

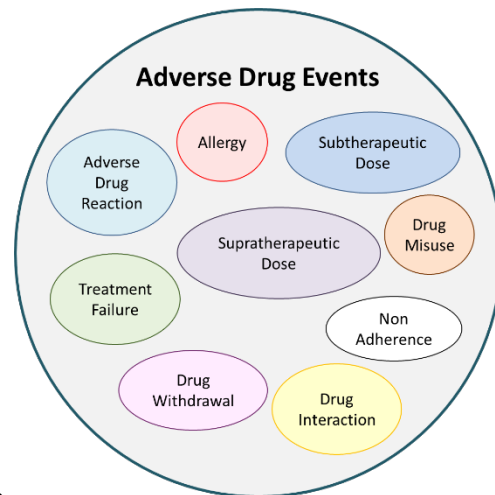
## Adverse Drug Events vs Adverse Drug Reaction

An Adverse Drug Event (ADE) is “Harm caused by appropriate or inappropriate use of a drug whereas adverse drug reactions are a **subset** of these events, where harm is directly caused by a drug under appropriate use (i.e. at normal doses). Adverse drug events may include cases of provider error, non-adherence, or incorrect dosages. (Nebeker, Barach, & Samore, 2004).

Information recorded by acute care providers in PharmaNet will include a broad range of ADEs, including as a subset ADRs. As the PharmaNet system will flag these ADEs for review upon subsequent dispensations of the medication, it is important for community pharmacists to review the information contain in the comments of recorded ADR/ADEs to determine the most appropriate action.

The ActionADE research team have completed significant research into what details of an ADE should be recorded to accurately, but succinctly inform other care providers of the event. For more information on ActionADE you can visit their web page - <https://actionade.org/>

**NOTE: ActionADE is a research project and thus there will be limited patients with ADE records. Pharmacists will still record ADRs as per the usual process in PharmaNet.**



## Display of ADE information in a Patient’s PharmaNet Profile

Depending on the version of your WinRx software, ADE information will display differently. The most recent update to WinRx will present ADE information as a unified record “Adverse Event” in the patient profile. Previous versions of the software will present the information separated in the “condition” and “Reaction” sections; use \*ADE to match the information together in this case.

**The following ADE information will be recorded in the PharmaNet record:**

CLINICAL CONDITIONS SECTION		
Data element	What it contains & allowed values	Comments
<b>ADE Identifier</b>	*ADE	Flags that this condition is associated with an ADE and its impact to therapy should be considered in the context of the ADE. The user must look for further details of the ADE in the 'Adverse Reaction' section. This can be done by matching the *ADE identifier.
<b>Time Stamp</b>	hh=hour (00 - 23) / mm=minutes (00 - 60)	Where a patient has multiple ADEs recorded, permits the matching of symptoms experienced in Clinical Conditions section to the correct ADE information recorded in the Adverse Reaction section.
<b>Clinical Condition</b>	Name of condition or symptom	Primary symptom/condition experienced as part of the ADE.
<b>Comment Detail</b>	Up to two further conditions/symptoms or lab value	Provides further details of symptoms experienced as part of the ADE, may also include a relevant lab value (eg. INR)
ADVERSE REACTION SECTION		

