED IN LABORATORY: 11-Mar-97

DATE REPORTED BY LABORATORY: 11-Mar-97

SEX: F BIRTHDATE: 18-Jun-62 AGE: 34

Clinical	*Comments
Significance	
No Yes	

HEMATOLOGY

HGB	14.2	11.6-16.4 g/dL
HCT	40	34-48%
RBC	4.7	4.1-5.6 x10 ⁶ /uL
MCV	87	79-98 fL
MCH	30	26-34 pg
MCHC	35	31-38 g/dL
RBC Morph	Normocytic	
WBC	3.77 L	3.80-10.70 x10 ³ /uL
Neutrophil	2.06	1.96-7.23 x10 ³ /uL
Bands	0.00	0.00-0.27 x10 ³ /uL
Lymphocyte	1.34	0.91-4.28 x10 ³ /uL
Monocytes	0.30	0.12-0.92 x10 ³ /uL
Eosinophil	0.05	0.00-0.57 x10 ³ /uL
Basophils	0.03	0.00-0.20 x10 ³ /uL
Platelets	229	140-400 x10 ³ /uL

[] []

*If Clinically significant, please comment.

Investigator's Signature: *[Signature]*

Date

3/13/97

d="delta" significant change (+ or -) from patient's baseline

H(High) or L(Low)=Values above or below SciCor reference range

T=Telephoned P="Panic" EX=Exclusion-as specified by the sponsor

L3713

(INV)

****TESTING COMPLETE**** PROTOCOL: 1042-0112 INVESTIGATOR: 01
VISIT: SCRIN

CORNING SciCor, Inc.

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LABORATORY REPORT
ACCESSION NO. C570812

Page 3 of 3

INVESTIGATOR: (L3713)

Jerome Goldstein, M.D.
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San Francisco Headache Clin.
909 Hyde St
San Francisco, CA 94109

PROTOCOL: 1042-0112

INVESTIGATOR: 01

SUBJECT NUMBER: 0101

PATIENT INITIALS: JAC

VISIT: SCRIN

Screening

SPONSOR REPORT TO:

Herbert Swarz, M.D.
c/o Nancy Westergaard
CoCensys, Inc.
213 Technology Drive
Irvine, CA 92718

COLLECTION TIME: 15:30 DATE: 10-Mar-97

DATE RECEIVED IN LABORATORY: 11-Mar-97

DATE REPORTED BY LABORATORY: 11-Mar-97

SEX: F BIRTHDATE: 18-Jun-62 AGE: 34

Clinical *Comments
Significance
No Yes

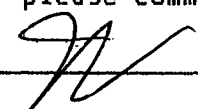
URINALYSIS

Color	Norm	Normal
Spec Grav	1.023	1.010-1.034
pH	5	5-8
Protein	Neg	Negative
Ketones	Neg	Negative
Urobilinog	Norm	Normal
Leuk Est	Neg	Negative
RBC	0	0-8 /HPF
WBC	4	0-12 /HPF
Other	Neg	

SERUM BETA hCG, QUALITATIVE

beta hCG Negative Negative

*If Clinically significant, please comment.

Investigator's Signature: 

Date

3/13/97

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H(High) or L(Low)=Values above or below SciCor reference range

T=Telephoned P="Panic" EX=Exclusion-as specified by the sponsor

L3713

(INV)

TESTING COMPLETE PROTOCOL: 1042-0112 INVESTIGATOR: 01
VISIT: SCRIN

CORNING SciCor, Inc.

