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# STOP: Satisfaction and Tolerability in Overactive bladder Patients (less than 65 years versus greater than or equal to 65 years)

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 12/06/2008 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 04/07/2008 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 13/07/2012 | Urological and Genital Diseases | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
018-010

# Study information

### Scientific Title

### Acronym
STOP

### Study objectives
Patients and physician satisfaction with study drug 018 will not be different in elderly and non-elderly patients.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Ethics approval for the lead centre was obtained from IRB Services, Aurora, Ontario (Canada) on November 23, 2006. All other participating centres obtained ethics approval before recruiting study patients.

### Study design
Multi-centred open label trial

### Primary study design
Interventional

### Secondary study design
Non randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet
Not available in web format. Please have your family physician use the contact details below to request information on the study.

### Health condition(s) or problem(s) studied
Overactive bladder

### Interventions
Oral anticholinergic-antispasmodic (018) over a four-week open label phase.

### Intervention Type
Drug

### Phase
Not Specified

### Drug/device/biological/vaccine name(s)
Study drug 018

### Primary outcome measure
Measured after four weeks of treatment:
1. Quality of life
2. Patient and physician satisfaction

### Secondary outcome measures
Measured after four weeks of treatment:
1. Tolerability
2. Cognitive status
3. Adverse events

### Overall study start date
07/01/2007

### Completion date
31/12/2007

## Eligibility

### Key inclusion criteria
1. Males or non-pregnant, non-nursing females greater than or equal to 18 years of age
2. Diagnosis of overactive bladder and currently experiencing incontinent episodes and frequent micturitions or urgency
3. Newly diagnosed patients or patients not currently taking medication for overactive bladder
4. Capable of completing questionnaires in English or French

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
300

### Key exclusion criteria
1. Patient who will initiate treatment with any drug prescribed for the treatment of overactive bladder (except oestrogen) during the study period
2. Patient with a primary diagnosis of stress incontinence or a concurrent diagnosis of functional or overflow incontinence

3. Patients with conditions contra-indicating anticholinergic therapy or have hepatic or renal disease
4. Patients using an indwelling catheter or who had bladder electrostimulation therapy or participated in bladder training within the previous 14 days prior to study entry

### Date of first enrolment
07/01/2007

### Date of final enrolment
31/12/2007

## Locations

### Countries of recruitment
Canada

### Study participating centre
**Purdue Pharma**
Pickering
Canada
L1W 3W8

## Sponsor information

### Organisation
Purdue Pharma Canada

### Sponsor details
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### Sponsor type
Industry

### Website
http://www.purdue.ca

### ROR
https://ror.org/023sxys58

# Funder(s)

**Funder type**
Industry

**Funder Name**
Purdue Pharma Canada

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/08/2012 | | Yes | No |