Data Element	What it contains	Comments
<b>Drug Name and DIN</b>	Drug name and DIN of the drug associated with the ADE.	This is often referred to as the culprit drug. PharmaNet will check any future dispenses against this DIN and flag as a prior ADR where a <u>potential</u> cross sensitivity exists. Users must review the ADE record to determine the appropriate action.
<b>ADVERSE REACTION TAB – Comment Details</b>		
<b>1. ADE Identifier</b>	<b>*ADE</b>	Flags that this record should be treated as an ADE versus ADR.
<b>2. Time Stamp</b>	hh=hour (00 - 23) / mm=minutes (00 - 60)	Where a patient has multiple ADE recorded, permits the matching of symptoms experienced in clinical conditions to the ADE information recorded in the ADR section
<b>3. Adverse Drug Event Type</b>	Adverse Drug Reaction	Defines the type of Adverse Drug Event. This informs users of the most appropriate clinical intervention. For example, a patient arrives in the ER experiencing seizures due to not taking their phenytoin. This would be documented as an ADE due to non-compliance, the expectation is that clinicians will encourage the patient to take their medication as prescribed to prevent a repeat of the ADE.
	Allergy	
	Subtherapeutic dose	
	Supratherapeutic dose	
	Treatment failure	
	Drug Withdrawal	
	Drug Interaction	
	Non-Adherence	
	Drug Misuse	
<b>4. Certainty</b>	Certain	The level of certainty the acute care provider has that the culprit drug caused the associated symptoms/diagnosis. 'Refuted' indicates that the provider has determined that the drug did not cause this ADE. For example, allergy testing reveals that a rash subsequent to amoxicillin was likely attributed to use during a viral infection not a true allergy.
	Likely	
	Possible	
	Unlikely	
	Refuted	
<b>5. ADE Outcome</b>	Death	The outcome of the ADE event, it provides some insight to the severity of the ADE.
	Permanent Disability	
	Worsen Preexist Cond	
	Fetal Defect	
	Hospitalization	
	Hospital Extended	
	Emergency Visit	
	Life Threatening	
<b>6. Dose with Units</b>	free text	Included where applicable, eg. Subtherapeutic and Supratherapeutic dose.
<b>7. Frequency</b>	free text	
The information in the comment is entered in the above order with each data element separated by an underscore. Comment: *ADE_hhmm_Adverse Drug Event Type_Certainty_ADE Outcome_Dose_Frequency		

## Example

<b>CLINICAL CONDITION (ZPB1)</b>	<b>*ADE_1450_Deep vein thrombosis</b>
Clinical Condition Comment: INR=1	

<b>ADVERSE REACTION (ZPB2)</b>	<b>Warfarin - DIN 2240205</b>
Adverse Reaction Comment: *ADE_1450_Subtherapeutic Dose_Certain_Hospital extended_3mg_daily	

**Recording your Clinical Decisions**

The ActionADE research is dependent upon pharmacists recording in PharmaNet their clinical decisions based upon the ADE information presented to them.

The PharmaNet Drug Use Evaluation (DUE) will alert on an ADE as part of the claim process. The user must review the comment details of the ADR and match to the associated Clinical Condition, via \*ADE\_hhmm identifier, to assess how the ADE alert should be managed clinically. If your software does not permit you to review the details of the DIN on record which triggered the alert, users must review the patient profile to see the details of the ADE. As these are ADEs versus ADRs, **do not** assume the medication should be discontinued or replaced. In some cases, it is appropriate to ensure the patient takes their medication as in the case of an ADE due to non-adherence.

- A) To record the clinical decision in response to ADE information subsequent to the DUE alert a pharmacist must manually reverse and resubmit any further claim with the appropriate reversal and rationale codes
- B) If an issue is noted prior to submission of a claim, the pharmacist can enter the rationale intervention code on the initial claim submission after making their clinical intervention.

#### PharmaNet Intervention Codes for Reversals due to ADE

Code	Description
RA	Due to ADE alert.
RD	Defer clinical decision.
RO	Override alert.

