

# Diet and Health Study 2018



## The 24-hour urine collection leaflet

We are interested in measuring electrolytes in urine (such as potassium) which provide useful information about diet. We can only get this essential information from the analyses of the urine sample you provide. We are aiming to collect urine from 600 different people for a nutrition and health study. We are not testing for drugs or viruses in this study.

### What will happen to me?

We will ask you to collect all your urine over a 24-hour period. We will also ask that you take three tablets of a marker, called paraaminobenzoic acid (PABA), which helps to check how complete your urine sample is. PABA is part of the B vitamin folic acid. The nurse will give you a leaflet providing more information about PABA. If you would rather not take the PABA tablets, please discuss this with the nurse.

## Why 24 hours?

The levels of electrolytes in human bodies change according to what we eat and how much fluid we drink. Measuring electrolytes provides useful indicators about diet. A collection over 24 hours, if collected according to protocol, gives much more reliable information about the usual levels in a person's diet than a single urine collection. Please eat and drink as you normally would during this time.

## Equipment

The nurse will provide you with the following equipment for making your collection:

- 5 litre screw-capped plastic collection container
- 1 litre plastic jug
- A funnel
- 2 litre screw-capped container (optional)
- Plastic bag for carrying the equipment

## Before the urine collection

The start date of your 24-hour urine collection will be selected at random so that we get representative results for all days of the week. If the selected day is not convenient for you, the nurse will be able to allocate a more suitable day for you. Women should not make their collection during their period.

## How to make your collection:

### **24-hour urine collection instructions**

#### **Choose a Start time suitable for both days (e.g 7am):**

At Start time on day 1 go to the toilet as normal and **do not** collect urine. Note time on form.

At Start time on day 1 take **PABA tablet 1** and note time on form.

Pass all subsequent urine into the jug and add to the 5L container. Keep container in a cool place and note any missed collections.



#### **At 4-6 hours after Start time:**

Take **PABA tablet 2** and note time on form.

Pass all subsequent urine into the jug and add to the 5L container. Keep container in a cool place and note any missed collections.



#### **At 4-6 hours after PABA tablet 2 time:**

Take **PABA tablet 3** and note time on form. Keep PABA packaging to give to nurse.

Pass all subsequent urine into the jug and add to the 5L container. Keep container in a cool place and note any missed collections.



**Exactly 24 hours after Start time (e.g 7am):** Pass urine into the jug and add to the container. The urine collection is now finished. Write time on form.

## **If you miss a sample or forget PABA**

---

If, for any reason (e.g. because of a bowel motion) a urine sample is missed – even a small spillage – please record this on the urine collection sheet. This means we can still use your sample for the research.

PABA should be taken at evenly spaced intervals throughout the collection period as detailed in the flow diagram. If a tablet is forgotten or taken at different times, then please record this on the urine collection sheet.

## **Once your collection is complete**

---

The nurse will arrange an appointment with you to come and collect the urine sample as soon as possible after completion of your 24hour urine collection. In the mean time, please store your complete collection in a cool, dark place (e.g. a cupboard or utility room).

At this appointment the nurse will weigh the urine collection and take two small samples from your 24-hour collection, which will be sent to the lab for analysis.

The nurse will dispose of the equipment at the end of the visit.

## **Any other questions**

---

We hope this leaflet answers any questions you may have. If you have any other questions, please speak to the nurse.

## Diet and Health Study 2018

### *Protocol for 24-hour urine collection*

#### 1. Background & aims

Dietary sodium (salt) consumption has been shown to contribute to high blood pressure which is a major risk factor in the development of cardiovascular disease. There is documented evidence that on average Western diets contain too much sodium (salt) and too little potassium. The Foods Standards Agency (FSA) has estimated that 75% of dietary salt intake comes from processed foods.

In May 2003 The Scientific Advisory Committee on Nutrition (SACN) published its report on Salt and Health. This recommended that salt levels should be reduced to a daily average of 6g per day for adults and children aged 11 and older.