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 8211 SciCor Drive • Indianapolis, IN 46214-2985
 800.327.7270

LABORATORY REPORT
ACCESSION NO. C571101

Page 1 of 3

INVESTIGATOR: (L3713)

Jerome Goldstein, M.D.
 c/o Earnest V. De Guzman
 San Francisco Headache Clin.
 909 Hyde St - Ste 230
 San Francisco, CA 94109

SPONSOR REPORT TO:

Herbert Swarz, M.D.
 c/o Nancy Westergaard
 CoCensys, Inc.
 213 Technology Drive
 Irvine, CA 92718

PROTOCOL: 1042-0112

INVESTIGATOR: 01

SUBJECT NUMBER: 0101

PATIENT INITIALS: JAC

VISIT: POST

Post Dosing

COLLECTION TIME: 14:00 DATE: 24-Mar-97

DATE RECEIVED IN LABORATORY: 25-Mar-97

DATE REPORTED BY LABORATORY: 25-Mar-97

SEX: F BIRTHDATE: 18-Jun-62 AGE: 34

Clinical Significance	*Comments
No	Yes

CHEMISTRY

Total Bili	0.3	0.2-1.2 mg/dL
Alk Phos	64	31-110 U/L
ALT (SGPT)	23	6-34 U/L
AST (SGOT)	14	9-34 U/L
Urea Nitr	10	4-24 mg/dL
Creatinine	0.8	0.4-1.1 mg/dL
Glucose	89	70-115 mg/dL
Calcium	9.4	8.4-10.3 mg/dL
Phosphorus	4.1	2.2-5.1 mg/dL
Total Prot	7.0	6.1-8.4 g/dL
Albumin	4.1	3.3-4.9 g/dL
Cholest	243	140-261 mg/dL
Triglycer	115	44-213 mg/dL
LDH	178	53-234 U/L
Sodium	141	132-147 mEq/L
Potassium	4.1	3.4-5.4 mEq/L
Chloride	109	94-112 mEq/L
Bicarb	24.0	17.0-30.6 mEq/L

*If Clinically significant, please comment.

Investigator's Signature: _____

Date

3/24/97

d="delta" significant change (+ or -) from patient's baseline
 H(High) or L(Low)=Values above or below SciCor reference range
 T=Telephoned P="Panic" EX=Exclusion-as specified by the sponsor

L3713

(INV)

****TESTING COMPLETE**** PROTOCOL: 1042-0112 INVESTIGATOR: 01
 SUBJECT NUMBER: 0101 VISIT: POST

CORNING SciCor, Inc.

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LABORATORY REPORT
ACCESSION NO. C571101

Page 2 of 3

INVESTIGATOR: (L3713)

Jerome Goldstein, M.D.
 c/o Earnest V. De Guzman
 San Francisco Headache Clin.
 909 Hyde St - Ste 230
 San Francisco, CA 94109

SPONSOR REPORT TO:

Herbert Swarz, M.D.
 c/o Nancy Westergaard
 CoCensys, Inc.
 213 Technology Drive
 Irvine, CA 92718

PROTOCOL: 1042-0112

INVESTIGATOR: 01

SUBJECT NUMBER: 0101

PATIENT INITIALS: JAC

VISIT: POST

Post Dosing

COLLECTION TIME: 14:00 DATE: 24-Mar-97

DATE RECEIVED IN LABORATORY: 25-Mar-97

DATE REPORTED BY LABORATORY: 25-Mar-97

SEX: F BIRTHDATE: 18-Jun-62 AGE: 34

Clinical	*Comments
Significance	
No Yes	

HEMATOLOGY

HGB	14.2	11.6-16.4 g/dL
HCT	42	34-48%
RBC	4.7	4.1-5.6x10 ⁶ /uL
MCV	89	79-98 fL
MCH	30	26-34 pg
MCHC	34	31-38 g/dL
RBC Morph	Normocytic	
WBC	4.29	3.80-10.70 x10 ³ /uL
Neutrophil	2.45	1.96-7.23 x10 ³ /uL
Bands	0.00	0.00-0.27 x10 ³ /uL
Lymphocyte	1.46	0.91-4.28 x10 ³ /uL
Monocytes	0.30	0.12-0.92 x10 ³ /uL
Eosinophil	0.04	0.00-0.57 x10 ³ /uL
Basophils	0.04	0.00-0.20 x10 ³ /uL
Platelets	222	140-400 x10 ³ /uL

*If Clinically significant, please comment.