#### PharmaNet Intervention Codes to indicate a decision to proceed with the dispense despite the ADE information

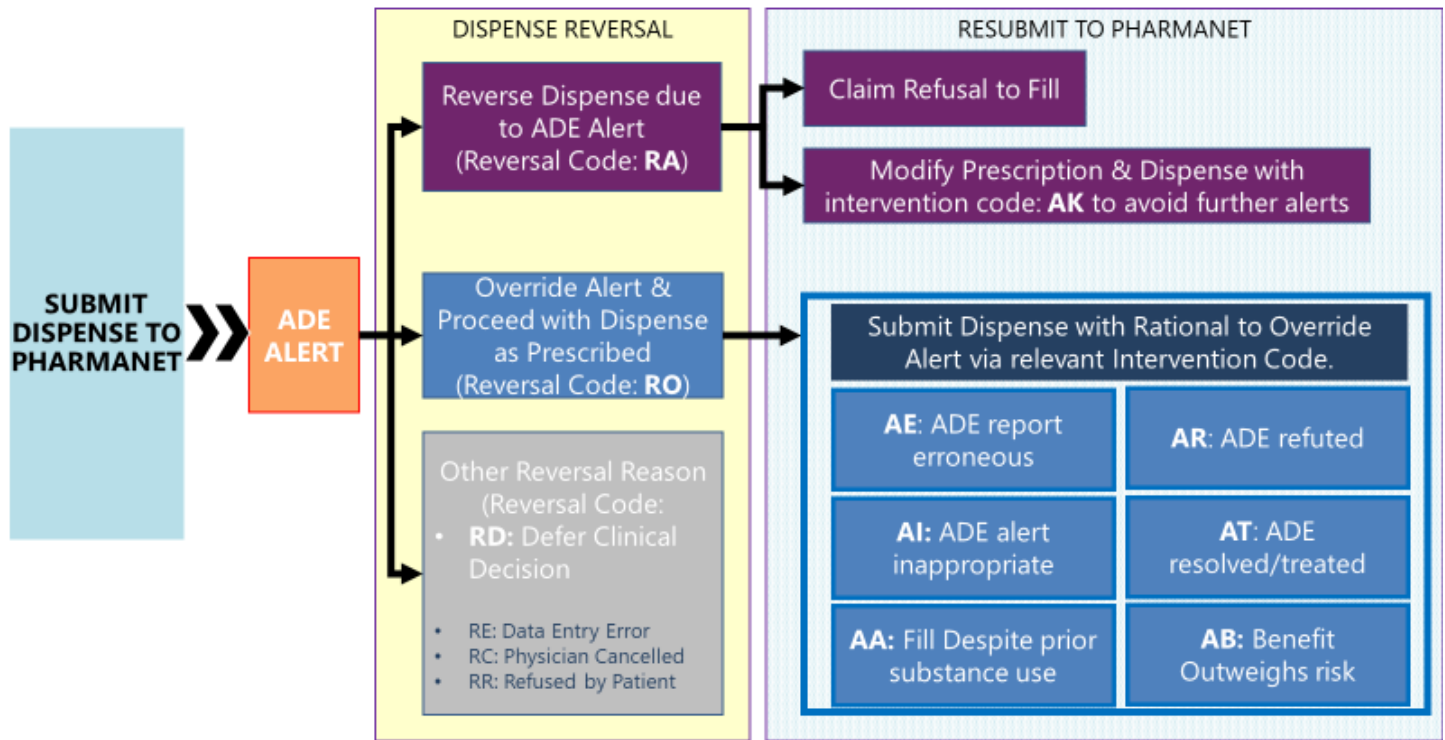
Code	Description
AA	Fill despite prior substance use.
AB	Benefit outweighs risk.
AE	ADE report erroneous.
AI	ADE alert inappropriate.
AR	ADE refuted.
AT	ADE resolved/treated.

#### PharmaNet Intervention Codes to indication a therapeutic change as a result of ADE information

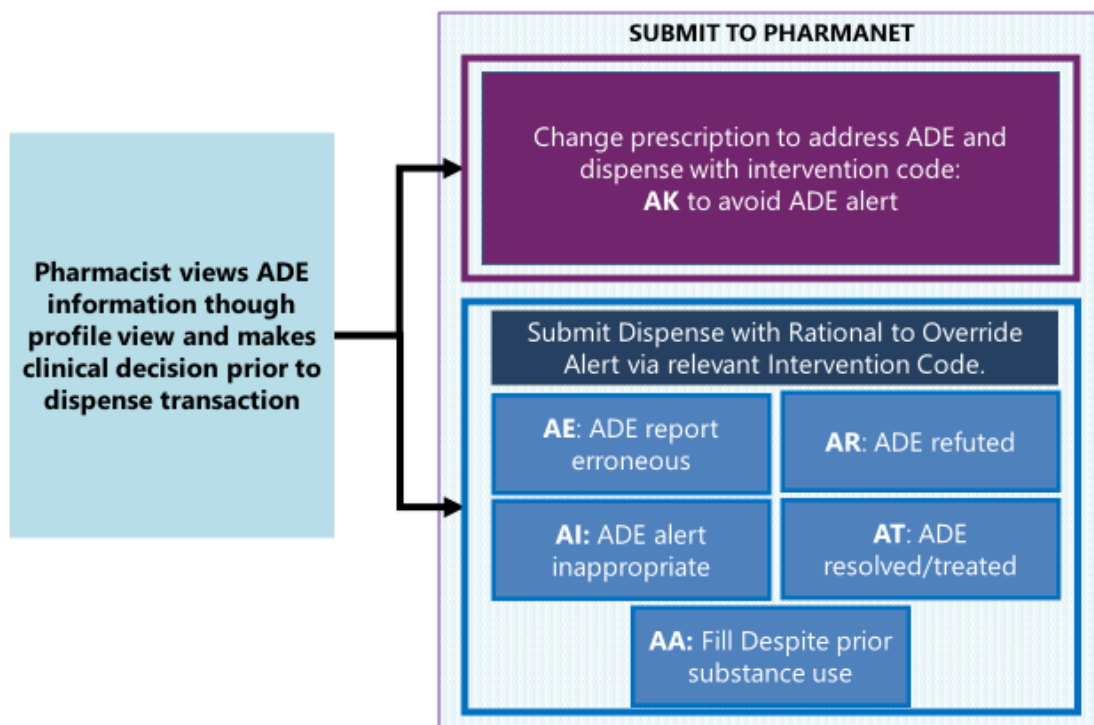
Code	Description
AK	ADE acknowledged and prescription changed.