It is not possible to obtain accurate estimates of salt intake from food intake information, mainly because the amount of salt added to food in cooking or at the table is not captured. Therefore, the best way to estimate salt intake is to analyse its presence in the urine using a complete 24-hour collection.

We are also measuring potassium (a marker of fruit and vegetable intake).

We do not want to draw too much attention to the fact that our main interest is sodium excretion, a measure of salt intake, because this may prompt participants to eat less salt than usual during the collection period. Therefore, we would like nurses to repeat the following information, provided in the leaflet for participants:

*“We are interested in measuring useful dietary indicators in the urine, such as electrolytes and potassium.*

*We can only get this information from the analyses of the urine sample you provide”*

## 2. Eligibility for 24-hour urine collection

### **Men and women aged 19-64 years**

- **Including** participants who refuse to take PABA (*para*-aminobenzoic acid) tablets but are willing to carry out the 24-hour urine collection.
- **Including** participants who CANNOT take PABA (e.g. those allergic to hair dye, sunscreen or supplements or those on sulphonamides) but are willing to carry out the 24-hour urine collection without PABA.

### *Before the visit*

The participant will have been contacted by phone and agreed to be visited by a nurse. The participant is sent a letter with an FAQ leaflet explaining the study. The nurse follows up with a phone call to make an appointment and follows up with a letter confirming the appointment.

### *First visit*

At the first nurse visit, the nurse will explain the purpose and procedures of the urine collection in more detail, encourage and answer questions, check eligibility, provide the participant with detailed leaflets about PABA and the urine collection instructions, obtain written consent and deliver the equipment to the participant.

The nurse will assign a day of the week to the participant when they are to carry out the 24-hour collection. This day will be chosen randomly by CAPI, and is done in order to ensure that sufficient samples are collected on weekdays, as our diet differs between weekdays and weekends. If a participant cannot collect on this day, another day will be chosen randomly and assigned.

At this visit the nurse will also make arrangements for the second visit to sub-sample and post the urine (the same day or the day after 24-hour collection) to MRC Epidemiology Unit/Biorepository for analysis.

### *Second visit*

This will take place on the day or one day after the 24-hour urine collection. The nurse will thoroughly mix and collect two aliquots of the 24-hour urine sample and dispose of the remaining urine down the participant's toilet and equipment in the household waste. The nurse will ensure that the samples are labelled correctly, and prepare packaging and despatch of the samples. The nurse will also check that the participant completed the 24-hour urine collection sheet) - in particular checking start and end time, any missed collections or missed PABA tablets, certain medication and dietary supplements/vitamins taken during the collection period. Finally, participants will be handed a **£15** gift card for their participation in this study. This gift card will be activated in CAPI by the nurse and be ready for the participant to use between 48 and 72 hours after the nurse's visit.

## 3. Participant documents

The following documents will be provided for the study:

Participant Documents
Advance Letter
FAQ leaflet
Pre-nurse card
Nurse appointment letter
24-hour urine leaflet
PABA leaflet
Consent form
24-hour urine collection sheet

### *Consent form (carbonised)*

The consent form will be signed by the participant and the nurse to indicate whether the participant is willing to take part and to take PABA as part of the 24-hour urine collection. The consent form will be carbonised so that the participant can retain one copy and a second copy can be returned to the office.

### *Participant instructions*

The 24-hour urine collection leaflet provides the participant with details about how to collect the 24-hour sample.

### *PABA information leaflet*

The PABA information leaflet gives information about the PABA tablets. Each participant will be asked to take three tablets during the 24-hour collection period and to record details about when these were taken. PABA levels will be measured in the urine sample to assess the completeness of the 24-hour collection.

### *24-hour urine collection sheet*

The 24-hour urine collection sheet will be completed by the participant, checked by the nurse and sent to MRC Epidemiology Unit with the samples. Information from the urine collection sheet will be entered by the nurse into CAPI. The participant will be asked to choose a start time that will work for both days.

