

Recall of Valsartan Containing Medicines

AUDIENCE:

Healthcare Professionals, General Public

BACKGROUND:

On 5th of July European Medicine Agency issued an Alert (EMA: EMA/459276/2018) regarding recall of some Valsartan containing medicines in European Union. These medicines were found to have a cancer-causing impurity N-nitroso dimethylamine (NDMA). These medicines were made using active substance from Zhejiang Huahai Pharmaceuticals, Linhai, China. Later, various Medicine Regulatory Authorities across the globe issued similar alerts.

On 12-07-2018, Provincial Pharmacovigilance Center Punjab also issued an Alert (DSA-167) and asked manufacturers to review their sources of raw materials of Valsartan. On the same day, Drug Regulatory Authority of Pakistan (DRAP) triggered a recall of all Valsartan containing medicines having made using same source of active substance (F. No. 3-38/2018-QC, Dated: 12 & 13-07-2018).

DRAP also issued a list of 12 manufacturers who had imported Valsartan from the Zhejiang Huahai Pharmaceuticals, Linhai, China, which is as follows;

LIST OF MANUFACTURERS WHO IMPORTED VALSARTAN FROM ZHEJIANG HUAHAI PHARMACEUTICALS, LINHAI, CHINA:

1. Genome Pharmaceuticals Hattar
2. WNS Field Pharmaceuticals Hattar
3. Ferozsons Laboratories, Nowshera
4. Amarant Pharmaceuticals (Pvt) Ltd Karachi
5. Efroze Chemical Industries, Karachi
6. High-Q Pharmaceuticals, Karachi
7. PharmEvo (Pvt) Ltd, Karachi
8. Safe Pharmaceuticals (Pvt) Ltd, Karachi
9. Sami Pharmaceuticals (Pvt) Ltd, Karachi
10. Tabros Pharmaceuticals (Pvt) Ltd, Karachi
11. Searle Pharmaceuticals, Lahore
12. Genetics Pharmaceuticals, Lahore

The list above does not cover all the manufacturers who manufacture medicines containing Valsartan.



VALSARTAN CONTAINING MEDICINES THAT SHOULD BE AVOIDED:

Name of Medicine	Generic Name
Amarant Pharmaceuticals	
Listan	Valsartan 80mg
Listan	Valsartan 160mg
Listan	Valsartan 80 mg+ Hydrochlorothiazide 12.5mg
Listan	Valsartan 160 mg+ Hydrochlorothiazide 12.5mg
Efroz Pharmaceuticals	
Angiotan	Valsartan 80mg
Angiotan	Valsartan 160mg
Angiotan-H	Valsartan 160mg+ Hydrochlorothiazide 25mg
Valcard	Amlodipine 5mg + Valsartan 80mg
Valcard	Amlodipine 5mg + Valsartan 160mg
Valcard	Amlodipine 10mg + Valsartan 160mg
Ferozsons Laboratories	
Covance	Amlodipine 5mg + Valsartan 80mg
Covance	Amlodipine 5mg + Valsartan 160mg
Covance	Amlodipine 10mg + Valsartan 80mg
Covance	Amlodipine 10mg + Valsartan 160mg
Genetics Pharmaceuticals	
Amsart	Amlodipine 5mg + Valsartan 80mg
Amsart	Amlodipine 5mg + Valsartan 160mg
Amsart	Amlodipine 10mg + Valsartan 160mg
Genome Pharmaceuticals	
Amlortan	Amlodipine 5mg + Valsartan 80mg
Amlortan	Amlodipine 5mg + Valsartan 160mg
Amlortan	Amlodipine 10mg + Valsartan 160mg
PharmEvo Pvt Ltd	
Nuval	Valsartan 80 mg
Nuval	Valsartan 160 mg
Nuval-D	Valsartan 80 mg+ Hydrochlorothiazide 12.5mg
Nuval-D	Valsartan 160 mg+ Hydrochlorothiazide 12.5mg
Avsar	Amlodipine 5mg + Valsartan 80mg
Avsar	Amlodipine 5mg + Valsartan 160mg



