

#### STOP GAP RESEARCH STUDY

#### PATIENT DIARY 1 (0-6 WEEKS) RCT patients

ID number	
Initials	

Thank you for taking part in this medical research study which is looking at the best way to treat pyoderma gangrenosum.

This booklet is for you to keep and record the following:

- How much pain your ulcer has caused you
- Whether your pyoderma gangrenosum has affected your daily activities
- Whether you are still using dressings for your ulcer
- · Any illnesses you have experienced
- · Any visits you have made to your GP or hospital

This diary should be completed every day for 6 weeks.

Once you have completed the diary, please take it to the hospital when you see the doctor who is treating your pyoderma gangrenosum.

From time to time, we may call you to find out how you are getting on. Please have this diary to hand during these telephone calls.

# If you have any queries about completing this diary, please do not hesitate to contact the study team: **0115 8844926 or 0115 8844941**

EudraCT No 2008-008291-14

Patient Diary 1 (0-6 weeks) RCT\_v2\_221111

#### Your local STOP GAP study doctor is:

Name	
Hospital name	
Telephone number	

#### The co-ordinating centre is:

Trial Manager	Eleanor Mitchell
Trial Administrator	Sally Kucyj
Address	Nottingham Clinical Trials Unit Nottingham Health Science Partners C Floor, South Block Queen's Medical Centre Nottingham NG7 2UH
Telephone number	0115 8844926 / 0115 8844941
Email address	stopgap@nottingham.ac.uk

If you decide at any time that you would like to withdraw from this research study, you are free to do so, without having to give a reason.

Please telephone either your study doctor or trial manager (details above) to let us know.

It is important, however, that you **do not** stop taking the tablets suddenly as this can be very dangerous. Please talk to your doctor first who will be able to advise you what to do.



# It is also important that you tell us as soon as you stop using your dressings. Please remember to contact us when you stop using dressings for your ulcer.

The ulcer being studied is:

This is the ulcer we are most interested in. All the answers you provide should be based on this ulcer. WEEK 1: week commencing date: \_\_\_\_\_

The **date** I started taking tablets on: \_\_\_\_\_

		Monday	1	[uesday	V	Vednesday	T	hursday	Friday	S	aturday	Sunday
How much pain has your		None		None		None		None	None		None	None
pyoderma		Mild		Mild		Mild		Mild	Mild		Mild	Mild
gangrenosum (PG)		Moderate		Moderate		Moderate		Moderate	Moderate		Moderate	Moderate
given you <b>today</b> ?		Severe		Severe		Severe		Severe	Severe		Severe	Severe
		Extreme		Extreme		Extreme		Extreme	Extreme		Extreme	Extreme
Have you taken any		Yes		Yes		Yes		Yes	Yes		Yes	Yes
painkillers?		No		No		No		No	No		No	No
Have you been able to		Yes		Yes		Yes		Yes	Yes		Yes	Yes
work/do usual activities?		No		No		No		No	No		No	No
Have you been using		Yes		Yes		Yes		Yes	Yes		Yes	Yes
dressings?		No		No		No		No	No		No	No
Have you had any health problems?												
Please specify												
	e fo	llowing ser	vice	s this week	If	yes, please tic	- kify					
Please specify Have you used any of th	e fo	llowing ser	vice	s this week	If		- kify					
Please specify	e fo	2	vice		If	<b>yes</b> , please tic oderma gangre	- kify	um or becaus	possible side		ects of the m	ation
Please specify <b>Have you used any of th</b> GP Surgery GP Home	e fo		vice		If	<b>yes</b> , please tic oderma gangre	- kify	um or becaus	possible side		ects of the m	ation
Please specify Have you used any of th GP Surgery	e fo		vice		If	yes, please tic oderma gangre	- kify	um or becaus	possible side		ects of the m	ation
Please specify Have you used any of th GP Surgery GP Home Practice Nurse			vice		If	yes, please tic oderma gangre	- kify	um or becaus	possible side		ects of the m	ation
Please specify Have you used any of th GP Surgery GP Home Practice Nurse District Nurse					If	yes, please tic oderma gangre	- kify	um or becaus	possible side		ects of the m	ation