Investigator's Signature: JW

Date

3/26/97

d="delta" significant change (+ or -) from patient's baseline
 H(High) or L(Low)=Values above or below SciCor reference range
 T=Telephoned P="Panic" EX=Exclusion-as specified by the sponsor

L3713

(INV)

****TESTING COMPLETE**** PROTOCOL: 1042-0112 INVESTIGATOR: 01
 SUBJECT NUMBER: 0101 VISIT: POST

CORNING SciCor, Inc.

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LABORATORY REPORT
ACCESSION NO. C571101

Page 3 of 3

INVESTIGATOR: (L3713)

Jerome Goldstein, M.D.
 c/o Earnest V. De Guzman
 San Francisco Headache Clin.
 909 Hyde St - Ste 230
 San Francisco, CA 94109

PROTOCOL: 1042-0112

INVESTIGATOR: 01

SUBJECT NUMBER: 0101

PATIENT INITIALS: JAC

VISIT: POST

Post Dosing

SPONSOR REPORT TO:

Herbert Swarz, M.D.
 c/o Nancy Westergaard
 CoCensys, Inc.
 213 Technology Drive
 Irvine, CA 92718

COLLECTION TIME: 14:00 DATE: 24-Mar-97

DATE RECEIVED IN LABORATORY: 25-Mar-97

DATE REPORTED BY LABORATORY: 25-Mar-97

SEX: F BIRTHDATE: 18-Jun-62 AGE: 34

Clinical	*Comments
Significance	
No Yes	

URINALYSIS

Color	Norm	Normal
Spec Grav	1.023	1.010-1.034
pH	5	5-8
Protein	Neg	Negative
Ketones	Neg	Negative
Urobilinog	Norm	Normal
Leuk Est	Trace	Negative
RBC	0	0-8 /HPF
WBC	12	0-12 /HPF
Other	Bacteria	

*If Clinically significant, please comment.

Investigator's Signature: _____

Date

3/26/97

d="delta" significant change (+ or -) from patient's baseline
 H(High) or L(Low)=Values above or below SciCor reference range
 T=Telephoned P="Panic" EX=Exclusion-as specified by the sponsor

L3713

(INV)

****TESTING COMPLETE**** PROTOCOL: 1042-0112 INVESTIGATOR: 01
 SUBJECT NUMBER: 0101 VISIT: POST

6 Hours PostdoseActual date
of entry19970321
year month day

Actual time:

19:15
24-hour time**Please answer the following questions:**

1. Have you experienced any **recurrence** of a migraine headache or the associated symptoms since your last evaluation?

(Note: If symptoms never disappeared, answer "no")

☒ No

☐ Yes: number of migraine recurrences: _____
number of symptom recurrences: _____

2. How do you judge the severity of the pain associated with your headache at this time?

☒ 0 Absent
☒ 1 Mild Pain
☐ 2 Moderate Pain
☐ 3 Severe Pain

3. How would you judge the effect of your migraine headache on your level of normal daily activities?

☒ 0 Normal
☒ 1 Mildly Impaired
☐ 2 Severely Impaired
☐ 3 Requires Bedrest

4. Which of the following symptoms do you now have?

absent	present	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	1 Photophobia
<input type="checkbox"/>	<input checked="" type="checkbox"/>	2 Phonophobia
<input type="checkbox"/>	<input checked="" type="checkbox"/>	3 Nausea
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4 Vomiting

5. Rate your Global Satisfaction with the investigational product:

(choose one)

☐ 1 Completely satisfied (couldn't be better)
☐ 2 Very satisfied
☐ 3 Somewhat satisfied
☐ 4 Neither satisfied nor dissatisfied
☐ 5 Somewhat dissatisfied
☐ 6 Very dissatisfied
☒ 7 Completely dissatisfied (couldn't be worse)

DIARY NOT COMPLETED - Explain:

☐ Sleeping at scheduled time
☐ Other (specify): _____

8 Hours PostdoseActual date
of entry19970321
year month day

Actual time:

21:15
24-hour time**Please answer the following questions:**

1. Have you experienced any **recurrence** of a migraine headache or the associated symptoms since your last evaluation?

(Note: If symptoms never disappeared, answer "no")

