

Case Report Form

Post-Marketing Surveillance 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

Investigator Name:

Address:

Patient's Initials

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Patient's No

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Visit 1 / Week 0

Date:

Day	Month	Year

Personal Information:

Age:

--	--

 Years

Sex: Male Female

Weight (kg):

--	--	--

Height (cm):

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Hypertension History:

Newly diagnosed?

Yes No

Date of diagnosis:

Day	Month	Year

Prior treatment

<input type="checkbox"/> Yes	<input type="checkbox"/> No
<input type="checkbox"/> 6 months	
<input type="checkbox"/> 6-12 months	
<input type="checkbox"/> 1-5 years	
<input type="checkbox"/> > 5 years	

Severity of Hypertension:

Stage 1 Stage 2 Stage 3

Concomitant Disease	Yes	No
Coronary Artery Disease	<input type="checkbox"/>	<input type="checkbox"/>
Cerebrovascular Disease	<input type="checkbox"/>	<input type="checkbox"/>
Left Ventricular Hypertrophy (LVH)	<input type="checkbox"/>	<input type="checkbox"/>
Congestive Heart Failure	<input type="checkbox"/>	<input type="checkbox"/>
Diabetes Mellitus	<input type="checkbox"/>	<input type="checkbox"/>
Peripheral Vascular Disease	<input type="checkbox"/>	<input type="checkbox"/>
Renal Impairment	<input type="checkbox"/>	<input type="checkbox"/>
Chronic Respiratory Disease	<input type="checkbox"/>	<input type="checkbox"/>
Dyslipidemia	<input type="checkbox"/>	<input type="checkbox"/>
Family History of Atherosclerosis or HTN	<input type="checkbox"/>	<input type="checkbox"/>
Smoking	<input type="checkbox"/>	<input type="checkbox"/>

Current Medications:

Disease	Medication

Current Antihypertensive Medications:

Yes

No

* If yes:

Diuretic _____

ACEI _____

Beta Blocker _____

Calcium Channel Blocker _____

Others _____

Others _____

Assigned Trial Medications:

Valsartan 80 mg

Monotherapy

Valsartan | HCT 80 / 12.5

Add on

Vital Signs:

Sitting Pulse Rate

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/ min

Sitting Blood Pressure (mmHg)

SBP		

/

DBP		

Signature of Investigator

Date

Visit 2 / Week 4-6

Date:

Day	Month	Year

Vital Signs:

Sitting Pulse Rate

--	--	--

 / min

Sitting Blood Pressure (mmHg)

SBP		

 /

DBP		

Premature Drug Discontinuation:

Yes No

* If yes please write below why:

Adverse Events

Yes No

* If yes please refer to the Adverse Events report form.

Blood Pressure Controlled (SBP < 140 & DBP < 90)

Yes No

* If no what measures are taken

Signature of Investigator

Date

Visit 3 / Week 12

Date:

Day	Month	Year

Vital Signs:

Sitting Pulse Rate

--	--	--

/ min

Sitting Blood Pressure (mmHg)

SBP		

/

DBP		

Premature Drug Discontinuation:

Yes

No

* If yes please write below why:

Adverse Events

Yes

No

* If yes please refer to the Adverse Events report form.

Blood Pressure Controlled (SBP < 140 & DBP < 90)

Yes

No

* If no what measures are taken

Signature of Investigator

Date

Global Overall Assessments

A. Tolerability and Safety

- Excellent : No adverse events
- Good : Mild adverse events
- Fair : Moderate adverse events
- Poor : Severe adverse events and drug discontinuation

B. Efficacy {Response}

- Excellent DBP < 85 mmHg
- Good DBP 85-89 mmHg
- Fair DBP 90-99 mmHg
- Poor DBP > 99 mmHg

C. Controlled:

- Yes (SBP < 140 and DBP < 90 mmHg)
- No (SBP > 140 and/or DBP > 90 mmHg)

Signature of Investigator

Date