### WEEK 2: week commencing date: \_\_\_\_\_

		Monday	1	Fuesday	V	Vednesday	Т	hursday	Friday	S	aturday	Sunday
How much pain has your pyoderma gangrenosum (PG) given you today?		None Mild Moderate Severe Extreme		None Mild Moderate Severe Extreme		None Mild Moderate Severe Extreme		None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme		None Mild Moderate Severe Extreme	None Mild Moderate Severe Extreme
Have you taken any painkillers? Have you been able to		Yes No Yes		Yes No Yes		Yes No Yes		Yes No Yes	Yes No Yes		Yes No Yes	Yes No Yes
work/do usual activities?		No		No		No		No	No		No	No
Have you been using dressings?		Yes No		Yes No		Yes No		Yes No	Yes No		Yes No	Yes No
Have you had any health problems? <i>Please specify</i>												
Have you used any of th	e fo	llowing ser	vice	s this week	If	Yes □ N <b>yes</b> , please tic oderma gangre	k if y					
GP Surgery												
GP Home												
Practice Nurse												
District Nurse												
Out Patient Appointment												
In Patient												
Other, please specify:												

WEEK 3: week commencing date: \_\_\_\_\_

		Monday	Т	uesday	V	Vednesday	Т	hursday	Friday	S	Saturday	Sunday
How much pain has your pyoderma gangrenosum (PG) given you today? Have you taken any painkillers?		None Mild Moderate Severe Extreme Yes No		None Mild Moderate Severe Extreme Yes No		None Mild Moderate Severe Extreme Yes No		None Mild Moderate Severe Extreme Yes No	None Mild Moderate Severe Extreme Yes No		None Mild Moderate Severe Extreme Yes No	None Mild Moderate Severe Extreme Yes No
Have you been able to work/do usual activities? Have you been using dressings?		Yes No Yes No		Yes No Yes No		Yes No Yes No		Yes No Yes No	Yes No Yes No		Yes No Yes No	Yes No Yes No
Have you had any health problems? Please specify		NU				NO				<u> </u>		
Harris and the second		llowing cor	vicor	thic wook		Vee D N						
Have you used any of th	ie to	nowing ser	vices	uns week	If	yes, please tic	- kify					
			vices		If		- kify					
GP Surgery		_	vices		If	<b>yes</b> , please tic oderma gangre	- kify	im or becaus	possible side		ects of the m	ation
GP Surgery GP Home			vices		If	<b>yes</b> , please tic oderma gangre	- kify	im or becaus	possible side		ects of the m	ation
GP Surgery GP Home Practice Nurse District Nurse					If	yes, please tic oderma gangre	- kify	Im or becaus	possible side		ects of the m	ation
GP Surgery GP Home Practice Nurse					If	yes, please tic oderma gangre	- kify	Im or becaus	possible side		ects of the m	ation
GP Surgery GP Home Practice Nurse District Nurse					If	yes, please tic oderma gangre	- kify	im or becaus	possible side		ects of the m	ation

WEEK 4: week commencing date: \_\_\_\_\_

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
How much pain has your pyoderma gangrenosum (PG) given you today?	<ul> <li>None</li> <li>Mild</li> <li>Moderate</li> <li>Severe</li> </ul>						
	Extreme						
Have you taken any painkillers?	Yes   No	Yes     No	Yes No	Yes     No	Yes     No	Yes     No	Yes     No
Have you been able to work/do usual activities?	Yes     No						
Have you been using dressings?	Yes     No	□ Yes □ No					
Have you had any health problems? <i>Please specify</i>							
Have you used any of th	e following sei	vices this week		- ck if you have ac	cessed any of the se of possible sid		
GP Surgery							
GP Home							
Practice Nurse							
District Nurse							
Out Patient Appointment							
In Patient							
Other, please specify:							

