# Summary of Results for Laypersons

## What was the Study Called?

An open-label, prospective interventional study of the tolerability and efficacy of oral Harnalidge® OCAS® (Tamsulosin) 0.4 mg in patients who are unsatisfied with the treatment of Tamsulosin 0.2 mg

## Why was this Study Needed?

Tamsulosin is a prescription medicine that treats urinary symptoms caused by an enlarged prostate. The prostate is a gland that surrounds the tube carrying urine from the bladder (urethra). The prostate can grow larger (called benign prostate hyperplasia) in older men and block the urine flow. An enlarged prostate can cause the following urinary symptoms.

- Symptoms related to urinating are a weak urine stream or a stream that stops and starts, straining while urinating, longer than usual wait for the stream of urine to begin and inability to completely empty the bladder.
- Symptoms related to storage of urine are a sudden need to urinate that is difficult to delay, having to empty the bladder more often than usual, not being able to control the emptying of the bladder and lose urine involuntarily and increased frequency of urination at night.
- A symptom at the end of urination is dribbling.

Patients take tamsulosin by mouth at a dose of 0.2 mg. Tamsulosin OCAS (also known as Harnalidge OCAS, Harnal OCAS, Alna OCAS, Omix OCAS, Pradif OCAS, Urolosin OCAS, Omnic OCAS and Mapelor OCAS) is a type of tablet that releases tamsulosin more continuously over 24 hours.

This study was conducted in patients who had taken tamsulosin 0.2 mg for at least 4 weeks and were not satisfied with that treatment. The study answered the question if tamsulosin OCAS 0.4 mg was effective in these patients. The study looked at the total score on a questionnaire. The questionnaire was about the impact of the patients' urinary symptoms on the perceived quality of their daily life. The study compared the scores at study start and after patients took the study medicine for 3 months. It was also important to find out what unwanted effects these patients had from the study medicine.

This study for tamsulosin took place at 1 clinic in Taiwan. The study took place from February 2014 to January 2015. When the study ended the sponsor (Astellas) reviewed all the study information and created a report of the results. This is a summary of that report.

## What Kind of Study was This and Who Took Part in it?

This was an "open-label" study. All patients knew that they took tamsulosin OCAS 0.4 mg.

Men aged 45 years or older could take part in the study if:

- A doctor had determined that they had urinary symptoms caused by an enlarged prostate.
- They were taking tamsulosin 0.2 mg by mouth for at least 4 weeks.

- They were not satisfied with their tamsulosin treatment.
- At the start of the study, their total score on a particular questionnaire was at least 3. The questionnaire was about the impact of their urinary symptoms on the perceived quality of their daily life.

Patients could not take part in this study if:

- Within 1 year before study start, they had surgery to remove part or all of their prostate.
- They had 1 of the following conditions:
    - problems with the wiring of the nerves controlling the bladder,
    - scarring in the bladder neck as a result of previous surgery,
    - narrowing of the urethra,
    - prostate cancer,
    - bladder stones,
    - urinary tract infection or
    - a severe problem with a pouch in the bladder wall.
- Their urinary symptoms were not caused by an enlarged prostate.
- Their liver or their kidneys worked poorly. They had a serious heart condition. Their blood pressure suddenly dropped when they stood up from sitting or lying down. Or they had dementia of old age especially of the type seen with Alzheimer's disease.
- The study doctor thought that the patients were too sick to be in the study.

The study doctor did a check-up of the patients at 5 study visits. At visit 1, patients were checked if they could be in the study. The study doctor checked their prostate. The patients returned to the clinic 1 week later for visit 2. They were checked if they could remain in the study. Patients who could remain in the study answered a questionnaire about the impact of their urinary symptoms on the perceived quality of their daily life. They took tamsulosin OCAS 0.4 mg by mouth once daily for 3 months. The patients returned to the clinic every month for a check-up and to answer the questionnaire (visits 3 to 5).

A total of 100 patients were in this study and took at least 1 dose of study medicine.

| **Adverse Reaction** | **Number of Patients (out of 100 patients)** |
|---|---|
| **Age Group** | |
| Aged between 45 and 99 years | 100 |
| **Sex** | |
| Men | 100 |
| **Clinic Location** | |
| Taiwan | 100 |

**What Were the Study Results?**

This study was conducted in patients who had urinary symptoms caused by an enlarged prostate. They were not satisfied with their previous treatment with tamsulosin 0.2 mg. The study helped answer the question if tamsulosin OCAS 0.4 mg was effective in these patients. The study looked at patients' total score on the questionnaire about the impact of their

urinary symptoms on the perceived quality of their daily life. The study compared the scores at study start and after patients took the study medicine for 3 months.

The study showed that tamsulosin OCAS 0.4 mg improved the bladder or urethra symptoms caused by an enlarged prostate. The questionnaire score on average was 15.16 at study start, which means that the symptoms were moderate. After patients took the study medicine for 3 months, their score on average was 7.78. This means that their symptoms were mild. After 3 months of treatment, the score was on average 7.13 lower (39%) than at study start. This means that after the 3-month treatment, the score was on average a little more than one-third of the score at study start.

**What Adverse Reactions did Patients Have?**

A lot of research is needed to know whether a medicine causes a medical problem. So when new medicines are being studied researchers keep track of all medical problems that patients have while they are in the study. These medical problems are called "adverse events" and are recorded whether or not they might be caused by the treatment taken. An "adverse reaction" is any medical problem or "adverse event" that is judged by the study doctor to be possibly caused by a medicine or treatment used in the study.

The table below shows the adverse reactions experienced by patients who took at least 1 dose of study medicine.

| **Adverse Reaction** | **Tamsulosin OCAS 0.4 mg (out of 100 patients)** |
|---|---|
| Dizziness (or sensation of lightheadedness, unsteadiness, or giddiness) | 5 (5.0%) |
| Headache or head pain | 2 (2.0%) |
| General feeling of discomfort or being unwell or out of sorts | 1 (1.0%) |

An adverse reaction is considered "serious" when it is life-threatening, causes lasting problems, or needs hospital care.

None of the patients had a serious adverse reaction.

**Where Can I Learn More About This Study?**

Astellas may perform additional studies to better understand tamsulosin.

This summary of the clinical study results is available online at http://www.astellasclinicalstudyresults.com.

Please remember that researchers look at the results of many studies to find out how well medicines work and which adverse reactions they might cause. If you have questions about tamsulosin, please discuss these with your doctor.

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