

**Recall Notice: Valsartan and Valsartan Combination Products are Recalled by FDA- Updates August 2018**

The medication valsartan and the combination drugs valsartan-hydrochlorothiazide (valsartan-hctz) and valsartan-amlodipine-hydrochlorothiazide (amlodipine-valsartan-hctz) **from certain manufacturers**, have been recalled by the U.S. Food and Drug Administration (FDA). **This list is being continually updated by the FDA.**

**The reason for this recall:**

An impurity (substance not intended to be included) called N-nitrosodimethylamine or “NDMA” was found in the recalled products. NDMA is a substance that occurs naturally in certain foods, drinking water, air pollution, and industrial processes. NDMA is a potentially cancer-causing substance and the FDA felt the recalled drugs pose an unnecessary risk to patients. **Specific manufacturers’ products identified as of August 22, 2018, impacted by this recall are listed on the following pages.** You can compare the information on your prescription bottles with this list (drug name and strength, drug manufacturer).

**FirstMedicare Direct Communications:**

- Letters have been sent to our members whose recent prescription claims indicate they may have a prescription that was filled with a recalled product
- Physicians are being provided with a list of their potentially impacted FirstMedicare Direct members that have been identified or with a copy of the notice provided to their patients, who are our members.

**If You Have Been Identified or Think You Have a Recalled Prescription, What is Recommended?**

- **Please share the information in this letter with your physician or other health care provider** that prescribes your medication.
- Please **contact your pharmacist immediately** to verify if you are currently taking one of the products impacted by this recall.

FirstCarolinaCare Insurance Company’s FirstMedicare Direct plans are HMO and PPO health plans with Medicare contracts. Enrollment in FirstMedicare Direct depends on contract renewal. FirstCarolinaCare complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. ATTENTION: If you speak a language other than English, assistance services, free of charge, are available to you. Call 1-844-499-5630 (TTY 711). ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1-844-499-5630 (TTY 711). 注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1-844-499-5630 (TTY 711)

- If you are currently using a recalled drug, **please ask your pharmacist to refill your prescription with a different manufacturer’s valsartan or valsartan combination product- or-** you and/or your pharmacy may **contact your physician** or other healthcare provider to obtain a prescription for a different medication.
- The U.S. Food and Drug Administration (FDA) recommends that you continue taking your current medication until your health care provider or pharmacist gives you a replacement or a different treatment option.

**For additional information:**

**Please contact your physician or healthcare provider for specific medical advice.**

**For products from Teva- labeled as Major Pharmaceuticals:** Consumers with questions regarding this recall should contact Major Pharmaceuticals Customer Support at 1-800-616-2471, Option #1 available Monday through Friday 8 a.m. – 8 p.m. EST.

**For products from Princeton- labeled as Solco Pharmaceuticals:** Consumers and patients with medical-related questions regarding this recall, please contact Solco at 888-679-5120 between the hours of 9:00 a.m. to 5:00 p.m. EST Monday through Friday.

**For products from Teva- labeled as Actavis Pharmaceuticals:** Customers and patients with questions regarding this recall should call Teva’s Medical Information at 888-838-2872 (Option #3, then Option #4, then Option #1). Live calls are received Monday-Friday, 9:00AM-5:00PM Eastern Time with Voicemail available 24 hours/day, 7 days/week or email [druginfo@tevapharm.com](mailto:druginfo@tevapharm.com).

**For products from Hetero Labs Limited, labeled as Camber Pharmaceuticals:** Consumers with questions regarding this recall can contact Qualanex, LLC by phone at 1-800-505-9291 or email [recall@qualanex.com](mailto:recall@qualanex.com) from Monday to Friday between 9am – 5pm Central Time.

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**For products from Torrent Pharmaceuticals:** Consumers with **medical questions regarding this recall or to report an adverse event** can contact Torrent Pharmaceuticals Limited at 1-800-912-9561 (live calls received 8:00 am – 5:00 pm Eastern Time, voicemail available 24 hours/day, 7 days/week) or at [Medinfo.Torrent@apcerls.com](mailto:Medinfo.Torrent@apcerls.com).