☒ No

☐ Yes: number of migraine recurrences: _____
number of symptom recurrences: _____

2. How do you judge the severity of the pain associated with your headache at this time?

☒ 0 Absent
☒ 1 Mild Pain
☐ 2 Moderate Pain
☐ 3 Severe Pain

3. How would you judge the effect of your migraine headache on your level of normal daily activities?

☒ 0 Normal
☒ 1 Mildly Impaired
☐ 2 Severely Impaired
☐ 3 Requires Bedrest

4. Which of the following symptoms do you now have?

absent	present	
<input checked="" type="checkbox"/>	<input type="checkbox"/>	1 Photophobia
<input checked="" type="checkbox"/>	<input type="checkbox"/>	2 Phonophobia
<input checked="" type="checkbox"/>	<input type="checkbox"/>	3 Nausea
<input checked="" type="checkbox"/>	<input type="checkbox"/>	4 Vomiting

5. Rate your Global Satisfaction with the investigational product:

(choose one)

☐ 1 Completely satisfied (couldn't be better)
☐ 2 Very satisfied
☐ 3 Somewhat satisfied
☐ 4 Neither satisfied nor dissatisfied
☐ 5 Somewhat dissatisfied
☒ 6 Very dissatisfied
☐ 7 Completely dissatisfied (couldn't be worse)

DIARY NOT COMPLETED - Explain:

☐ Sleeping at scheduled time
☐ Other (specify): _____



CoCensys

PROTOCOL 1042-0112

HOME DIARY TRANSCRIPTION

☒ SUBJECT RETURNED HOME DIARY.
☐ SUBJECT DID NOT RETURN HOME DIARY
 (explain on Comment page).

SITE NUMBER

01

SUBJECT NUMBER

071201

SUBJECT INITIALS

JAC

10 Hours Postdose

Actual date
of entry1997 03 21
year month day

Actual time:

23:15
24-hour time

Please answer the following questions:

1. Have you experienced any **recurrence** of a migraine headache or the associated symptoms since your last evaluation?

(Note: If symptoms never disappeared, answer "no")

☒ No☐ Yes: number of migraine recurrences: _____
number of symptom recurrences: _____

2. How do you judge the severity of the pain associated with your headache at this time?

☒ 0 Absent
☐ 1 Mild Pain
☐ 2 Moderate Pain
☐ 3 Severe Pain

3. How would you judge the effect of your migraine headache on your level of normal daily activities?

☐ 0 Normal
☒ 1 Mildly Impaired
☐ 2 Severely Impaired
☐ 3 Requires Bedrest

4. Which of the following symptoms do you now have?

absent present

☒ 1 Photophobia
☒ 2 Phonophobia
☒ 3 Nausea
☒ 4 Vomiting

5. Rate your Global Satisfaction with the investigational product:

(choose one)

☐ 1 Completely satisfied (couldn't be better)
☐ 2 Very satisfied
☐ 3 Somewhat satisfied
☐ 4 Neither satisfied nor dissatisfied
☐ 5 Somewhat dissatisfied
☐ 6 Very dissatisfied
☒ 7 Completely dissatisfied (couldn't be worse)

DIARY NOT COMPLETED - Explain:

☐ Sleeping at scheduled time
☐ Other (specify): _____

12 Hours Postdose

Actual date
of entry1997 03 22
year month day

Actual time:

01:20
24-hour time

Please answer the following questions:

1. Have you experienced any **recurrence** of a migraine headache or the associated symptoms since your last evaluation?

(Note: If symptoms never disappeared, answer "no")

☒ No☐ Yes: number of migraine recurrences: _____
number of symptom recurrences: _____

2. How do you judge the severity of the pain associated with your headache at this time?

☒ 0 Absent
☐ 1 Mild Pain
☐ 2 Moderate Pain
☐ 3 Severe Pain

3. How would you judge the effect of your migraine headache on your level of normal daily activities?

☐ 0 Normal
☒ 1 Mildly Impaired
☐ 2 Severely Impaired
☐ 3 Requires Bedrest

4. Which of the following symptoms do you now have?

absent present

☒ 1 Photophobia
☒ 2 Phonophobia
☒ 3 Nausea
☒ 4 Vomiting

5. Rate your Global Satisfaction with the investigational product:

(choose one)

