TriMix-gel®
(prostaglandin, papaverine, phentolamine)

Order Form

PD Labs
101 Commercial Parkway
Cedar Park, TX 78613

Phone: 888-368-1990
Fax: 888-363-7266

Patient Name: _____

Patient Phone #: _____

Physician Name: _____

Physician Phone #: _____

Place Rx Here

(Example Prescription)

TriMix-gel

1500mcg 300mcg 100mcg

#4

sig: as directed.

Use 5 to 10 minutes before sexual activity.
Not to exceed two (2) uses per 24 hr period.

No substitutions

Fax to 888-363-7266

TriMix-gel® The No Needle Choice

(prostaglandin, papaverine, phentolamine)

	Prostaglandin, Papaverine, Phentolamine	Quantity	# Refills	Price
TriMix-gel®	2000mcg-300mcg-100mcg	4		
TriMix-gel®	1500mcg-300mcg-100mcg	4		
TriMix-gel®	1000mcg-300mcg-100mcg	4		
TriMix-gel®	500mcg-300mcg-100mcg	4		

Attention Physicians:

- The patient cannot fax this prescription.
- The pharmacy must receive this fax from your office.
- The pharmacy will mail the medication directly to the patient.
- The pharmacy will call the patient for payment and shipping information usually within an hour.

TriMix-gel®
(prostaglandin, papaverine, phentolamine)

For more information, please call:
1-888-368-1990

Dear Doctor,

Your patient has expressed an interest in TriMix-gel® (prostaglandin, papaverine, phentolamine). TriMix-gel is a compound of prostaglandin, papaverine, and phentolamine just like trimix for injection. The difference is TriMix-gel is applied transurethrally and not self-injected with a hypodermic needle.

When Oral Therapy Fails

Many ED sufferers cannot take Viagra® type tablets for a variety of reasons. Contraindications include patients on nitrates, certain beta blockers or patients with nonarteritic anterior ischemic optic neuropathy (NAION). Still other patients cannot tolerate the side effects of PDES's which are numerous and can be harsh.

When Patients Cannot Self Inject

Some Physicians do not wish to encourage or train patients on injection therapy. Even more patients just cannot bring themselves to self-inject a needle into their own penis.

TriMix-gel

- No needles
- No pellets
- No refrigeration

The active ingredients in trimix liquid for injection have been prescribed by Physicians for many years. Trimix compound in gel form, called TriMix-gel, does not require a needle for self-injection.

To apply the medicine, TriMix-gel uses the TriMix-gel Easy Applicator™ (US patent 900S183) which stores, mixes and delivers the medicine at time of use.

Refrigeration is not required.

Clinical Trials

We presented data on TriMix-gel® clinical trials at the American Urological Association's World Conference. Only patients who failed on PDES Inhibitors were selected. All patients experienced some degree of tumescence and the Abstract reports forty percent of the patients who failed on PDES's experienced erections sufficient for penetration during sexual intercourse. Attached for you is a reprint of the abstract published in The Journal of Urology.*

*Please read the Abstract on the following page and the "Clinical Trials" page behind it for important information regarding perspective on clinical trials.

Phone: 888-368-1990 **Fax:** 888-363-7266

THE JOURNAL of UROLOGY®

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STUDIES WITH TRIMIX GEL IN MEN WHO FAILED PHOSPHODIESTERASE INHIBITORS

Joel L Marmar, Thomas J Harkins, John Riordan. Camden, NJ, and Cherry Hill, NJ.*

INTRODUCTION AND OBJECTIVE: Trimix (papaverine, phentolomine and PGE1) has been prepared by compounding pharmacists and used for intracavernous injections. After mixing, the shelf life is limited and refrigeration is recommended. As an alternative, topical Trimix gel seemed more stable and easier to use, but the results were poor due to limited absorption. Recently, we evaluated a new Trimix gel for administration at the urethral meatus. In this report, Erection Hardness Scores (EHS) and penile rigidity studies were recorded after the gel on 42 men with mixed morbidities who failed with PDE5 oral agents.

METHODS: Sixteen men were on anti hypertensive meds, 12 had type II diabetes,8 had high cholesterol and 6 were post radical prostatectomy. Ten men had co morbidies. Prior to the gel, an (EHS) was recorded for the experience with oral agents. The Trimix active ingredients and 0.3 ml of gel were maintained in separate interlocking syringes at room temperature until the time of use. The final preparation was completed by vigorous mixing between the interlocking syringes. The mixed gel was inserted painlessly into the urethral meatus, and the patient massaged the outer glans for 2 minutes to promote absorption. There was no other form of stimulation. After the gel, an EHS was recorded for each patient. In addition, 9 had measurement of buckling pressures, and 7 had rigiscans.