You can read the complete MedWatch Safety Alert that includes recommendations at: <https://www.fda.gov/Drugs/DrugSafety/ucm613916>.

**Products that are affected by this recall. Products identified as of 8/22/18 are listed on the following pages:**

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Products under the valsartan recall - Updated August 22, 2018

Company	Product	NDC	Lot	Expiration (Month-Year)		
Teva Pharmaceuticals labeled as Major Pharmaceuticals	Valsartan 80mg Tablets	0904-6594-61	T01795	May-19		
			T01807	May-19		
			T01712	Feb-19		
			T01625	Feb-19		
			T01596	Feb-19		
			T01500	Feb-19		
			T01466	Jul-18		
			T01270	Jul-18		
			Valsartan 160mg Tablets	0904-6595-61	T01646	May-19
					T01788	May-19
T01668	May-19					
T01524	Feb-19					
T01269	Jul-18					
Princeton Pharmaceutical Inc. labeled as Solco Healthcare LLC.	Valsartan 40mg Tablets, 30 count bottle	43547-367-03	All lots	07/2018 to 01/2020		
	Valsartan 80mg Tablets, 90 count bottle	43547-368-09				
	Valsartan 160mg Tablets, 90 count bottle	43547-369-09				
	Valsartan 320mg Tablets, 90 count bottle	43547-370-09				
	Valsartan and Hydrochlorothiazide (HCTZ) 80mg/12.5mg Tablets, 90 count bottle	43547-311-09				
	Valsartan and Hydrochlorothiazide (HCTZ) 160mg/12.5mg Tablets, 90 count bottle	43547-312-09				
	Valsartan and Hydrochlorothiazide (HCTZ) 160mg/25mg Tablets, 90 count bottle	43547-313-09				
	Valsartan and Hydrochlorothiazide (HCTZ) 320mg/12.5mg Tablets, 90 count bottle	43547-314-09				
Valsartan and Hydrochlorothiazide (HCTZ) 320mg/25mg Tablets, 90 count bottle	43547-315-09					

Company	Product	NDC	Lot	Expiration (Month-Year)
Teva Pharmaceuticals USA labeled as Actavis	Valsartan 40mg Tablets, 30 count bottle	0591-2167-30	1196936A	Sep-18
			1238463A	May-19
			1270617A	Oct-19
	Valsartan 40mg Tablets, 90 count bottle	0591-2167-19	1196934M	Sep-18
			1238462M	May-19
			1268429A	Oct-19
	Valsartan 80mg Tablets, 90 count bottle	0591-2168-19	1175947M	Jul-18
			1175948M	Jul-18
			1177115A	Jul-18
			1219361A	Feb-19
			1240434M	May-19
			1250704M	May-19
	Valsartan 80mg Tablets, 1000 count bottle	0591-2168-10	1177114A	Jul-18
			1219360M	Feb-19
			1250706A	May-19
	Valsartan 160mg Tablets, 90 count bottle	0591-2169-19	1177880A	Jul-18
			1220831A	Feb-19
			1263941A	Aug-19
	Valsartan 160mg Tablets, 1000 count bottle	0591-2169-10	1175922M	Jul-18
			1220826M	Feb-19
			1236294M	May-19
			1240427M	May-19
			1270616A	Aug-19