Avsar	Amlodipine 10mg + Valsartan 160mg
Avsar Plus	Amlodipine 5mg + Valsartan 160mg+ Hydrochlorothiazide 12.5mg
Avsar Plus	Amlodipine 5mg + Valsartan 160mg+ Hydrochlorothiazide 25mg
Avsar Plus	Amlodipine 10mg + Valsartan 160mg+ Hydrochlorothiazide 12.5mg
Avsar Plus	Amlodipine 10mg + Valsartan 160mg+ Hydrochlorothiazide 25mg
Avsar Plus	Amlodipine 10mg + Valsartan 320mg+ Hydrochlorothiazide 25mg
Sami Pharmaceuticals	
Sevia	Valsartan 40mg
Sevia	Valsartan 80mg
Sevia	Valsartan 160mg
Sevia-H	Valsartan 80 mg+ Hydrochlorothiazide 12.5mg
Sevia-H	Valsartan 160 mg+ Hydrochlorothiazide 12.5mg
Searle Pharmaceuticals	
Extor	Amlodipine 5mg + Valsartan 80mg
Extor	Amlodipine 5mg + Valsartan 160mg
Extor	Amlodipine 10mg + Valsartan 160mg
Co-Extor	Amlodipine 5mg + Valsartan 160mg+ Hydrochlorothiazide 12.5mg
Co-Extor	Amlodipine 5mg + Valsartan 160mg+ Hydrochlorothiazide 25mg
Co-Extor	Amlodipine 10mg + Valsartan 160mg+ Hydrochlorothiazide 12.5mg
Tabros Pharmaceuticals	
Valtec	Valsartan 40mg
Valtec	Valsartan 80mg
Valtec	Valsartan 160mg
Co-Valtec	Valsartan 80 mg+ Hydrochlorothiazide 12.5mg
Co-Valtec	Valsartan 160 mg+ Hydrochlorothiazide 12.5mg
Co-Valtec	Valsartan 160 mg+ Hydrochlorothiazide 25mg
Valtec-AM	Amlodipine 5mg + Valsartan 80mg
Valtec-AM	Amlodipine 5mg + Valsartan 160mg
Valtec-AM	Amlodipine 10mg + Valsartan 160mg
Valtec-AMH	Amlodipine 5mg + Valsartan 160mg+ Hydrochlorothiazide 12.5mg
Valtec-AMH	Amlodipine 5mg + Valsartan 160mg+ Hydrochlorothiazide 25mg



Valtec-AMH	Amlodipine 10mg + Valsartan 160mg+ Hydrochlorothiazide 12.5mg
Valtec-AMH	Amlodipine 10mg + Valsartan 160mg+ Hydrochlorothiazide 25mg
WNS Field Pharmaceuticals	
Alestra	Amlodipine 5mg + Valsartan 80mg
Alestra-DS	Amlodipine 10mg + Valsartan 160mg

Table-1: Valsartan Containing Medicines That Should Be Avoided: The table gives a list of medicines (Their Brand Names & Generic Names) registered in Pakistan and who have been found to import Active substance of Valsartan from M/s Zhejiang Huahai Pharmaceuticals China. The data is based upon list of manufacturers issued by Drug Regulatory Authority of Pakistan. Public is advised to avoid the use of these medicines until recalled from the market. Note: Product of High-Q and Safe Pharmaceuticals could not be found.