☐ 1 Completely satisfied (couldn't be better)
☐ 2 Very satisfied
☐ 3 Somewhat satisfied
☐ 4 Neither satisfied nor dissatisfied
☐ 5 Somewhat dissatisfied
☒ 6 Very dissatisfied
☐ 7 Completely dissatisfied (couldn't be worse)

DIARY NOT COMPLETED - Explain:

☐ Sleeping at scheduled time
☐ Other (specify): _____
CoCensys

HOME DIARY TRANSCRIPTION

PROTOCOL 1042-0112

SITE NUMBER

01

SUBJECT NUMBER

01101

SUBJECT INITIALS

JAC

16 Hours PostdoseActual date
of entry

year	month	day
------	-------	-----

Actual time:

24-hour time

Please answer the following questions:

1. Have you experienced any **recurrence** of a migraine headache or the associated symptoms since your last evaluation?

(Note: If symptoms never disappeared, answer "no")

☐ No
☐ Yes: number of migraine recurrences: _____
 number of symptom recurrences: _____

2. How do you judge the severity of the pain associated with your headache at this time?

- ☐ 0 Absent
☐ 1 Mild Pain
☐ 2 Moderate Pain
☐ 3 Severe Pain

3. Which of the following symptoms do you now have?

absent present

- ☐ ☐ 1 Photophobia
☐ ☐ 2 Phonophobia
☐ ☐ 3 Nausea
☐ ☐ 4 Vomiting

4. Rate your Global Satisfaction with the investigational product:

(choose one)

- ☐ 1 Completely satisfied (couldn't be better)
☐ 2 Very satisfied
☐ 3 Somewhat satisfied
☐ 4 Neither satisfied nor dissatisfied
☐ 5 Somewhat dissatisfied
☐ 6 Very dissatisfied
☐ 7 Completely dissatisfied (couldn't be worse)

DIARY NOT COMPLETED - Explain:☒ Sleeping at scheduled time☐ Other (specify): _____**20 Hours Postdose**Actual date
of entry

19970322

Actual time:

09:20

Please answer the following questions:

1. Have you experienced any **recurrence** of a migraine headache or the associated symptoms since your last evaluation?

(Note: If symptoms never disappeared, answer "no")

☒ No
☐ Yes: number of migraine recurrences: _____
 number of symptom recurrences: _____

2. How do you judge the severity of the pain associated with your headache at this time?

- ☒ 0 Absent
☐ 1 Mild Pain
☐ 2 Moderate Pain
☐ 3 Severe Pain

3. Which of the following symptoms do you now have?

absent present

- ☒ ☒ 1 Photophobia
☒ ☒ 2 Phonophobia
☒ ☒ 3 Nausea
☒ ☒ 4 Vomiting

4. Rate your Global Satisfaction with the investigational product:

(choose one)

- ☐ 1 Completely satisfied (couldn't be better)
☐ 2 Very satisfied
☐ 3 Somewhat satisfied
☐ 4 Neither satisfied nor dissatisfied
☐ 5 Somewhat dissatisfied
☐ 6 Very dissatisfied
☒ 7 Completely dissatisfied (couldn't be worse)

DIARY NOT COMPLETED - Explain:☐ Sleeping at scheduled time☐ Other (specify): _____

CoCensys
HOME DIARY TRANSCRIPTION**PROTOCOL 1042-0112**

SITE NUMBER

01

SUBJECT NUMBER

0101

SUBJECT INITIALS

JAC

24 Hours PostdoseActual date
of entry19970322
year month day

Actual time:

13:15
24-hour time**Please answer the following questions:**

1. Have you experienced any **recurrence** of a migraine headache or the associated symptoms since your last evaluation?

(Note: If symptoms never disappeared, answer "no")

☒ No

☐ Yes: number of migraine recurrences: _____
number of symptom recurrences: _____