Company	Product	NDC	Lot	Expiration (Month-Year)
Teva Pharmaceuticals USA labeled as Actavis...continued...	Valsartan 320mg Tablets, 90 count bottle	0591-2170-19	1208002A	Oct-18
			1247282M	May-19
			1263944M	Aug-19
	Valsartan 320mg Tablets, 500 count bottle	0591-2170-05	1208000M	Oct-18
			1208001M	Oct-18
			1240425A	Jun-19
	Valsartan and Hydrochlorothiazide (HCTZ) 80mg/12.5mg Tablets, 90 count bottle	0591-2315-19	1191191M	Aug-18
			1191192M	Aug-18
			1191193M	Aug-18
			1191194M	Aug-18
			1191195M	Aug-18
			1238466M	Jun-19
			1238467M	Jun-19
			1253261M	Jul-19
			1256125M	Jul-19
			1277709M	Sep-19
	Valsartan and Hydrochlorothiazide (HCTZ) 160mg/12.5mg Tablets, 90 count bottle	0591-2316-19	1191160M	Sep-18
			1191161M	Sep-18
			1191162A	Sep-18
			1219363M	Feb-19
			1219364M	Feb-19
			1219365A	Feb-19
			1225613A	Feb-19

Company	Product	NDC	Lot	Expiration (Month-Year)
Teva Pharmaceuticals USA labeled as Actavis...continued...			1233944M	Apr-19
			1233945M	Apr-19
			1253253M	Jul-19
			1253254M	Jul-19
	Valsartan and Hydrochlorothiazide (HCTZ) 160mg/25mg Tablets, 90 count bottle	0591-2317-19	1191164M	Sep-18
			1191165M	Sep-18
			1191166M	Sep-18
			1191167A	Oct-18
			1225612M	Feb-19
			1250717M	Jul-19
			1256111M	Jul-19
			1288798M	Oct-19
	Valsartan and Hydrochlorothiazide (HCTZ) 320mg/12.5mg Tablets, 90 count bottle	0591-2318-19	1191185M	Sep-18
			1191186M	Sep-18
			1225615M	Feb-19
			1233948M	Feb-19
			1250718M	Aug-19
			1253257M	Jul-19
	Valsartan and Hydrochlorothiazide (HCTZ) 320mg/25mg Tablets, 90 count bottle	0591-2319-19	1191188M	Sep-18
			1191189M	Sep-18
			1191190M	Sep-18
			1199220M	Aug-18
			1217576M	Jan-19
			1217577M	Jan-19

Company	Product	NDC	Lot	Expiration (Month-Year)
Teva Pharmaceuticals USA labeled as Actavis...continued...			1217578M	Jan-19
			1220832M	Jan-19
			1220833M	Feb-19
			1247283M	Jun-19
			1247284M	Jun-19
			1247285M	Jun-19
			1247286M	Jun-19
			1247287A	Jun-19
			1280632M	Oct-19
			1280633M	Oct-19
AvKARE	Valsartan and Hydrochlorthiazide (HCTZ) 80mg/12.5mg Tablets, 90 count bottle	42291-884-90	17349	Aug-18
			18395	Aug-18
			19221	Jun-19
			20029	Jun-19
			20158	Jul-19
			20843	Jul-19
			21411	Sep-19
	Valsartan and Hydrochlorothiazide (HCTZ) 160mg/12.5mg Tablets, 90 count bottle	42291-885-90	17325	Sep-18
			17856	Sep-18
			18396	Sep-18
			18702	Feb-19
			19020	Feb-19
			19222	Feb-19
			20030	Apr-19
			20381	Apr-19



Company	Product	NDC	Lot	Expiration (Month-Year)
AvKARE continued..	Valsartan and Hydrochlorothiazide (HCTZ) 320mg/12.5mg Tablets, 90 count bottle	42291-886-90	17780	Sep-18
			18029	Sep-18
			18398	Sep-18
			18723	Sep-18
			19017	Feb-19
			19224	Feb-19
			20032	Aug-19
			20289	Aug-19
			21076	Aug-19
			21382	Aug-19
	Valsartan and Hydrochlorothiazide (HCTZ) 160mg/25mg Tablets, 90 count bottle	42291-887-90	17307	Sep-18
			17857	Sep-18
			18397	Sep-18
			18722	Sep-18
			19016	Oct-18
			19223	Feb-19
			20031	Jul-19
			20382	Jul-19
			21281	Jul-19
	Valsartan and Hydrochlorothiazide (HCTZ) 320mg/25mg Tablets, 90 count bottle	42291-888-90	17308	Sep-18
			18158	Sep-18
			18539	Jan-19
			19021	Jan-19
			19225	Jan-19
			20033	Jun-19
			20290	Jun-19
			20565	Jun-19
			21369	Oct-19

