

Thank you for completing this diary, please return it to the hospital at your next visit or when the trial Nurse/Doctor asks for it

Centre use only

Participant initials:

Patient number:



Patient Treatment Diary

Participant initials

Patient trial number

If this Diary has been found please send it to:

SYCAMORE Trial Co-ordinator
MCRN CTU
Institute of Child Health
Alder Hey Children's NHS Foundation Trust
Eaton Road
Liverpool
L12 2AP

Site use only:

Date given to the patient:

Date diary collected from the patient:

How to complete this diary

It is very important that you complete all sections of this diary, if you have any questions please contact the study team at the hospital or speak to them at your next study visit.

Pages 3 – 4

Please record on these pages the date and time of your study injections. We would also like to know how much of the study drug you have taken at each time and where the drug was taken, please record this in the space given. Please also record the number on the vial when you have your injection. We would also like to know if you have had any side effects after your treatment such as headaches, nausea or a rash. We would also like you to record when you have your Methotrexate. Please complete the table on page 4 each time you take Methotrexate.

Page 5

We would like to know if you are taking any other medicines such as Paracetamol etc at the same time period that you are having your study injections. Please record any other medicines on the table on page 5, please complete all rows in the table for each medicine. Please leave this table blank if you have not taken any other medicines.

Pages 6 – 7

We would like to know if you have had any support from other services, such as your GP or School Nurse. We would also like to know if you have had any trips to the hospital that have not been part of the SYCAMORE trial. Please answer the questions on pages 6 and 7 as completely as you can.

Have you had any hospital admissions since your last SYCAMORE study visit?	Ward speciality (e.g. Paediatrics, Rheumatology)	Total number of nights spent in Hospital	Department Visited e.g. A&E, X-RAY, Outpatients clinic	Total number of visits?
Reason for Admission 1:				
Reason for Admission 2:				
Reason for Admission 3:				
Have you had any Hospital visits since your last SYCAMORE study visit that has not involved overnight admission?				
Reason for Visit 1:				
Reason for Visit 1:				
Reason for Visit 1:				

Have you used any of these services since your last SYCAMORE hospital visit? If yes please provide the number of visits.

GP (family doctor):	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Number of Visits <input type="text"/>
Practice/District Nurse:	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Number of Visits <input type="text"/>
Physiotherapist:	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Number of Visits <input type="text"/>
Occupational Therapist:	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Number of Visits <input type="text"/>
Optician:	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Number of Visits <input type="text"/>
Social Worker:	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Number of Visits <input type="text"/>
Psychologist	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Number of Visits <input type="text"/>
School Nurse:	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Number of Visits <input type="text"/>
School Counsellor:	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Number of Visits <input type="text"/>
Help in school (Mentor, Teaching Assistant):	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Number of Visits <input type="text"/>

Please list any visual aids or other appliances that you have received since your last SYCAMORE hospital visit

Are you in full time education? Yes No

If yes, have you been off sick from school/college since your last study visit?

Yes No

If yes, how many days in total have you been off sick in the last study visit?

Total Number =

Details of study injections :

Date of Injection <input type="text"/> - <input type="text"/> - <input type="text"/>	Time (24hrs) <input type="text"/> : <input type="text"/>
Volume of study drug taken <input type="text"/> mg	Vial Number <input type="text"/>
Did you have any problems injecting the study drug or any side effects afterwards?	Where was the drug administered? At home <input type="checkbox"/> At hospital <input type="checkbox"/>

Date of Injection <input type="text"/> - <input type="text"/> - <input type="text"/>	Time (24hrs) <input type="text"/> : <input type="text"/>
Volume of study drug taken <input type="text"/> mg	Vial Number <input type="text"/>
Did you have any problems injecting the study drug or any side effects afterwards?	Where was the drug administered? At home <input type="checkbox"/> At hospital <input type="checkbox"/>

Date of Injection <input type="text"/> - <input type="text"/> - <input type="text"/>	Time (24hrs) <input type="text"/> : <input type="text"/>
Volume of study drug taken <input type="text"/> mg	Vial Number <input type="text"/>
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Date of Injection <input type="text"/> - <input type="text"/> - <input type="text"/>	Time (24hrs) <input type="text"/> : <input type="text"/>
Volume of study drug taken <input type="text"/> mg	Vial Number <input type="text"/>
Did you have any problems injecting the study drug or any side effects afterwards?	Where was the drug administered? At home <input type="checkbox"/> At hospital <input type="checkbox"/>

Date of Injection <input type="text"/> - <input type="text"/> - <input type="text"/>	Time (24hrs) <input type="text"/> : <input type="text"/>
Volume of study drug taken <input type="text"/> mg	Vial Number <input type="text"/>
Did you have any problems injecting the study drug or any side effects afterwards?	Where was the drug administered? At home <input type="checkbox"/> At hospital <input type="checkbox"/>

Date of Injection <input type="text"/> - <input type="text"/> - <input type="text"/>	Time (24hrs) <input type="text"/> : <input type="text"/>
Volume of study drug taken <input type="text"/> mg	Vial Number <input type="text"/>
Did you have any problems injecting the study drug or any side effects afterwards?	Where was the drug administered? At home <input type="checkbox"/> At hospital <input type="checkbox"/>

Date of Injection <input type="text"/> - <input type="text"/> - <input type="text"/>	Time (24hrs) <input type="text"/> : <input type="text"/>
Volume of study drug taken <input type="text"/> mg	Vial Number <input type="text"/>
Did you have any problems injecting the study drug or any side effects afterwards?	Where was the drug administered? At home <input type="checkbox"/> At hospital <input type="checkbox"/>

Date of Injection <input type="text"/> - <input type="text"/> - <input type="text"/>	Time (24hrs) <input type="text"/> : <input type="text"/>
Volume of study drug taken <input type="text"/> mg	Vial Number <input type="text"/>
Did you have any problems injecting the study drug or any side effects afterwards?	Where was the drug administered? At home <input type="checkbox"/> At hospital <input type="checkbox"/>

4 Details of Methotrexate treatment taken:

Route of Methotrexate:

Oral (tablets)

(Please tick)

Subcutaneous injection



Centre use only

Participant initials:

Patient number:

If you have taken any other medicines apart from the study injections and the Methotrexate, please record them in the table below:

Date and Time Methotrexate taken	Date received from Pharmacy	Strength (e.g. 1mg/ml)	Quantity Supplied (e.g. 100ml)	Manufacturer	Batch/Lot Number
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

Name of other medication taken	Date medication started	Dose taken e.g. 2 tablets, 5ml	Dose frequency e.g. 2 tablets twice a day	Date medication stopped	Cost of medication
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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