PIL of **VEBRION** 75 mg Tablet - NPD.

Front **Size: 100 x 265 mm** Back

VEBRION™ 75 MG Tablet
(V i b e g r o n)

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COMPOSITION:
Each film coated tablet contains:
Vibegron ..... 75 mg.

Product Specs.: Innovator

CLINICAL PARTICULARS:
Therapeutic Indications:
Indicated in adults for the treatment of:
- Overactive bladder (OAB) with symptoms of:
- Urinary urgency
- Urge urinary incontinence
- Increased urinary frequency

Posology and Method of Administration:
Adults:
- One tablet (75 mg) once daily

Administration:
- To be taken orally with water
- Can be taken with or without food
- Swallow whole or tablet may be crushed and mixed with soft food (e.g., applesauce)

SPECIAL POPULATIONS:
Renal Impairment:
- Mild to severe (eGFR ≥15 mL/min/1.73m²): No dose adjustment required
- End-stage renal disease (eGFR <15 mL/min/1.73m² or dialysis): Not recommended

Hepatic Impairment:
- Mild to moderate (Child-Pugh A/B): No dose adjustment required
- Severe (Child-Pugh C): Not recommended

CONTRAINDICATIONS:
- Hypersensitivity to vibegron or any excipient

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:
Risk of urinary retention, especially in patients with:
- Bladder outlet obstruction
- Concomitant anticholinergic therapy
- Monitor patients for urinary retention

INTERACTION WITH OTHER MEDICINAL PRODUCTS:
Digoxin:
- Vibegron may increase digoxin plasma concentrations monitor levels

Other drugs:
- No clinically significant CYP-mediated interactions observed

FERTILITY, PREGNANCY AND LACTATION:
Pregnancy:
- Limited human data; use only if benefit outweighs risk

Lactation:
- Unknown if excreted in human milk

Fertility:
- No significant effects observed in animal studies

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES:
- No or negligible influence

UNDESIRABLE EFFECTS:
Common:
- Headache
- Urinary tract infection
- Nasopharyngitis
- Diarrhea
- Nausea

Uncommon:
- Urinary retention

Rare:
- Hypersensitivity reactions

PHARMACOLOGICAL PROPERTIES (Expanded):
Pharmacodynamic Properties:
Pharmacotherapeutic group:
Drugs for urinary frequency and incontinence
ATC code: G04BD15
Mechanism of Action:
Vibegron is a highly selective β3-adrenergic receptor agonist.
β3 receptors are predominantly expressed in the urinary bladder detrusor smooth muscle.
Upon activation, vibegron:
- Stimulates adenylate cyclase
- Increases intracellular cyclic adenosine monophosphate (cAMP)
- Leads to relaxation of detrusor smooth muscle during the storage phase

This results in:
- Increased bladder capacity
- Reduced detrusor overactivity
- Decreased urgency and frequency

Receptor Selectivity:
- High selectivity for β3 receptors over β1 and β2 receptors

Minimal activity on:
- β1 receptors (cardiac) reduces risk of tachycardia
- β2 receptors (bronchial/vascular) minimal systemic effects

This selectivity contributes to:
- Favorable cardiovascular safety profile
- Low incidence of hypertension or arrhythmias

PHARMACODYNAMIC EFFECTS:
Clinical studies demonstrate:
Significant reduction in:
- Daily micturition frequency
- Urgency episodes
- Urge urinary incontinence episodes

Increase in:
- Mean voided volume per micturition
- Bladder capacity

Urodynamic Effects:
- Relaxation of detrusor muscle during filling phase
- No impairment of voiding contraction
- Minimal increase in post-void residual volume

Onset and Duration of Action:
- Initial symptom improvement: within 2–4 weeks
- Maximum clinical benefit: ~8 weeks

SUSTAINED 24-HOUR EFFICACY WITH ONCE-DAILY DOSING:
Cardiovascular Safety:
No clinically significant effect on:
- Blood pressure
- Heart rate
- QT interval
- Does not significantly inhibit hERG channels

Comparison within Class:
Compared to anticholinergics:
- No anticholinergic side effects (e.g., dry mouth, constipation)
- Better tolerability in elderly patients

Pharmacokinetic Properties:
Absorption:
- Rapidly absorbed after oral administration
- Tmax: ~1–3 hours
- Absolute bioavailability: Moderate to high

Food Effect:
- No clinically significant impact on exposure
- Can be administered with or without food

Distribution:
- Plasma protein binding: ~50%
- Volume of distribution: Moderate to high

Distributes to:
- Bladder tissue
- Smooth muscle

Metabolism:
- Minimal hepatic metabolism

Not significantly dependent on major CYP enzymes:
- CYP3A4 minor role
- CYP2D6 negligible role

Metabolic pathways include:
- Oxidation
- Glucuronidation
- Majority of circulating drug remains unchanged parent compound

Elimination:
Eliminated via both renal and fecal routes
Excretion:
- Feces: ~59–60%
- Urine: ~20–25%
- Significant portion excreted as unchanged drug

Half-Life (t½):
- Terminal elimination half-life: ~60–70 hours

This supports:
- Once-daily dosing
- Stable plasma concentrations

Clearance:
- Apparent clearance: Moderate
- Not significantly altered in mild–moderate organ impairment

Steady-State:
- Achieved within ~7 days
- Minimal accumulation due to predictable kinetics

Special Populations:
Renal Impairment:
Mild to severe (eGFR ≥15 mL/min):
- No clinically significant PK changes
- End-stage renal disease:
- Not studied not recommended

Hepatic Impairment:
Mild to moderate (Child-Pugh A/B):
- No significant exposure change

Severe impairment:
- Not studied avoid use

Elderly Population:
- Slight increase in exposure
- Not clinically significant
- No dose adjustment required

Drug Transporters:
- Substrate of P-glycoprotein (P-gp)
- May increase exposure of P-gp substrates:
- Example: digoxin requires monitoring

Drug–Drug Interaction Potential:
- Low potential for CYP-mediated interactions
- Does not significantly inhibit or induce:
- CYP3A4
- CYP2D6
- CYP2C9

PK/PD Relationship:
Clinical response correlates with:
- Sustained β3 receptor activation
- Continuous detrusor relaxation

Exposure-response relationship:
- Plateau effect observed at 75 mg dose

INSTRUCTIONS:
- Store below 30°C.
- Protect from heat, sunlight & moisture.
- Keep out of the reach of children.
- To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:
VEBRION Tablet 75 mg : Pack of 2 x 10 tablets.

FOR FURTHER INFORMATION PLEASE CONTACT:

ہدایات:
۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
گرمی، دھوپ اور نمی سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔
صرف مستند ڈاکٹر کے نسخے پر فروخت کریں۔

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