Company	Product	NDC	Lot	Expiration (Month-Year)
RemedyRepack Inc. (Prinston/SOLCO)	Valsartan and Hydrochlorothiazide (HCTZ) 320mg/12.5mg Tablet, 90 count bottle	70518-0925-0	B0383153- 122917	Dec-18
	Valsartan and Hydrochlorothiazide 160mg/12.5mg Tablets, 90 count bottle	70518-0607-0	B0318652- 070617	Jul-18
A-S Medication Solutions LLC	Valsartan 80mg Tablets, 90 count bottle	54569-6582-1	342B17019	Sep-19
			342B17018	Aug-19
			342B17004	Feb-19
			342B17002	Nov-18
	Valsartan 80mg Tablets, 30 count bottle	54569-6582-0	342B17003	Nov-18
			342B17004	Feb-19
	Valsartan 160mg Tablets, 90 count bottle	54569-6583-1	343B17056	Aug-19
			343B17053	Aug-19
			343B17024	Mar-19
			343B17016	Feb-19
	Valsartan 160mg Tablets, 30 count bottle	54569-6583-0	343B17019	Feb-19
			343B17023	Mar-19
			343B17056	Aug-19
	Valsartan and Hydrochlorothiazide (HCTZ) 160mg/12.5mg Tablets, 30 count bottle	54569-6480-0	1233944M	Apr-19
			1253253M	Jul-19

Company	Product	NDC	Lot	Expiration (Month-Year)
A-S Medication Solutions LLC continued	Valsartan and Hydrochlorothiazide (HCTZ) 160mg/12.5mg Tablets, 90 count bottle	54569-6480-1	1253253M	Jul-19
	Valsartan and Hydrochlorothiazide (HCTZ) 320mg/25mg Tablets, 30 count bottle	54569-6488-0	1191188M	Sep-18
			1191189M	Sep-18
			1217576M	Jan-19
			1247283M	Jun-19
			1247285M	Jun-19
Bryant Ranch Prepack Inc.	Valsartan 80mg Tablets, 28 count bottle	63629-6922-4	111158	Feb-19
	Valsartan 80mg Tablets, 60 count bottle	63629-6922-3	111158	Feb-19
	Valsartan 80mg Tablets, 90 count bottle	63629-6922-2	111158	Feb-19
	Valsartan 320mg Tablets, 28 count bottle	63629-6905-3	114319	Oct-18
			109004	Dec-18
	Valsartan 320mg Tablets, 30 count bottle	63629-6905-1	114319	Oct-18
			109004	Dec-18
	Valsartan 320mg Tablets, 90 count bottle	63629-6905-2	114319	Oct-18
			109004	Dec-18
	Valsartan 320mg Tablets, 90 count bottle	71335-0567-2	120879	Oct-19
H J Harkins Company Inc. dba Pharma Pac	Valsartan 160mg Tablets, 90 count bottle	76519-1158-9	VSA0000V	Feb-19
Proficient Rx LP	Valsartan and Hydrochlorothiazide (HCTZ) 320mg/12.5mg Tablets, 90 count bottle	71205-004-90	All lots	09/2018 to 07/2019
Northwind Pharmaceuticals	Valsartan 80mg Tablets, 30 count bottle	51655-652-52	UT48310002	Oct-18
	Valsartan 160mg Tablets, 30 count bottle	51655-460-52	UT48320002	Jul-18
			UT48320003	May-19
	Valsartan 320mg Tablets, 30 count bottle	51655-654-52	UT48100001	Sep-19
	Valsartan and Hydrochlorothiazide (HCTZ) 160mg/12.5mg Tablets	51655-950-52	UTB23790003	Feb-19