RESULTS: For all 42 patients (mean age 55.2 yrs) the EHS was recorded as 1 for the oral agents (penis was larger but not hard), but 22 of these patients actually had no increase in size. After the gel, the mean EHS was 2.2, but 11 pts had an EHS of 3 (26.1%), and 6 Had a 4 (16.6%). Thus, 40.4% of the study group had erections that were sufficient for penetration. In those with an ESH of 4, the buckling pressure was >90mm Hg. The 7 rigiscans provided real time information about the gel response and documented some tumescence in all cases. In a comparison of 3 and 4 scores, oral agents vs. gel, X^2= 10.0, df 1, p<0.001.

CONCLUSIONS: Trimix gel may have several advantages over oral agents and intrcavernous injections. The active ingredients and gel may be carried by the patient at room temp. The shelf life is long because the active ingredients are mixed only at the time of use. The interlocking syringes permit thorough mixing. Administration is painless, and message of the glans may enhance mucosal absorption. Even without stimulation by a partner or videos, these patients demonstrated statistically significant greater EHS with gel versus oral agents. These pilot data support the use of Trimix gel for ED, but more prospective trials are needed.

SATISFACTION PROFILES AND THEIR DETERMINANTS IN MEN USING INTRACAVERNOSAL INJECTION THERAPY

Nelson E Bennett, Patricia Guhring, Joseph Narus, John P Mulhall. New York, NY.*

INTRODUCTIONAND OBJECTIVE: Intracavernosal injection therapy (ICI) is a well-established treatment strategy for men with erectile dysfunction (ED). Several reports have discussed drop-out rates and the predictors of such attrition. This study was undertaken in men using ICI for at least 6 months to define satisfaction levels and what predicts satisfaction with treatment.

METHODS: Men using ICI completed baseline IIEF and those that had used ICI for greater than 6 months completed a second IIEF questionnaire at least 6 months after starting ICI. At this time they also had erectile rigidity scored using the erection hardness core (EHS). Patient demographic, comorbidity and prior treatment information was compiled. Patients who had had radical pelvic surgery were excluded. Attention was focused on the satisfaction domains of the IIEF, specifically intercourse satisfaction (Q 6-8; max score 25) and overall satisfaction (Q 13-14; max score 10). Multivariable analysis was performed to define predictiors of satisfaction. Pearson correlation coefficient was generated for the correlation between EF domain (EFD) score and satisfaction domains.

RESULTS: 122 men were analyzed. Mean age and duration of ED were 68+32 and 3.6+4.2 years. 10% of men had on vascular comorbidity, 42% two, 36% three and 12% >4. Baseline IIEF-EF domain score was 13+12 and this rose to 26+2 after 6 months of ICI)p<0.001). 88% of men used trimix, 7% bimix, 2.5% papaverine and 2.5% PGE1 monotherapy. 62% continued to inject at a mean follow-up time-point of 22+7 months. Baseline satisfaction domain scores were: intercourse satisfaction 5+2; overall satisfaction 3+2.5 (Total 9+4.5). These scores rose to 12 (p<0.01) and 7 (p<0.05) respectively (total (19+4) after ICI treatment. Pearson correlation coefficient between EF and total satisfaction scores was 0.66. Predictors of satisfaction included: increased patient age, partner age and greater levels of erectile rigidity (see Table)

CONCLUSIONS: One third of men cease injection therapy within 2 years of initiation. The predictors of continued use included older patient age, young partner age, a clinically meaningful increase in IIEF-EF domain score and obtaining a fully rigid erection.

Multivariable Analysis of Predictors of Satisfaction with ICI

	OR	95% CI	p Value
Increase >10 years in patient age	2.1	1.1-3.2	<0.01
Decrease >10 years in partner age	2.5	2.0-4.5	<0.01
QFUHDVH RI 6 SRLQWV RQ WKH ( ) VFRUH	3.1	1.9-6.3	<0.01
Obtaining an EHS 4 (fully rigid) erection	6.8	2.7-9.8	<0.01

Source of Funding: None

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IMPROVEMENT IN SEXUAL SATISFACTION OF FEMALE PARTNERS OF MEN WITH PREMATURE EJACULATION (PE) TREATED WITH DAPOXETINE (DPX)

Gerald B Brock, Jacques Buvat, Francois A Giuliano, Stanley Althof, Ridwan Shabsigh, Fisseha Tesfaye, Margaret Rothman, David Rivas. London, ON, Canada, Lille, France, Garches, France, Cleveland, OH, Brooklyn, NY, and Raritan, NJ.*

INTRODUCTION AND OBJECTIVE: Improving partner satisfaction with sexual intercourse is essential to men with PE, and was evaluated with DPX, a PE treatment in development.

