

YOUR PERFECT RELATIONSHIP



IS OUR GOAL



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Prescription-
based Medicine
Class No. 259

36-hour lasting Erectile Dysfunction Medicine

Fast-Absorbing Oral Dissolve Film Type

24-36 hour lasting therapeutic effect

This medicine's therapeutic effect
is not influenced by food-ingestion.



SEINTRIP

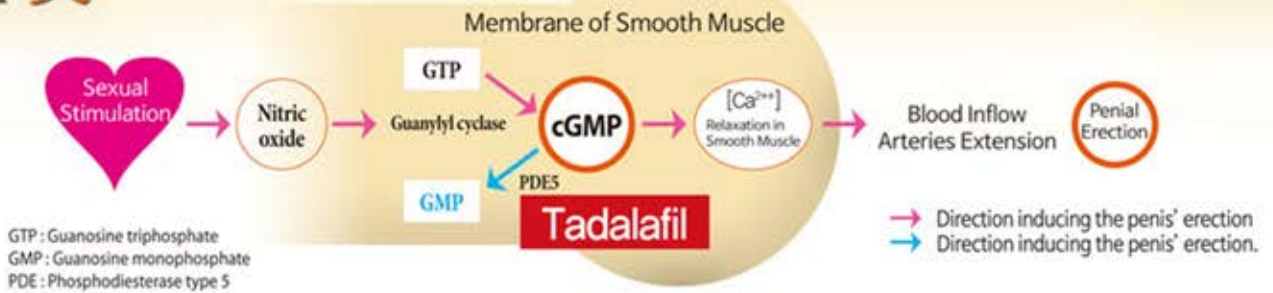
Orodispersible Film
Tadalafil 10mg 20mg



SUITABLE FOR FEMALE AND MALE



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Mechanism of Tadalafil

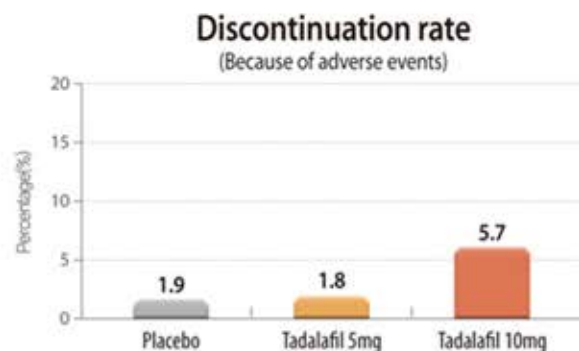
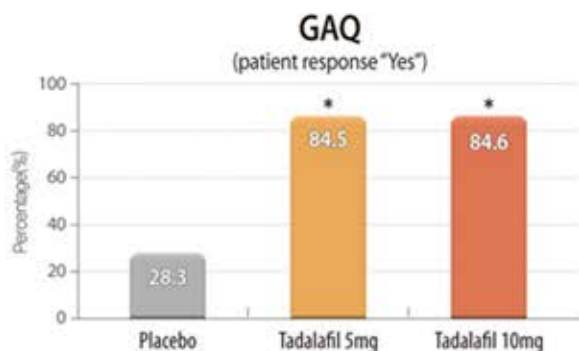
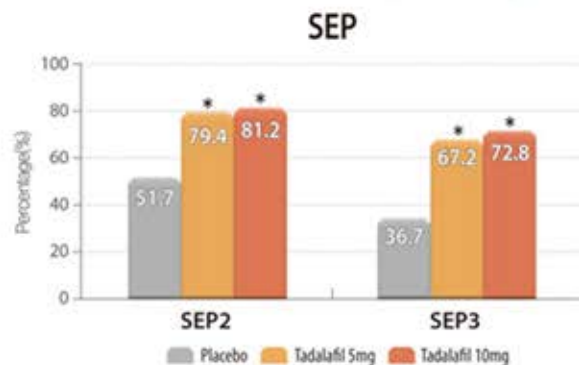
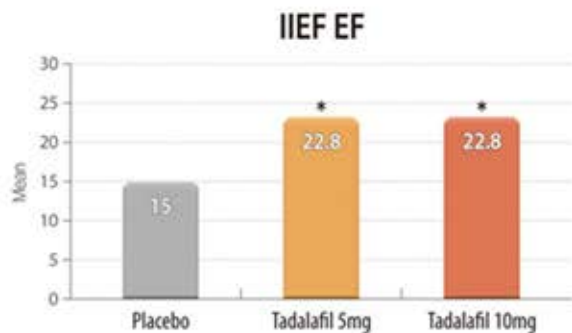
Tadalafil prevents cGMP's decomposition in cells by suppressing the PDE5's action, relaxes the smooth muscle in penis and increases the blood flow by inducing to inflow more blood in penis, and consequently improves the patients' erectile dysfunction.

