



D♦I♦A♦M♦O♦N♦D♦S♦ Study

Diary 1 (Day 1 to day 5)

*Please apply here sticker
with randomization
number.*

Diary for self evaluation of the treatment.
*(Please write clearly and use the study pen.)
Thank you.*



Initials:

Date of birth:

d d m m y y





Instructions:

1. The study tablets you received are for your own use and for the symptoms you complained about in the pharmacy.
2. Take an initial dose of 2 tablets. If needed, continue with 1 or 2 tablets every 4 to 6 hours. Take the tablets with a glass of water.

◆ Do not take more than 6 tablets per day
3. Do not take the study tablets for more than 5 days for pain and 3 days for fever.
4. If symptoms persist or worsen, please consult your doctor, to ensure that the symptoms are not due to another illness.
5. Please keep medication out of reach of children.

6. Every day, please fill in this diary, answering all the questions.
7. Please record on the pink page 11 all other medications you took during this period besides the study tablets you have received.
8. At the end of the treatment (up to a maximum of 5 days for pain or 3 days for fever) or if you decide to stop the treatment earlier for whatever reason please:
 - Complete the final question on pages 12 to 14 of the diary.
 - Place the diary in the white pre-stamped, addressed envelope.
 - Take the blisters, both used and un-used and put them in the brown pre-stamped, addressed envelope.
 - Put both envelopes in the post.





Day 1

Initials:

Randomization Nr:

Please check:

Date:

Mo	Tue	We	Thu	Fr	Sat	Su
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

d	d	m	m	y	y
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

◆ Did you take any study tablets today?

Yes No

If Yes, please record when you took the study tablets as shown in the example below.

Example:

Time: : Tablets:

:

:

:

:

:

:

:

:

Did you have any unexpected medical complaint today?

Yes No

If Yes, please enter details on the blue pages 8-10 (medical complaints)





Day 2

Initials:

Randomization Nr:

Please check:

Date:

Mo	Tue	We	Thu	Fr	Sat	Su
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

d	d	m	m	y	y
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

◆ Did you take any study tablets today?

Yes No

If Yes, please record when you took the study tablets as shown in the example below.

Time: : Tablets:

:

:

:

:

:

Did you have any unexpected medical complaint today?

Yes No

If Yes, please enter details on the blue pages 8-10 (medical complaints)





Day 3

Initials:

Randomization Nr:

Please check:

Date:

Mo	Tue	We	Thu	Fr	Sat	Su
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

d d	m m	y y
<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>

◆ Did you take any study tablets today?

Yes No

If Yes, please record when you took the study tablets as shown in the example below.

Time:	<input type="text"/> <input type="text"/> :	<input type="text"/> <input type="text"/>	Tablets:	<input type="checkbox"/>
	<input type="text"/> <input type="text"/> :	<input type="text"/> <input type="text"/>		<input type="checkbox"/>
	<input type="text"/> <input type="text"/> :	<input type="text"/> <input type="text"/>		<input type="checkbox"/>
	<input type="text"/> <input type="text"/> :	<input type="text"/> <input type="text"/>		<input type="checkbox"/>
	<input type="text"/> <input type="text"/> :	<input type="text"/> <input type="text"/>		<input type="checkbox"/>
	<input type="text"/> <input type="text"/> :	<input type="text"/> <input type="text"/>		<input type="checkbox"/>

Did you have any unexpected medical complaint today?

Yes No

If Yes, please enter details on the blue pages 8-10 (medical complaints)





Day 4

Initials:

Randomization Nr:

Please check:

Date:

Mo	Tue	We	Thu	Fr	Sat	Su
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

d	d	m	m	y	y
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

◆ Did you take any study tablets today?

Yes No

If Yes, please record when you took the study tablets as shown in the example below.

Time: : Tablets:

:

:

:

:

:

Did you have any unexpected medical complaint today?

Yes No

If Yes, please enter details on the blue pages 8-10 (medical complaints)





Day 5

Initials:

Randomization Nr:

Please check:

Date:

Mo	Tue	We	Thu	Fr	Sat	Su
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

d	d	m	m	y	y
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

◆ Did you take any study tablets today?

Yes No

If Yes, please record when you took the study tablets as shown in the example below.

Time:	<input type="text"/>	:	<input type="text"/>	Tablets:	<input type="checkbox"/>
	<input type="text"/>	:	<input type="text"/>		<input type="checkbox"/>
	<input type="text"/>	:	<input type="text"/>		<input type="checkbox"/>
	<input type="text"/>	:	<input type="text"/>		<input type="checkbox"/>
	<input type="text"/>	:	<input type="text"/>		<input type="checkbox"/>
	<input type="text"/>	:	<input type="text"/>		<input type="checkbox"/>

Did you have any unexpected medical complaint today?

Yes No

If Yes, please enter details on the blue pages 8-10 (medical complaints)





Medical complaints

- ◆ Please enter details of any medical problems that occurred during the treatment period here.