VALSARTAN CONTAINING MEDICINES THAT ARE DOUBTED:

Name of Medicine	Manufacturer
Diaval	Ethical Laboratories (Manufacturer intimated that the product is not being manufactured).
Listan	Lexicon Pharma
Valtan	English Pharma
Varlan	Siza International (Manufacturer intimated that the product is not being manufactured from last 10 years).
Vatin	Everest Pharma (De-Registered)
Tulurik	Medisure
Avcard	Hilton Pharma
Listan HT	Lexicon Pharma
Trivalsan	Hilton Pharma
Vamlodip	Swan Pharma
Valtan Plus	English Pharma
Valken	Kanel Pharma
Valken-H	Kanel Pharma
Valken-A	Kanel Pharma
V-Med	Cell Laboratories

Table-2: Valsartan Containing Medicines That are Doubted: The table gives a list of medicines sold in Pakistan and who have neither declared not to import or use Active substance of Valsartan from M/s Zhejiang Huahai Pharmaceuticals China, nor their investigation has yet been done by federal or provincial Inspectors. The data is based upon DRAP notification and www.druginfosys.com.

VALSARTAN CONTAINING MEDICINES THAT ARE SAFE FOR USE:

Name of Product	Manufacturer
Diovan	Novartis Pharmaceuticals
Co-Diovan	Novartis Pharmaceuticals
Exforge	Novartis Pharmaceuticals
Exforge-HCT	Novartis Pharmaceuticals



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Cova	Getz pharmaceuticals
Cova-H	Getz pharmaceuticals
Covam	Getz pharmaceuticals
Sofvasc-V	Wilson's Pharma
Valstar	CCL Pharma
Alevia	Atco Laboratories
Co-Sartan	Werrick Pharma
Dioplus	Atco Laboratories
Newday	Werrick Pharma
Valam	CCL Pharma
Aksilez V	CCL Pharma
Alevia-V	Atco Laboratories
Co-Valstar	CCL Pharma
Nuvasc	Wilson's Pharma
Valam-H	CCL Pharma
Aksilez V Plus	CCL Pharma
Address 5/80, 5/160	Scottman Pharmaceuticals
Diotan 3H	Hamaz Pharma
Valid	Scilife Pharma
Amodip V	Mass Pharma
Co-Valid	Scilife Pharma
Valsar M	Helix Pharma
Co-Valseta, Valseta	Maple Pharma (Manufacturer declared that the product is not in the market)
Prestor 5/80, 5/160, 10/160	Saffron Pharma
Amstan	Scilife Pharma
Triforge	Highnoon Laboratories
Valmo	Pharmatec
Valmo Plus	Pharmatec
Exava-A	Genix Pharma

Table-3: Valsartan Containing Medicines That are Safe for Use: The table gives a list of medicines registered in Pakistan and who have declared not to import or use Active substance of Valsartan from M/s Zhejiang Huahai Pharmaceuticals China. The data is based upon declaration of manufacturers submitted to Provincial Pharmacovigilance Center Punjab.

MESSAGE FOR HEALTHCARE PROFESSIONALS:

All Healthcare Professionals (Prescribers, Nurses, Pharmacists) are advised not to prescribe or dispense the medicines given in table-1, un-till recalled. Medicines given in table-3 may be prescribed, dispensed or used.

MESSAGE FOR CONSUMERS/PUBLIC:

Valsartan is a blood pressure lowering medicine and is present in many available brands as given in table-1, 2 and 3. It is found alone or in combination with other medicines. Recently it was found by European laboratories that Valsartan which was manufactured



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by Zhejiang Huahai Pharmaceuticals China contained a probable cancer-causing impurity. The European Medicine Agency asked to recall these specific brands. Some of the Manufacturers in Pakistan have also used the same source of medicine Valsartan and the Drug Regulatory Authority of Pakistan have issued their list, as given above. Consumers and public are advised that if they are using any of the medicines given in table-1, they should stop using it and seek healthcare professional advice. Status of medicines given in table-2 is not clear and should also not be used.

Your prescriber may write you another brand (like those given in table-3) or switch to another medicine for blood pressure control.

DISCLAIMER:

Recall of products (medicines) does not mean that it is permanently un-fit for use. Any manufacturer may witness issues during manufacturing or a problem may even occur during transportation or handling which may be a cause of recall. Issuance of lists herein this alert does not indicate a ban on sale of the mentioned companies or brands.



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