Effect on Erectile dysfunction

Taking 10mg or 20mg dose of Tadalafil once a day significantly improved the patients' erectile function, and it showed good tolerance.

- Targeting the patients over 18 years old who have experienced some symptoms of erectile dysfunction for over 3 months.
- Placebo (n=54) VS. Tadalafil 5mg (n=109) qd for 12weeks VS. Tadalafil 10mg (n=105) qd for 12weeks
- The efficacy analysis included all patients, regardless of IIEF EF domain score at baseline.

* p < 0.001 versus placebo



IIEF EF : International Index of Erectile Function domain
 SEP2 : Sexual Encounter Profile diary Questions 2 (successful penetration)
 SEP3 : Sexual Encounter Profile diary Questions 3 (successful completion of intercourse)
 GAQ : Global Assessment Question (Has the treatment you have been taking during this study improved your erections?)

Erectile dysfunction

- Erectile dysfunction is defined as the inability to keep his penis erecting condition necessary for successfully performing sexual intercourse. 12~52% of total men experience the erectile dysfunction.

Disease Cause

- Systematic causes—vascular lesions, neurological disorders, hormonal disorders, dysfunction of smooth muscle in corpus cavernosum penis

- Psychological cause— the penile erection mechanism' s pivotal suppression without any physical damage.

Characteristics of Tadalafil

- Fast-absorbing erection dysfunction medicine
- Erection dysfunction medicine not being influenced by meal intake.
- Erectile dysfunction medicine having the longest half-life.
- Erectile dysfunction medicine long-time lasting up to 24~36 hours.

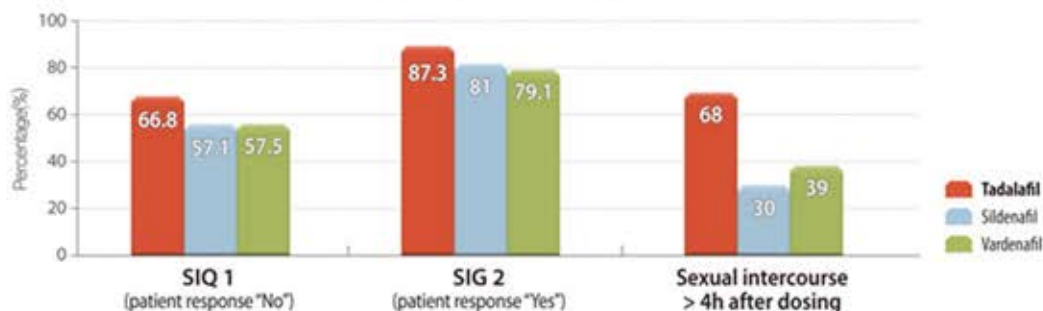
J Korea Med Assoc. (2003) 46(11), 1050–1056

Comparison of PDE5 inhibitors

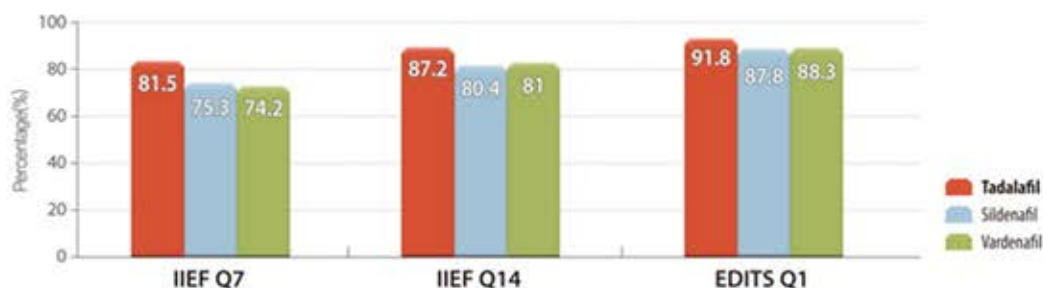
Although Tadalafil, sildenafil, and vardenafil were all therapeutically effective and increased patients' satisfaction, Tadalafil showed the highest therapeutic effect and satisfaction.