METHODS: Data were from an integrated analysis of 2 US phase III trials (N = 2,614) and a worldwide phase III trial (N = 1,162). These double-blind, parallel-group studies randomized men >18 years of age, diagnosed with PE based on the DSM-IV-TR criteria, with intravaginal ejaculatory latency time <2 min in >75% of intercourse episodes, to receive placebo, DPX 30 mg, or DPX 60 mg, on-demand for 12 wks (US trials) or 24 wks (worldwide trial). In the US trials, partners reported their perception of the man's control over ejaculation and their own satisfaction with sexual intercourse at Wks 4, 8, and 12 (5-point scales). In the worldwide trial, partners completed the Premature Ejaculation Profile (PEP) at Wks 4, 8, 12, and 24, including measuresof their perception of the man's control over ejaculation and their own satisfaction with sexual intercourse and ejaculation-related personal distress and interpersonal difficulty (5-point scales).

RESULTS: In the US trials, <26% of partners reported "good" or "very good" satisfaction with sexual intercourse at baseline, which increased to 39.1% and 47.4% with DPX 30 mg and 60 mg at Wk 12 (vs 25.3% with placebo; P <0.001 for both); similar improvements were reported in perception of the man's control over ejaculation. In the worldwide trial, mean scores on all partner PEP measures were significantly (P <0.05 for all) improved with DPX 30 mg and 60 mg vs placebo at all time points from Wk 4 through Wk 24. At baseline, 16% of partners reported "good" or "very good" satisfaction with sexual

When people hear the term "clinical trials", many may think of the trials conducted by the FDA. We want to make clear the TriMix-gel (prostaglandin, papaverine, phentolamine) clinical trial is different than a FDA clinical trial. FDA trials are extremely more comprehensive. They include a New Product Application (NDA) to the FDA, an Independent Review Board (IRB) opinion/approval, testing on a much larger population for more scientific certainty, and a review by the independent National Academy of Medicine for advertising classification.

The FDA's purpose is to protect the public by ensuring new drug products are sufficiently tested to be effective and safe. It does so by monitoring a drug company's manufacturing process under scrutiny of cGMP (Current Good Manufacturing Practices). Then the new drug is tested on usually thousands of test volunteer subjects.

After a drug manufacturer has successfully completed the trials on a new product by scientifically and empirically demonstrating the new drug is safe and effective, then, and only then may a drug be FDA approved so it can be mass-produced for public use.

TriMix-gel trials were directed by Dr. Joel L. Marmar. A graduate of the University of Pennsylvania Medical School, Dr. Marmar is an accomplished urologist and prolific medical investigator. He has relentlessly contributed to the scientific and clinical advancement of urology throughout his entire career.

He has been published by mostly every significant urological and andrological peer review journal in the world. He, as well, has participated on the editorial review boards for several of these science and medical journals too.

He has traveled the world teaching physicians the "Marmar In-Line Vasectomy". Dr. Marmar has held several patents over the years and has been a member and/or office holder for the most prestigious medical societies.

Upon completion of the TriMix-gel trial, Dr. Marmar memorialized the data along with his observations, and presented them for consideration to the American Urological Association's World Conference. It was accepted. Then it joined other scientific medical projects being presented to the scientists and physicians at the AUA World Conference where TriMix-gel was peer reviewed by urologists from around the world.

The Abstract for that research, then published in the Journal of Urology, became part of the preeminent publication and repository for peer review of clinical and scientific advancements in urology.

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Insurance Information for Patient Reimbursement

Insurance policies greatly differ as to the extent of prescription coverage or whether certain medications will be covered at all.

On the back of your insurance card or prescription card you will find a telephone number for customer service. Call that number and ask for the address of where to send your receipt for prescription reimbursement. Send them the receipt for your TriMix-gel® and retain a copy for your records.

The amount of your reimbursement will vary due to the conditions and terms of your individual policy.

Your insurance company will tell you:

- Whether they will cover medications
- How much they will cover
- Range of reimbursement: zero to full reimbursement. Typically $l00-$l25.

Due to the variations in insurance companies' coverage, TriMix-gel® will be reimbursed according to your specific plan. Whether your insurance company covers this medicine or not, your TriMix-gel® will always be available for purchase after the pharmacy receives your physician's prescription.