WEEK 5: week commencing date: \_\_\_\_\_

	Monday Tuesday		Wednesday			Saturday	Sunday
How much pain has your <b>pyoderma</b> <b>gangrenosum (PG)</b> given you <b>today</b> ? Have you taken any painkillers? Have you been able to	<ul> <li>None</li> <li>Mild</li> <li>Moderate</li> <li>Severe</li> <li>Extreme</li> <li>Yes</li> <li>No</li> <li>Yes</li> </ul>	<ul> <li>None</li> <li>Mild</li> <li>Moderate</li> <li>Severe</li> <li>Extreme</li> <li>Yes</li> <li>No</li> <li>Yes</li> </ul>	<ul> <li>None</li> <li>Mild</li> <li>Moderate</li> <li>Severe</li> <li>Extreme</li> <li>Yes</li> <li>No</li> <li>Yes</li> </ul>	<ul> <li>None</li> <li>Mild</li> <li>Moderate</li> <li>Severe</li> <li>Extreme</li> <li>Yes</li> <li>No</li> <li>Yes</li> </ul>	Friday None None Nild Severe Extreme Yes No Yes Yes	<ul> <li>None</li> <li>Mild</li> <li>Moderate</li> <li>Severe</li> <li>Extreme</li> <li>Yes</li> <li>No</li> <li>Yes</li> </ul>	<ul> <li>None</li> <li>Mild</li> <li>Moderate</li> <li>Severe</li> <li>Extreme</li> <li>Yes</li> <li>No</li> <li>Yes</li> </ul>
work/do usual activities? Have you been using dressings?	No     Yes     No	No     Yes     No	No     Yes     No	No     Yes     No	No     Yes     No	No     Yes     No	No     Yes     No
Have you had any health problems? <i>Please specify</i> Have you used any of th	e following se	rvices this week	If yes, please tio	k if you have acc			
			pyoderma gangre	enosum or becau	se of possible side	e-effects of the m	
GP Surgery							
GP Home							
Practice Nurse							
District Nurse							
Out Patient Appointment							
In Patient							
Other, please specify:							
!!! IMPORTANTPLE#	ASE REMEMBER	TO CONTACT T	HE CO-ORDINATI	NG CENTRE AS	500N AS YOU S	TOP USING DR	ESSINGS!!!!

WEEK 6: week commencing date: \_\_\_\_\_

		Monday		Fuesday	V	<b>Vednesday</b>	Т	hursday	Friday	5	Saturday	Sunday
How much pain has your		None		None		None		None	None		None	None
pyoderma		Mild		Mild		Mild		Mild	Mild		Mild	Mild
gangrenosum (PG) given you today?		Moderate		Moderate		Moderate		Moderate	Moderate		Moderate	Moderate
given you today?		Severe		Severe		Severe		Severe	Severe		Severe	Severe
		Extreme		Extreme		Extreme		Extreme	Extreme		Extreme	Extreme
Have you taken any		Yes		Yes		Yes		Yes	Yes		Yes	Yes
painkillers?		No		No		No		No	No		No	No
Have you been able to		Yes		Yes		Yes		Yes	Yes		Yes	Yes
work/do usual activities?		No		No		No		No	No		No	No
Have you been using		Yes		Yes		Yes		Yes	Yes		Yes	Yes
dressings?		No		No		No		No	No		No	No
Have you had any health problems? <i>Please specify</i>												
Have you used any of th	e fo	llowing ser	vice	s this week	If	l Yes □ N <b>yes</b> , please tic oderma gangre	k if y					
Have you used any of th GP Surgery	e fo	llowing ser	vice	s this week	If	yes, please tic	k if y					
	ie fo	_	vice		If	<b>yes</b> , please tic oderma gangre	k if y	um or becaus	possible side		ects of the m	ation
GP Surgery	e fo		vice		If	<b>yes</b> , please tic oderma gangre	k if y	um or becaus	possible side		ects of the m	ation
GP Surgery GP Home	e fo		vice		If	yes, please tic oderma gangre	k if y	Im or becaus	possible side		ects of the m	ation
GP Surgery GP Home Practice Nurse	e fo		vice		If	yes, please tic oderma gangre	k if y	um or becaus	possible side		ects of the m	ation
GP Surgery GP Home Practice Nurse District Nurse			vice		If	yes, please tic oderma gangre	k if y	Im or becaus	possible side		ects of the m	ation