Initials:

Randomization Nr:

1. Describe your medical complaint:

When did it start?

d d m m y y

When did it stop?

Is it still ongoing?

Yes No

Did you see a doctor for this?

Yes No

If Yes, when?

How would you rate the severity of your complaint ? (check one box):

Mild*

Moderate*

Severe*

2. Describe your medical complaint:

When did it start?

d d m m y y

When did it stop?

Is it still ongoing?

Yes No

Did you see a doctor for this?

Yes No

If Yes, when?

How would you rate the severity of your complaint ? (check one box):

Mild*

Moderate*

Severe*

- *Mild = does not interfere with daily life;
 *Moderate = interferes with activities of daily life;
 *Severe = prevents activities of daily life





Medical complaints (Continued)

- ◆ Please enter details of any medical problems that occurred during the treatment period here.

Initials:

Randomization Nr:

3. Describe your medical complaint:

When did it start?

d d m m y y

When did it stop?

Is it still ongoing?

Yes No

Did you see a doctor for this?

Yes No

If Yes, when?

How would you rate the severity of your complaint ? (check one box):

Mild* Moderate* Severe*

4. Describe your medical complaint:

When did it start?

d d m m y y

When did it stop?

Is it still ongoing?

Yes No

Did you see a doctor for this?

Yes No

If Yes, when?

How would you rate the severity of your complaint ? (check one box):

Mild* Moderate* Severe*

- *Mild = does not interfere with daily life;
- *Moderate = interferes with activities of daily life;
- *Severe = prevents activities of daily life





Medical complaints (Continued)

- ◆ Please enter details of any medical problems that occurred during the treatment period here.

Initials:

Randomization Nr:

5. Describe your medical complaint:

When did it start?

d d m m y y

When did it stop?

Is it still ongoing?

Yes No

Did you see a doctor for this?

Yes No

If Yes, when?

How would you rate the severity of your complaint ? (check one box):

Mild* Moderate* Severe*

6. Describe your medical complaint:

When did it start?

d d m m y y

When did it stop?

Is it still ongoing?

Yes No

Did you see a doctor for this?

Yes No

If Yes, when?

How would you rate the severity of your complaint ? (check one box):

Mild* Moderate* Severe*

- *Mild = does not interfere with daily life;
- *Moderate = interferes with activities of daily life;
- *Severe = prevents activities of daily life





Medications

Initials:

- ◆ Please enter any other medication taken during the treatment period here.

Randomization Nr:

Medication name

For what medical reason did you take this medication?

1.	<input type="text"/>	<input type="text"/>
2.	<input type="text"/>	<input type="text"/>
3.	<input type="text"/>	<input type="text"/>
4.	<input type="text"/>	<input type="text"/>
5.	<input type="text"/>	<input type="text"/>
6.	<input type="text"/>	<input type="text"/>
7.	<input type="text"/>	<input type="text"/>





Final questions

Initials:

Randomization Nr:

- ◆ Please fill in these final questions after you have stopped taking the study tablets.

Why did you stop taking the study tablets?

(Tick one of the following boxes only)

- I did not need the study tablets any more because my condition improved.
- The study tablets did not give me sufficient relief.
- The study tablets upset me.
- I did not want to continue for personal reasons not depending on the study tablets.
- I have used all the study tablets given to me.

How would you rate the treatment you have taken for your medical complaint?

(Tick one of the 5 boxes)

- Overall the study tablets gave me a **complete relief**.
- Overall the study tablets gave me a **lot of relief**.
- Overall the study tablets gave me **moderate relief**.
- Overall the study tablets gave me a **little relief**.
- Overall the study tablets gave me **no relief**.

How did you tolerate the treatment?

(Tick one of the 4 boxes)

- Overall the tolerability was **excellent**: the study tablets did not upset me at all.
- Overall the tolerability was **good**: the study tablets did not really upset me.
- Overall the tolerability was **moderate**: the study tablets did upset me.
- Overall the tolerability was **poor**: the study tablets did upset me a lot.





◆ Did you see a doctor during the treatment?

Yes No

Initials:

Randomization Nr:

if Yes, why?

- Because my fever/pain got worse
- Because I got a health problem
- Because the treatment did not work

if Yes, when?

d d m m y y

Please give us the name and address of the doctor you saw:

Name:

Street/Nr:

ZIP/City:

Phone:

Would you take these tablets again?

Yes No

Did you recognize the treatment?

Yes No

If Yes, which treatment
do you think it was?:





Thank you

Initials:

Randomization Nr:

- ◆ I confirm that I have truthfully completed all the information in this diary:

Date:

d d m m y y

Signature:

Thank you for your help with this study.

Please return the diary and study tablets by using the pre-stamped addressed envelopes (see point 8 of instructions).
Do not forget to complete the diary 2 until Day 10 and diary 3 until Day 20.

Novartis Consumer Health SA, Nyon, Schweiz,

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