The nurse will fill in the participant details and the assigned date for the 24-hour collection, and remind the participant about when to take the PABA tablets. Ideally, the tablets should be taken at evenly spaced intervals during the collection period:

- **Start day:** get up and go to the toilet, flush it away and note the time. This will be the 24-hour urine start time. (DO NOT COLLECT THIS URINE)
- Take the first PABA tablet and note the time
- Collect all urine into the equipment provided
- Take the second PABA tablet 4-6 hours after taking the first tablet
- Continue to collect all urine into the equipment provided
- Take the third tablet 4-6 hours after the second tablet
- **Next day:** get up and go to the toilet and collect the urine sample into the equipment provided. Note the time. This will be the end time of the urine collection and should be EXACTLY 24-hours after the start time. (COLLECT THIS URINE)

As noted above, CAPI will randomly assign start dates for participants. This is to ensure that sufficient samples are collected on weekdays, as our diet differs between weekdays and weekends.

The participant will be asked to complete the 24-hour urine collection sheet during the collection period. Details needed are: date and time of 24-hour sample and date and time PABA tablets are taken. The date and time of any missed urine collections and the names of dietary supplements/vitamins and certain medication taken during this period will also be recorded.

## 4. The first nurse visit: introducing the 24-hour urine collection

### *CAPI Prompt*

If participants are eligible, a prompt will appear in CAPI asking the nurse to explain the purpose of the 24-hour urine collection and the use of PABA, explain the instructions for collection in detail, obtain consent and provide participants with written instructions and equipment needed for the study.

The nurse will also answer any questions the participant may have. If the participant is willing to take part, they will be asked to initial the appropriate boxes on the consent form.

### *PABA exclusion criteria*

Participants are still eligible if they do not want to take PABA but are willing to carry out the 24-hour urine collection. The following participants cannot take PABA, but they are still eligible to take part if they are willing to carry out the 24-hour urine collection:

- those who are allergic to dietary supplements/vitamins, hair dyes or sunscreen lotions
- those who take sulphonamide antibiotics during the 24-hour urine collection

## *Informed consent*

The participant should initial the consent form to indicate that they have read the 24-hour urine leaflet and PABA leaflet and would like to take part in the study. Participants will be encouraged to take PABA if they can do so. Participants are still eligible if they do not want to take PABA but are willing to carry out the 24-hour urine collection. The nurse will go through the instructions as per protocol except for PABA.

All participants will be instructed on the completion of the urine collection sheet.

## *Equipment*

At the first nurse visit the following equipment will be provided:

- 5 litre capacity screw cap container to collect urine.
- *Optional:* 2 litre capacity screw cap container for urine
- Funnel
- Jug
- PABA tablets
- Carrier bags for transporting the equipment

## *Procedures*

The nurse will assign a day of the week to the participant when they are to carry out the 24-hour collection. This day will be chosen randomly by CAPI, and is done in order to ensure that sufficient samples are collected on weekdays, as our diet differs between weekdays and weekends. If a participant cannot collect on this day, another day will be chosen randomly and assigned. There is no limit to the number of times randomisation can occur.

Reassignment of dates should only be offered if the random date is impractical for the participant or if the date falls on a period day for female participants.

## *Sample collection*

The requirement is to collect all urine which enters the bladder over 24 hours. Therefore, the 24-hour collection period should start immediately after the first urine void of day 1 is disposed down the toilet. From this moment the bladder is starting to fill with urine again so this is recorded as the START time. The 24-hour period will include the first void at the same time on the following day and should be EXACTLY 24 hours after the start time. For example, if the participant starts the 24-hour collection after the first void on a Tuesday at 7am then they stop collecting after their first void on Wednesday which should also be at 7am. If the participant starts collecting at midday on Wednesday (it should start after their first void of the day), then the collection finishes at midday on Thursday (and must include their first void on Thursday).

During the period of collection, participants will be asked to pass all urine into the plastic jug and then pour it in the 5 litre container using the funnel provided.

