

# **Clinical Trial Protocol Post-Marketing Surveillance (PMS) Study**

**An Observational Study on the Efficacy, Safety and Tolerability of Valsartan and Valsartan HCT Combination in Managing Patients with Essential Hypertension in Actual Practice in Syria**

## **VHEST**

**Valsartan in Hypertension, Efficacy, Safety & Tolerability**

### **Introduction:**

Clinical trials of different types have shown clearly that high blood pressure is associated with increased cardiovascular morbidity and mortality, and lowering high blood pressure reduces these complications, mainly, heart failure, myocardial infarction & stroke.

Suppression of the Renin-Angiotensin Aldosterone System (RAAS) by means of Angiotensin Converting Enzyme (ACE) inhibitors has been employed successfully for long time in the treatment of essential hypertension. However, ACE inhibitors are associated with characteristic adverse events such as Angioneurotic edema and dry cough

### **Organization:**

Prior to participation in the study, Ibn-Alhaytham Pharmaceutical Industry cardiovascular line -medical representatives will visit the selected physicians for signing up a participation agreement stating physician's approval to conduct the study according to the plans provided by Ibn-Alhaytham Pharmaceutical Industry – Scientific Department and to provide the company with the case report form for each patient after study completion.

Each participating physician will receive a copy of the product leaflet sheet with details of indications, contraindications and dosage etc.

A meeting will be conducted with participating physicians before starting the study for introducing the study and having the agreement form signed. Another meeting will be organized after data analysis to introduce the results.

**Follow up:**

Ibn-Alhaytham Pharma will assign medical representatives to conduct regular follow up visits to all participating physicians in Syria.

**Trial Period:**

March, 2008	:	Study introduction
April, 2008	:	Patients enrollment
July, 2008	:	Data collection
July, 2008	:	Study Data analysis
Aug, 2008	:	Study data presentation

**Methods and Objectives:**

Previous studies with Valsartan / Diovan™ have been conducted on patients with hypertension but no large scale studies has been conducted on Valsartan produced by National pharmaceutical company in Syria. Controlled clinical trials cannot provide data that reflect real life usage of the drug. This is an observational, prospective, open label, post marketing study, non interventional drug monitoring program to collect data on the use of Valsartan and Valsartan

HCT combination in daily medical practice conditions in Syria and in line with the current applicable local laws.

This Study aims at evaluating the efficacy, safety and tolerability of Valsartan <sup>TM</sup> / Valsartan HCT <sup>TM</sup> (Ibn-Alhaytham) given as monotherapy or as part of a combination regimen with other antihypertensive agents for the management of patients with essential hypertension as per actual practice in Syria.

This study involves follow up of large patients' sample (1500 patients) over 12 weeks follow up period.

From previous data the maximum reduction of blood pressure is achieved 2-4 weeks from starting medication and significant reduction is achieved when adding HCT

#### **Trial Patients & Physicians:**

Patients should meet certain criteria in order to be included in the study. This study will be conducted out on 1500 essential: Stage I & Stage II hypertensive patients either newly diagnosed (preferable) or uncontrolled on their current medications. **We will recruit patients with;**

- 1) Essential hypertension
- 2) Age between 18 – 80 years old
- 3) Patients of either gender.

#### **Exclusion criteria:**

- 1) Patients already on ARBs.
- 2) Significant Renal Failure (Creatinine > 3 – K > 5.5).

- 3) Overt Congestive Heart Failure.
- 4) Bilateral Renal Artery Stenosis.
- 5) Sever Hypertension..
- 6) Acute Coronary Syndrome.
- 7) Acute Cerebrovascular Accident.
- 8) Treatment with ARBs within the last 4 weeks.

One hundred medical physicians (Internists, Cardiologists, Nephrologists and Neurologists) from all major provinces in Syria will be selected. Each participating physician will be asked to provide complete data on 15 patients he/she has decided to treat with Valsartan | Valsartan HCT (Ibn-Alhaytham)

**Ethics:**

The name of the participating physician will not be disclosed. The data from any participating physician will not be disclosed and will be used only for the sake of the aim and objective of the study.

This study does not require the approval from an independent ethical committee and the protocol only require observation and reporting date and describes no intervention in the management and/or behavior of the patient and no deviation from usual practice.

Patient's informed consent is not needed as this is an observational PMS study.

**Documentation:**

A case report form is provided for data collection.

## **Medication and Dosage**

Valsartan™ 80 mg or Valsartan™ 80 mg / HCT 12.5 mg fixed combination given once daily according to physician decision as per the basic prescribing information of the product.

## **Statistical Analysis**

This is will be done on Efficacy, Safety and Tolerability.

## **Overall Assessments:**

### A. Safety & Tolerability

1. Reporting any adverse drug reaction with clear data about type, date & time of onset & resolution and global relationship to trial treatment.
2. Overall assessment will be conducted at last visit.

### B. Efficacy

1. Change from baseline in blood pressure.
2. Overall assessment will be stated by the investigator at last visit.

### C. Control

This will document if blood pressure is controlled or not (SBP below 140 mmHg & DBP below 90 mmHg)

## **Questions & Contacts :**

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