- Targeting patients over 18-years old who have experienced symptoms of erectile dysfunction and have had sexual life.
- Tadalafil (n=5315) for 6 month vs. Sildenafil (n=1252) for 6 month vs. Vardenafil (n=993) for 6 month
- Precise dosage information was not collected; investigators recorded only the maximum dose of drug a patient received.

Therapeutic effectiveness



Patient satisfaction



SIQ1 : Single-item question1 (Has your erection during the past 4 weeks been insufficient to initiate or complete intercourse?)

SIQ2 : Single-item question2 (Has the treatment you have been taking in the last 4 weeks solved the problem?)

IIEF Q7 : International Index of Erectile Function question7 (intercourse satisfaction)

IIEF Q14 : International Index of Erectile Function question14 (relationship satisfaction)

EDITS Q1 : the Erectile Dysfunction Inventory of Treatment Satisfaction question1 (treatment satisfaction)





36-hour lasting Erectile Dysfunction Medicine

SENTRIP

Orodispersible Film
Tadalafil 10mg 20mg

Drug Information

Product Name	Sentrip ODF 10mg	Sentrip ODF 20mg
Main Ingredient & Content	Tadalafil, 10mg	Tadalafil, 20mg
Shape	 Yellow, rectangular oral dissolve film	 Yellow, rectangular oral dissolve film
Effects	Treatment of Erectile Dysfunction In order for this medicine to be effective, some sexual stimulation is required. This medicine is not designed to apply for woman's use.	
Usage & Dose	<p>Oral Film Use only for male adult. This medicine's recommendable dosage is 10mg, and is taken before an expected sexual intercourse regardless of meal. The patients not showing enough therapeutic effect with 10mg Tadalafil are allowable to take 20mg of dosage. This medicine can be taken from at least 30 minutes before sexual intercourse. Maximum recommendable intake frequency is once a day. Place the medicine on tongue after opening the package, and let it dissolve without water. As its long-term safety about the extended daily intake of medicine is not established yet and its effect usually lasts for over a day, it is not recommended to take this medicine every day. See Clause 1. Warning and 11.1 Pharmacodynamic Characteristics.</p> <p style="text-align: right;">(See the Directions of Medicine Use.)</p>	
Use Precautions	<p>Don't administer this medicine to following patients.</p> <ol style="list-style-type: none"> 1) To a patient regularly and/or intermittently taking any medicine containing organic nitrate, the administration of this medicine is prohibited. See Clause 1. Warning, and Clause 6. Interaction. From clinical trials, it was found that Tadalafil increased the nitrate's action inducing the hypotension. As Tadalafil expands blood vessels, it temporarily reduces the patient's blood pressure slightly (See Clause 11.1 Pharmacodynamic Characteristics). As a result, it increases the nitrate's action lowering the blood pressure. It is judged that this may be a result from the mixing effect of the nitrate and Tadalafil on the nitric oxide/cGMP route. 2) Any erectile dysfunction medicines including this product should not be used to a man having cardiac disease. Before a patient having cardio-vascular disease/diseases uses this medicine, his doctor should consider potential cardiac risk from sexual intercourse. 3) The following patient group having cardio-vascular diseases are not included in this medicine's clinical trials, therefore should not use this medicine. <ul style="list-style-type: none"> - Patient experiencing an episode of MI (myocardial infarction) within the last 90 days. - Patient experiencing unstable angina or angina during sexual intercourse. - Patient experiencing heart failure under the New York Heart Association Class 2 or higher within the last 6 months - Patient having uncontrolled arrhythmias, hypotension(90/50mmHg) or uncontrolled hypertension(170/100mmHg) - Patient experiencing stroke within the last 6 months 4) Patients having already known genetic, degenerative retina diseases including the Retinitis Pigmentosa were not included in this medicine's clinical trials, so such patients are not recommended to use this medicine. 5) This medicine should not be administered to patients who are hypersensitive to Tadalafil or other ingredient in this medicine. 6) No research has been conducted on the safety and the effectiveness of taking this medicine jointly with other erectile dysfunction agent. Therefore, it is not recommended to jointly administer this medicine with any other erectile dysfunction medicine. 7) To a patient losing eyesight in one eye due to the Non-arteritic anterior ischemic optic neuropathy (NAION), this medicine should not be administered. <p style="text-align: right;">(See the Directions of Medicine Use.)</p>	
How to Store	Store it in an airtight container in room temperature (1-30°C).	
Expiration Date	36 months from the manufacture date	
Packing Unit	10 Strips / 30 Strips	

2016.01

Instruction



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