It is extremely important that all urine produced over the 24-hour period is included in the combined collection sample. During this period, participants will be asked to pass stools after passing urine, so that urine is not lost. When participants are away from home they will have the option to take a 2 litre collection container, the jug and funnel with them instead of the



larger container. However, on return anything collected into the 2 litre container must be transferred to the main 5 litre container to mix it with the preservative.

Females will be instructed to collect urine on non-period days.

### *PABA (Para-aminobenzoic acid)*

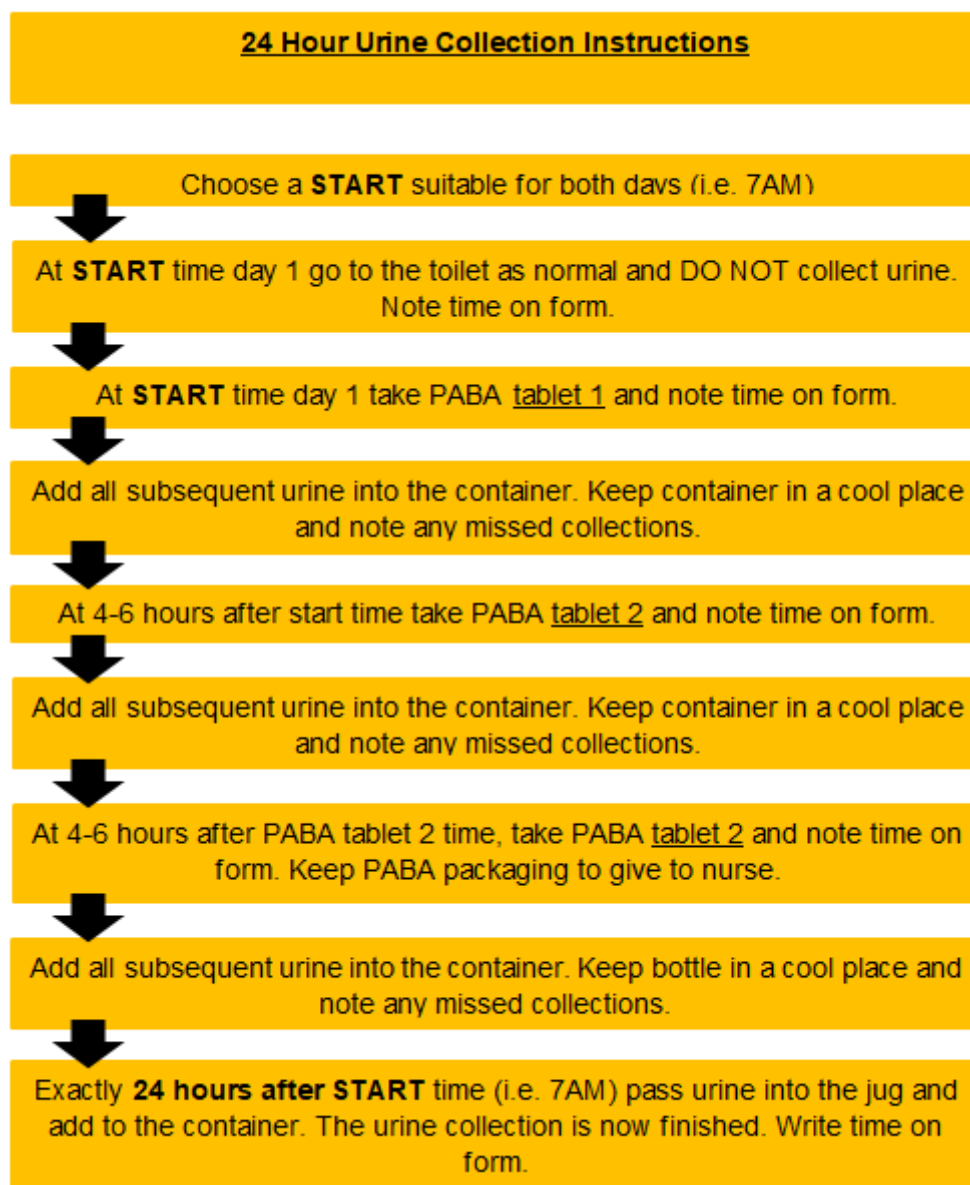
Each participant will have three PABA tablets which are to be taken at evenly spaced intervals throughout the collection period. The last PABA tablet should be taken at least 8 hours before the final urine collection on the second day. This time is needed for PABA clearance through the kidneys to ensure that all PABA is excreted by the time the participant collects their final sample. The participant will be asked to retain the silver PABA blister pack and return it to the nurse on the second visit.