Company	Product	NDC	Lot	Expiration (Month-Year)
Camber Pharmaceuticals, Inc.	Valsartan 40mg Tablets, 30 count bottle	31722-745-30	All lots	07/2018 - 06/2020
	Valsartan 80mg Tablets, 90 count bottle	31722-746-90		
	Valsartan 160mg Tablets, 90 count bottle	31722-747-90		
	Valsartan 320mg Tablets, 90 count bottle	31722-748-90		
NuCare Pharmaceuticals Inc.	Valsartan and Hydrochlorothiazide (HCTZ) 160mg/12.5mg Tablets, 90 count bottle	68071-4311-9	U01779	Apr-19
	Valsartan and Hydrochlorothiazide (HCTZ) 160mg/25mg Tablets, 30 count bottle	68071-2119-3	T11443	Feb-19
	Valsartan and Hydrochlorothiazide (HCTZ) 320mg/25mg Tablets, 30 count bottle	68071-4183-3	T11577	Jun-19
RemedyRepack, Inc. (Hetero/Camber)	Valsartan 80mg Tablets , 90 count bottle	61786-0791-19	B0335344-081717	Aug-18
			B0363364-110917	Nov-18
			B0391225-012218	Jan-19
			B0408458-030618	Mar-19
			B0384871-010318	Jan-19
			B0436862-051518	May-19
	Valsartan 160mg Tablets, 90 count bottle	61786-0792-19	B0335344-081717	Aug-18
			B0363364-110917	Nov-18
			B0391225-012218	Jan-19
			B0408458-030618	Mar-19
			B0384871-010318	Jan-19
			B0436862-051518	May-19

Company	Product	NDC	Lot	Expiration (Month-Year)
RemedyRepack, Inc. (Hetero/Camber) continued	Valsartan 320mg Tablets, 90 count bottle	61786-0793-19	B0362988-110917	Oct-18
			B0432265-050318	May-19
			B0450321-061218	Jun-19
			B0450322-061218	May-19
			B0408652-030718	Feb-19
AvKARE (Hetero/Camber)	Valsartan 40mg Tablets	50268-783-15	All lots	07/2018 - 06/2020
	Valsartan 80mg Tablets	50268-784-15		
	Valsartan 160mg Tablets	50268-785-15		
	Valsartan 320mg Tablets	50268-786-13		
Preferred Pharmaceuticals, Inc.	Valsartan 320mg Tablets, 90 count bottle	68788-6882-9	G2017F	Oct-18
Torrent Pharmaceuticals Limited	Amlodipine, Valsartan and Hydrochlorothiazide (HCTZ) 10mg/320mg/25mg Tablets, 30 count	13668-325-30	BBX2D001	Dec-18
			BBX2D002	Dec-18
			BBX2D003	Mar-19
			BBX2D004	Mar-19
			BBX2D005	Mar-19
			BBX2D006	Mar-19
			BBX2D007	Mar-19
			BBX2D008	Mar-19
			BBX2D009	Mar-19
			BBX2D010	Apr-19
			BBX2D011	Apr-19
			BBX2D012	May-19
			BBX2D013	May-19
			BBX2D014	Aug-19
			BBX2D015	Oct-19
			BBX2D016	Oct-19