2. How do you judge the severity of the pain associated with your headache at this time?

- ☒ 0 Absent
☐ 1 Mild Pain
☐ 2 Moderate Pain
☐ 3 Severe Pain

3. How would you judge the effect of your migraine headache on your level of normal daily activities?

- ☒ 0 Normal
☐ 1 Mildly Impaired
☐ 2 Severely Impaired
☐ 3 Requires Bedrest

4. Which of the following symptoms do you now have?

- absent present
- ☒ 1 Photophobia
☒ 2 Phonophobia
☒ 3 Nausea
☒ 4 Vomiting

5. Rate your Global Satisfaction with the investigational product:

- (choose one)
- ☐ 1 Completely satisfied (couldn't be better)
☐ 2 Very satisfied
☐ 3 Somewhat satisfied
☐ 4 Neither satisfied nor dissatisfied
☐ 5 Somewhat dissatisfied
☐ 6 Very dissatisfied
☒ 7 Completely dissatisfied (couldn't be worse)

Note: If the 24 hour diary page is not completed at the scheduled time, it must be completed **AS SOON AS POSSIBLE** following the missed time.

Please complete the following Quality of Life Questionnaire

Check only one box for each question.

- A: In the past 24 hours after you took the investigational product, how much of the time did you:

1. have increased sensitivity to light and/or noise
2. have nausea
3. have throbbing head pain
4. feel upset about having migraine
5. feel physically uncomfortable
6. feel concerned that your medication would not relieve your migraine symptoms

- B: In the past 24 hours after you took the investigational product, how much of the time did your migraine and symptoms limit your ability to:

7. do normal everyday work (job outside of home, school work, or housework)
8. stay alert
9. operate machinery or a motor vehicle (incl. home appliances and office equipment)
10. enjoy life

- C: In the past 24 hours after you took the investigational product, how much did your migraine and symptoms negatively affect your:

11. interactions with people that are close to you
12. interactions with other people
13. energy level
14. mood

CoCensys**HOME DIARY TRANSCRIPTION**

PROTOCOL 1042-0112

SITE NUMBER

01

SUBJECT NUMBER

01701

SUBJECT INITIALS

JAC

48 Hours Postdose

Actual date
of entry1 9 7 7 0 3 2 3
year month day

Actual time:

13:15
24-hour time

Please answer the following questions:

1. Have you experienced any **recurrence** of a migraine headache or the associated symptoms since your last evaluation?

(Note: If symptoms never disappeared, answer "no")

☒ No

☐ Yes: number of migraine recurrences: _____
number of symptom recurrences: _____

2. How do you judge the severity of the pain associated with your headache at this time?

☒ 0 Absent
☐ 1 Mild Pain
☐ 2 Moderate Pain
☐ 3 Severe Pain

3. How would you judge the effect of your migraine headache on your level of normal daily activities?

☒ 0 Normal
☐ 1 Mildly Impaired
☐ 2 Severely Impaired
☐ 3 Requires Bedrest

4. Which of the following symptoms do you now have?

absent	present	
<input checked="" type="checkbox"/>	<input type="checkbox"/> 1	Photophobia
<input checked="" type="checkbox"/>	<input type="checkbox"/> 2	Phonophobia
<input checked="" type="checkbox"/>	<input type="checkbox"/> 3	Nausea
<input checked="" type="checkbox"/>	<input type="checkbox"/> 4	Vomiting

5. Rate your Global Satisfaction with the investigational product:

(choose one)

☐ 1 Completely satisfied (couldn't be better)
☐ 2 Very satisfied
☐ 3 Somewhat satisfied
☐ 4 Neither satisfied nor dissatisfied
☐ 5 Somewhat dissatisfied
☒ 6 Very dissatisfied
☐ 7 Completely dissatisfied (couldn't be worse)

Note: If the 48 hour diary page is not completed at the scheduled time, it must be completed **AS SOON AS POSSIBLE** following the missed time.



CoCensys

PROTOCOL 1042-0112

HOME DIARY TRANSCRIPTION

SITE NUMBER

01

SUBJECT
NUMBER

0191

SUBJECT INITIALS

JAC