PABA is an intermediate in the synthesis of folic acid in bacteria. PABA is consumed in small amounts as part of our usual diet and is found, for example, in liver, kidney, brewer's yeast, molasses, whole grains, mushrooms and spinach, and can be made by intestinal bacteria. Larger amounts of PABA are found in some supplement preparations. Following ingestion, PABA is passively absorbed mainly from the small intestine. From there, it enters the portal circulation. Some metabolism of PABA occurs in the liver and PABA and its metabolites are mainly excreted in the urine. PABA may interfere with sulphonamide based antibiotics. The latter excludes participants from taking PABA. Although not directly harmful to the participant PABA may stop the anti-bacterial from working. Please note we will not ask participants to stop any of their sulphonamide medication but simply ask to not take PABA. In CAPI the nurse will have a short list of medications that exclude participants from taking PABA and on a laminated sheet.

Because some medications and dietary supplements/vitamins may interfere with the assay we use to determine PABA it is important to record them on the urine collection sheet.

The PABA tablet is very small and most people find it easy to swallow whole. It is not recommended to dissolve it in water or any other drink. The participant can crush the tablet between teeth. PABA has an acidic taste but there is no long lasting after taste.

Analysis of the PABA will allow us to check whether the sample is complete, however, it is important that participants also record any missing samples on the urine collection sheet, even if just through spillage.



## 5. The second nurse visit: Pick up samples

During the second visit the nurse will weigh the 24-hour urine collection, thoroughly mix and obtain two aliquots of the 24-hour sample. This visit should take place as soon as possible on the day or the day after the 24-hour sample collection is complete so that samples reach the MRC Epidemiology Unit for processing without further delay.

**Note:** The participant must be present for the second visit so that the nurse can go through the collection sheet with the participant and hand over the gift card.

If samples are delayed for any reason, nurses should still send the samples but clearly indicate the reason for the delay on the despatch note.

## *24-hour urine collection equipment for the nurse*

- Scales for weighing the urine collection container set to kg
- 2 x 10ml Sarstedt urine monovettes with extension tubes
- Disposable gloves and work mat
- Postal bag and packing material for despatching the samples
- 24-hour urine collection sheet and despatch note
- Labels for the Sarstedt urine monovettes

## *Urine sub-sampling procedure*

The container with the 24-hour collection must be weighed twice and the weight recorded on the despatch note. After weighing the urine, the collection container must be **inverted and rotated at least 20 times** so that the 24-hour urine sample is mixed thoroughly.

The disposable working mat should be used when performing the sub-sampling. Some urine from the 24-hour collection should be transferred to the jug. For each participant, two aliquots should be collected from the 24-hour urine sample. The Sarstedt monovettes should be filled with urine from the jug using the extension tubes and labelled using the labels provided, after they have been checked. After each monovette has been filled, the extension tube is removed, the monovette sealed with a plastic cap and the monovette plunger stalk snapped.

After collecting the samples, the nurse or participant will dispose of the rest of the 24-hour collection in the toilet (not from a height). Containers can be rinsed and disposed of with household waste. If it is not possible to dispose of equipment at the address, the nurse will pack away the equipment used and take this away for disposal at home or in public waste containers.