WEEK 7: week commencing date: \_\_\_\_\_

		Monday	-	Fuesday	V	Nednesday	T	hursday	Friday	S	Saturday	Sunday
How much pain has your pyoderma gangrenosum (PG) given you today? Have you taken any painkillers?		None Mild Moderate Severe Extreme Yes No		None Mild Moderate Severe Extreme Yes No		None Mild Moderate Severe Extreme Yes No		None Mild Moderate Severe Extreme Yes No	None Mild Moderate Severe Extreme Yes No		None Mild Moderate Severe Extreme Yes No	None Mild Moderate Severe Extreme Yes No
Have you been able to work/do usual activities? Have you been using dressings?		Yes No Yes No		Yes No Yes No		Yes No Yes No		Yes No Yes No	Yes No Yes No		Yes No Yes No	Yes No Yes No
Have you had any health problems? Please specify												
Have you used any of th	e to	llowina ser	vice	sthis week	? 🗆	Yes 🗆 N						
		, in the second second			If	yes, please tic	- kify					
					If		- kify					
GP Surgery		_			If	<b>yes</b> , please tic oderma gangre	- kify	um or becaus	possible side		ects of the m	ation
GP Surgery GP Home					If	<b>yes</b> , please tic oderma gangre	- kify	Im or becaus	possible side		ects of the m	ation
GP Surgery GP Home Practice Nurse District Nurse					If	yes, please tic oderma gangre	- kify	Im or becaus	possible side		ects of the m	ation
GP Surgery GP Home Practice Nurse					If	yes, please tic oderma gangre	- kify	Im or becaus	possible side		ects of the m	
GP Surgery GP Home Practice Nurse District Nurse					If	yes, please tic oderma gangre	- kify	IM or becaus	possible side		ects of the m	

## WEEK 8: week commencing date: \_\_\_\_\_

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
How much pain has your pyoderma gangrenosum (PG) given you today?	<ul> <li>None</li> <li>Mild</li> <li>Moderate</li> <li>Severe</li> <li>Extreme</li> </ul>	None     Mild     Moderate     Severe     Extreme					
Have you taken any painkillers? Have you been able to	Yes     No     Yes	Yes     No     Yes	Yes     No     Yes     Yes	Yes     No     Yes	Yes     No     Yes	Yes     No     Yes	Yes     No     Yes     Yes
work/do usual activities? Have you been using dressings?	No     Yes     No	No     Yes     No					
Have you had any health problems? <i>Please specify</i>							
Have you used any of th	e following se	rvices this week		lo ck if you have acc enosum or becau:			
GP Surgery							
GP Home							
Practice Nurse							
District Nurse							
Out Patient Appointment							
In Patient							
Other, please specify:							
!!! IMPORTANTPLE/	ASEREMEMBE	R TO CONTACT T	HE CO-ORDINATI	NG CENTRE AS	SOON AS YOU S	TOP USING DR	ESSINGS!!!!

Since you started your	have you taken your tablets:
Every day	
Most days	
Some days	
Never	
If you would like to add any comments, please do so h	nere:
Please now record any prescriptions you have been giv	ven for your pyoderma
gangrenosum (e.g tablets, creams, dressings, bandag	es etc).
Prescription type / name of medicine	Dose / number of items (if
	applicable)