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 #: ________________________________

TriMix-gel® (prostaglandin, papaverine, phentolamine)

<table>
<thead>
<tr>
<th>Prostaglandin, Papaverine, Phentolamine</th>
<th>Quantity</th>
<th># Refills</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>TriMix-gel® 2000mcg-300mcg-100mcg</td>
<td>4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>TriMix-gel® 1500mcg-300mcg-100mcg</td>
<td>4</td>
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<td>4</td>
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</tbody>
</table>

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.
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.

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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 predictors 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% Iwo, 36% three and 12% >4. Baseline IIEF-ED 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-ED domain score and obtaining a fully rigid erection.

Multivariable Analysis of Predictors of Satisfaction with ICI

<table>
<thead>
<tr>
<th>Predictor</th>
<th>OR (95% CI)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Increase &gt;10 years in patient age</td>
<td>2.1 (1.2-3.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Decrease &gt;10 years in partner age</td>
<td>2.5 (2.0-3.5)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Obtaining an EHS &gt;3 (fully rigid) erection</td>
<td>1.6 (1.3-2.0)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Source of Funding: None

1258 IMPROVEMENT IN SEXUAL SATISFACTION OF FEMALE PARTNERS OF MEN WITH PREMATURE EJACULATION (PE) TREATED WITH DAPoxetine (DPX)

Gerald B Brock*, Jacques Buval, 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 Ranitan, 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 measurement of 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%, 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 intercourse.
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.
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 $100-$125.

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.