The completeness of the 24-hour urine collection will be verified in two ways: through participants self-report and the use of PABA as an objective measure. During the 24-hour collection, participants are asked to record any missed urine collections on the urine collection sheet. Therefore, it is important that at the second visit that the nurse checks this sheet and ensures with participants whether the sample is complete, and if not, notes on how many occasions urine was not included in the sample. If urine has been missed, interpretation of result relies on having this information.

## *Participant incentives*

Finally, the nurse will thank the participant for their co-operation. The nurse will hand over a **£15** gift card and activate it by entering a unique 9 digit number as prompted by CAPI. The nurse will advise the participant that gift cards take up to 48 hours for activation, 72 hours in case of a weekend or bank holiday.

## 6. Labelling, packaging and despatch

The two aliquots from the 24-hour sample will be labelled. Packaging will take place during the second nurse visit and despatched as soon as possible after the visit.

The nurse will ensure that all samples are properly sealed. Both of the two samples will be placed into a clam-shell casing and put in a postal poly-envelope provided. The clam-shell

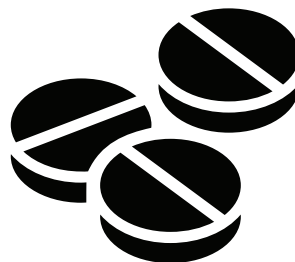
# NatCen

## Social Research that works for society

container is then placed in the pre-labelled poly-envelope and posted to the Biorepository at the MRC Epidemiology Unit at University of Cambridge.

Samples must be despatched within 48 hours of the end of the 24-hour urine collection. The delay may be longer if the second visit takes place on a Saturday, but the samples should be collected by Royal Mail on Monday morning. The samples should be stored in a cool place between the second visit and postage.

# Diet and Health Study 2018



## Information about PABA

Thank you for agreeing to collect a 24-hour urine sample. Our nurse will also ask you to take **3 PABA tablets during your collection period**. The tablets can be taken with food if you wish. This leaflet tells you more about what PABA is and how it works.

## What is PABA?

PABA is short for para-aminobenzoic acid. It is a naturally occurring substance which is part of the B vitamin folic acid.

Small amounts of PABA are found in foods such as liver, kidney, brewer's yeast, molasses, whole grains, mushrooms and spinach. Larger amounts are included in some vitamin tablets, so we need to know if you are taking any vitamin tablets or dietary supplements during your urine collection.

## Why are we asking you to take PABA?

By measuring the level of PABA in the urine we can tell you how complete your 24-hour urine sample is. It is important to know if the 24-hour urine collections are complete. Only then will we be able to look at the useful nutrition indicators that we get from the urine across the population and relate the results to nutrition guidelines.

## Is PABA safe?

PABA is very safe. Substances like PABA are used in some hair dyes, sunscreen products and dietary supplements. If you are allergic to any of these you will not be given PABA.

PABA is suitable for vegetarians and is gluten-free. However, PABA contains a very small amount of lactose (milk sugar).

PABA is safe for pregnant and breastfeeding women. However, if you are pregnant, think you might be pregnant or are breastfeeding, you are not eligible to take part in the study. This is because the diet markers we are measuring are different for pregnant and breastfeeding women.

## Taking other medication?

Some medicines and dietary supplements interfere with the test we use for PABA in the urine, so we also need to ask you about the medicines and supplements you may be taking. We will not ask you to stop taking your medicines and supplements; we only need to know about them.

Please keep your PABA tablets safe and remember to take them during the collection and to record when you take them on your urine collection sheet.

Please keep your empty blister pack and give it to the nurse at the second visit.