Company	Product	NDC	Lot	Expiration (Month-Year)
Torrent Pharmaceuticals Limited continued...			BBX2D017	Oct-19
			BBX2D018	Oct-19
			BBX2D019	Oct-19
			BBX2D020	Oct-19
			BBX2D021	Oct-19
			BBX2D022	Oct-19
			BBX2D023	Oct-19
			BBX2D024	Nov-19
			BBX2D025	Nov-19
			BBX2D026	Nov-19
			BBX2E001	Jan-20
			BBX2E002	Jan-20
			BBX2E003	Jan-20
			BBX2E004	Jan-20
			BBX2E005	Jan-20
	Amlodipine, Valsartan and Hydrochlorothiazide (HCTZ) 10mg/160mg/25mg Tablets, 30 count bottle	13668-328-30	BBX9D001	Feb-19
			BBX9D002	Mar-19
			BBX9D003	Jul-19
			BBX9D004	Nov-19
			BBX9E001	Jan-20
	Amlodipine, Valsartan and Hydrochlorothiazide (HCTZ) 5mg/160mg/12.5mg Tablets, 30 count bottle	13668-326-30	BBY1C002	Sep-18
			BBY1D001	May-19
			BBY1E001	Dec-19
			BBY1E002	Mar-20
			BBY1E003	Mar-20

Company	Product	NDC	Lot	Expiration (Month-Year)
Torrent Pharmaceuticals Limited continued...	Amlodipine, Valsartan and Hydrochlorothiazide (HCTZ) 10mg/160mg/12.5mg Tablets, 30 count bottle	13668-327-30	BBY2D001	Feb-19
			BBY2D002	Nov-19
			BBY2E001	Mar-20
	Amlodipine, Valsartan and Hydrochlorothiazide (HCTZ) 5mg/160mg/25mg Tablets, 30 count bottle	13668-329-30	BBY4D001	Apr-19
			BBY4D002	Apr-19
			BBY4D003	Jun-19
			BBY4D004	Nov-19
			BBY4E001	Jan-20
	Amlodipine and Valsartan 5mg/160mg Tablets, 30 count bottle	13668-207-30	BV53C006	Nov-18
			BV53D001	Feb-19
			BV53D002	Feb-19
			BV53D003	Sep-19
			BV53D004	Oct-19
	Amlodipine and Valsartan 10mg/160mg Tablets, 30 count bottle	13668-206-30	BV65C002	Sep-18
			BV65C003	Oct-18
			BV65C004	Nov-18
			BV65D001	Aug-19
			BV65D002	Oct-19

Company	Product	NDC	Lot	Expiration (Month-Year)
Torrent Pharmaceuticals Limited continued...	Amlodipine and Valsartan 10mg/320mg Tablets, 30 count bottle	13668-204-30	BV77C001	Oct-18
			BV77D001	Feb-19
			BV77D002	Feb-19
			BV77D003	Feb-19
			BV77D004	Feb-19
			BV77D005	Feb-19
			BV77D006	Feb-19
			BV77D007	Feb-19
			BV77D008	May-19
			BV77D009	Aug-19
			BV77D010	Sep-19
			BV77D011	Sep-19
			BV77D012	Sep-19
			BV77D013	Oct-19
	Amlodipine and Valsartan 5mg/320mg Tablets, 30 count bottle	13668-205-30	BV84C011	Oct-18
			BV84D001	Jan-19
			BV84D002	Jan-19
			BV84D005	Feb-19
			BV84D006	Feb-19
			BV84D007	Feb-19
			BV84D008	May-19
			BV84D009	May-19
			BV84D010	Oct-19
			BV84E001	Dec-19
	Valsartan 80mg Tablets, 90 count bottle	13668-068-90	BV46C007	Sep-18
			BV46C008	Oct-18
			BV46C009	Oct-18
			BV46C010	Oct-18
			BV46C011	Nov-18
			BV46C012	Nov-18



Company	Product	NDC	Lot	Expiration (Month-Year)
Torrent Pharmaceuticals Limited continued...	Valsartan 160mg Tablets, 90 count bottle	13668-069-90	BV47C005	Sep-18
			BV47C006	Sep-18
			BV47D001	Dec-18
	Valsartan 320mg Tablets, 90 count bottle	13668-070-90	BV48D001	Dec-18
			BV48D002	Dec-18
RemedyRepack, Inc. (Torrent)	Amlodipine, Valsartan and Hydrochlorothiazide (HCTZ) 10mg/320mg/25mg Tablets	70518-1220- 00	B0476653- 080218	Aug-19