## **Hiprex study**

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### What is Hiprex?

Hiprex is a supplement, which is widely used for the prevention of urinary tract infections (UTIs). Once ingested, it is absorbed by the body and then excreted through the urine. The active ingredient in Hiprex, methenamine, reacts at a low urinary pH to produce formaldehyde, which is known to kill bacteria in the urine.

## What is the purpose of this study?

We have developed a urine assay to measure methenamine and formaldehyde in the urine.

So once you have taken Hiprex orally, we can determine in a urine sample taken 1-2 hours later how much of the active ingredient has made it to your urine.

If this first step failed, we can consider a higher dose of Hiprex, and repeat the urine measurements above

If this first step is a success and you are responding well to Hiprex in your urine, we will invite you to join in a long-term study to determine if taking Hiprex daily for up to 12 months effectively reduces your chances of getting a recurrent UTI.

## Why have you been invited to take part in this study?

You have had recurrent UTIs and are willing to start, already have started, or are thinking about taking Hiprex to prevent further UTIs. You also took part in our urine pH acidity diary study an we found that you have a consistently low urine pH. Those are all the conditions necessary to qualify for our long term Hiprex study

#### What will you do during the study?

FOR THE FIRST VISIT, we will ask you to bring your Hiprex bottle to the office. You will provide a baseline urine sample and then take your Hiprex orally as if you were home. Make sure you did not take another Hiprex pill that day.

Then, you will provide urine samples 1 hour and 2 hours after taking Hiprex. These urine samples will be analyzed for acidity and urinary concentrations of methenamine and formaldehyde.

If the urinary values are satisfactory, you will be notified and invited to join in for a long term study.

So NEXT: there will be regular visits scheduled to make sure that you continue to show appropriate urinary concentrations of methenamine and formaldehyde in urine throughout the study period.

To that intent, you will be asked to return to clinic at: 1 week, 1 month, 3 months, 6 months, 9 months, and 12 months after starting Hiprex to provide urine samples similarly to the first visit. During these follow-up visits, you will also fill out a questionnaire regarding UTI symptoms. Compensation will be provided for three visits, at week 1, 1 month, and 9 month. The other visits are part of routine care.

IF you develop a UTI while on Hiprex, we will ask you to immediately notify our clinic so that we can take care of this problem for you. We will then decide if it is appropriate or not to continue with more Hiprex or not once the UTI episode has resolved.

#### What are the risks of this study?

Hiprex is known to be safe and well-tolerated; however, common side effects are nausea, vomiting, and skin rash.

#### Is there compensation for this study?

You will be compensated for study visits outside of your normal care visits as outlined above.