**If you have any questions about PABA, or if you are worried about any aspect of the urine collection, please discuss this with the nurse.**



# Diet and Health Study 2018 CONSENT FORM

Affix barcode  
label  
  
SOD-CON (1)

**MREC Reference Number: 18/EM/0241**  
Please use capital letters and write in ink

Please initial boxes

1. I confirm that I have read and understand the 24-hour urine leaflet dated 20.08.2018 and PABA leaflet dated 20.08.2018 for the above study. I have been given the opportunity to ask questions and have had these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw from the study, at any time, without giving a reason and without my medical care or legal rights being affected.
3. I agree to take PABA tablets to support the 24-hour urine collection.
4. I consent to provide a 24-hour urine sample for laboratory analysis.
5. I understand that samples I have given and the information collected about me can be stored by the MRC Epidemiology Unit, University of Cambridge and NatCen.
6. I understand that my anonymised samples and data will be used to support other research in the future, and may be shared anonymously with other researchers. This could include collaborators overseas.
7. I consent to the Diet and Health Study 2018 accessing data that I have previously given to the Health Survey for England and linking it to Diet and Health Study data using a study number.


<i>Name of Participant (Please print)</i>	<i>Date</i>	<i>Signature</i>

<i>Name of Nurse (Please print)</i>	<i>Date</i>	<i>Signature</i>

**When completed: please retain top copy for NatCen and give bottom copy to participant**

You can cancel this permission at any time in the future by writing to us at the following address:  
 NatCen Social Research, 35 Northampton Square, London EC1V 0AX.  
 Telephone: 0800 652 4572 and ask for Beverley Bates

# Diet and Health Study 2018

## 24-hour urine collection sheet

### SECTION A: NURSE TO COMPLETE

Please affix barcode label <b>SOD-COL(3)</b>	Nurse Name				
	Nurse Number				
		Check number	Person number		
<b>Serial number</b>					
<b>Participant Sex</b>					
<b>Participant DOB</b>					
<b>Start date of 24-hour collection</b>					
<b>Participant consented to take PABA tablets?</b>	Yes		No		

### SECTION B: PARTICIPANT TO COMPLETE

#### 1. DATE / TIME OF 24-HOUR COLLECTION PERIOD

Order of events	PABA tablet taken?	Date	Time	Please tick	
				AM	PM
<b>START:</b> Flush this urine away and record time		DD / MM / YY	HH : MM	AM	PM
<b>1<sup>st</sup> PABA tablet</b> Take at start	Y / N	DD / MM / YY	HH : MM	AM	PM
<b>2<sup>nd</sup> PABA tablet</b> Take 4-6hrs after 1 <sup>st</sup> tablet	Y / N	DD / MM / YY	HH : MM	AM	PM
<b>3<sup>rd</sup> PABA tablet</b> Take 4-6hrs after 2 <sup>nd</sup> tablet	Y / N	DD / MM / YY	HH : MM	AM	PM
<b>END:</b> Collect this urine and record time		DD / MM / YY	HH : MM	AM	PM

**Note: For collections at 12 o'clock mid-day, tick PM; at 12 o'clock mid-night, tick AM.**



## 2. MISSED URINE

It is **very** important that you collect **all** the urine you produce in the 24 hour period.

**However, if you have MISSED any urine collections, even just through spillage or overflowing, please make a note in the table below:**

	Date	Time	Please tick		Comments (e.g. spillage, overflow, full sample)
			AM	PM	
1	DD / MM / YY	HH : MM	AM	PM	
2	DD / MM / YY	HH : MM	AM	PM	
3	DD / MM / YY	HH : MM	AM	PM	
4	DD / MM / YY	HH : MM	AM	PM	

## 3. MEDICINES AND DIETARY SUPPLEMENTS

We also need to know about certain medicines and dietary supplements/vitamins you have taken over the 24-hour urine collection.

Did you take any sulphonamide based antibiotics? Yes  No

Did you take any diuretics (also known as water tablets)? Yes  No

Did you take any dietary supplements/vitamins? Yes  No

If you answered YES to any of these questions, please enter the names of these in the table below:

1	
2	
3	
4	

Please give this form to the nurse, along with your urine sample and silver PABA tablet packaging. The nurse may ask you to confirm some of the details you have recorded.

***Many thanks for taking part in this study!***