

## DRINELA Midodrine Hydrochloride 2.5 mg and 5 mg Tablets



# Drain the **Discomfort**



Drain the **Discomfort** A



## BACKGROUND:

- In cirrhosis, scar tissue and regenerative nodules increase intrahepatic vascular resistance, leading to portal hypertension.<sup>1</sup> Portal hypertension secondary to cirrhosis and subsequent vasodilator production leads to splanchnic arterial vasodilation.<sup>2</sup>
- The majority (75%) of patients with ascites have underlying cirrhosis.<sup>3</sup> The development of ascites predicts 15% and 44% mortality at 1 and 5 years, respectively.<sup>4</sup>
- Arterial vasoconstrictors is useful in cirrhotic patients due to the constant splanchnic arterial vasodilation that occurs in cirrhosis.<sup>5</sup>

## THE CASCADE OF CHANGES LEADS TO ASCITES FORMATION:<sup>6</sup>



## A. BENEFICIAL EFFECT OF MIDODRINE IN HYPOTENSIVE CIRRHOTIC PATIENTS WITH REFRACTORY ASCITES.<sup>7</sup>

Effect of Midodrine on Large-Volume Paracentesis									
Patients	Dose	Pre-peak Midodrine Post-peak				ost-peak Mide	Midodrine		
		Systolic BP	Ascites		Systolic BP Ascites				
		(mmHg)	Frequency	Volume (L)	(mmHg)	Frequency	Volume (L)		
<b>Patient #1</b> (Man with cryptogenic cirrhosis)	5 mg TID	73	9	57	102	4	11		
<b>Patient #2</b> (59-year woman with alcoholic cirrhosis)	2.5 mg TID- 12.5 mg TID	67	6	45	93	4	19		

## Midodrine is found to be beneficial, with a decrease in both the frequency of LVP and the volume of ascitic fluid drained

## B. RIFAXIMIN AND MIDODRINE IMPROVE CLINICAL OUTCOME IN REFRACTORY ASCITES INCLUDING RENAL FUNCTION, WEIGHT LOSS, AND SHORT-TERM SURVIVAL.<sup>8</sup>

**Patients:** 600 patients with cirrhosis and refractory ascites (Diuretics Therapy (DT)=200 as a control group, Diuretics Therapy (DT) with midodrine and rifaximin=400)

#### **Duration:** 24 Months

**Result:** 



## Fig. Effect of midodrine and rifaximin on weight and mean arterial pressure (MAP) in the study and control patients.

## In Midodrine and Rifaximin group:

1. The mean arterial pressure (MAP) was significantly higher (P=0.000)

2. Highly significant weight loss seen after 12 weeks (12.5 kg) (P=0.000)

**Conclusion:** Adding rifaximin and midodrine to DT enhanced diuresis in refractory ascites with improved systemic and renal hemodynamics and short-term survival.



Midodrine Hydrochloride 2.5 mg and 5 mg Tablets

## DESCRIPTION:

Drinela-2.5/5 contains the active ingredient Midodrine Hydrochloride and is available as uncoated tablets in strengths of 2.5 mg and 5 mg.

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Midodrine hydrochloride is an orally available alpha-mimetic drug acting directly on the peripheral  $\alpha$ -receptor, which is widely used in the treatment of hypotensive disorders.

#### A novel drug to treat cirrhotic ascites.

#### MECHANISM OF ACTION:

Midodrine hydrochloride forms an active metabolite "desglymidodrine" that is an alpha1- agonist and exerts its actions via activation of the alpha-adrenergic receptors of the arteriolar and venous vasculature, producing an increase in vascular tone and elevation of blood pressure.

## KEY BENEFITS OF MIDODRINE:

- 1. Improve systemic and renal hemodynamics in nonazotemic cirrhotic patients by counteracting mesenteric vasodilatation.<sup>8</sup>
- 2. The use of midodrine in patients with ascites with or without HRS leads to:9
- A. Decrease Plasma renin activity (PRA), Antidiuretic hormone (ADH), Nitrite and nitrate activity (NOx), heart rate (HR) and cardiac output (CO).
- B. Increase renal plasma flow (RPF), glomerular filtration rate (GFR), urine sodium concentration and urine volume and mean arterial pressure (MAP).

## DOSAGE:

The recommended dose of midodrine is 2.5 mg to 10 mg TID or as directed by the Physician.

## PRESENTATION:

Drinela-2.5/5 is available as a strip of 10 tablets.

References:

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<sup>5.</sup> Journal of Hepatology 46 (2007) 213–221