**Pharmacy Users – Workflow to record clinical decisions due to ADE information by pharmacists in PharmaNet.**

A) Workflow if decision made at time of claim adjudication and display of PharmaNet DUE- prior ADE/ADR alert



B) Workflow if decision made at time of profile view prior to submission of claim adjudication.



## Display of ADE information in WinRx (Applied Robotics) – latest update

### Patient Profile

A new group for “Adverse Event” has been added with headers in the notes reflecting the information inputted into PharmaNet by ActionADE

Pharmanet profile containing All Rx's - 0 Operation successful

Sep 14, 2020 9:08 AM Total Prescriptions Found: 40

**SKIFFED GOOLEYS**  
 PHN: 9735355895 Sex: F DOB: Mar 03 2020 Age: 0 Ph: 555 2401734  
 Address: 1613 LAWNWOOD STREET, DITCHLING, BC, CAN V3G7A2

Pharmacy: Test Pharmacy  
 Store ID: BC000001AB  
 Practitioner: JOHN SMITH RPH [XXASD-PI]

Print Exit [Esc]  
 14 May 2019 To 14 Sep 2020 Summarize by DIN

Description	Prev Date	Qty/Dose	Drug	DIN	SIG / Clinical Notes	MaxDaily	Prescriber	Created
Reaction			PENICILLIN G POTASSIUM NOVOPHARM LTD 312.5MG TABLET	151432	Reported by:PA ANOTHER COMMENT		Entered by:XXASD-PI 2020-03-31	2020-03-31
Adverse event		1mg bid	WARFARIN SODIUM B-M SQUIBB 3 MG TABLET	2240205	ADE SYMPTOMS: CEREBRAL VASCULAR OCCLUSION,INTERNATIONAL NORMALIZED RATIO NORMAL TYPE:Subtherapeutic Dose CERTAINTY:Probable OUTCOME:Death		Entered by:XXANR-91 2020-02-20	2020-02-20
Adverse event					ADE SYMPTOMS: CEREBRAL VASCULAR OCCLUSION,INTERNATIONAL NORMALIZED RATIO NORMAL			2020-02-20
Adverse event			RAMIPRIL PHARMASCIENCE 5 MG CAPSULE	2247918	ADE SYMPTOMS: DIZZINESS,DEHYDRATION TYPE:Adverse Drug Reaction CERTAINTY:Refuted OUTCOME:Emergency Visit		Entered by:XXANR-91 2020-02-20	2020-02-20
Adverse event			PENICILLIN V POTASSIUM AA PHARMA INC. 300 MG TABLET	642215	ADE SYMPTOMS: ANAPHYLACTIC REACTION TYPE:Allergy CERTAINTY:Unlikely OUTCOME:Life Threatening		Entered by:XXANR-91 2020-02-20	2020-02-20
Adverse event			OLANZAPINE APOTEX INC 10 MG TABLET	2281821	ADE SYMPTOMS: HALLUCINATION,PARANOIA TYPE:Non-adherence CERTAINTY:Possible OUTCOME:Hospital Extended		Entered by:XXANR-91 2020-02-20	2020-02-20
Adverse event			TIOTROPIUM BROMIDE BOEHRINGER ING 2.5 MCG MIST INHAL	2435381	ADE SYMPTOMS: DYSPNEA,FATIGUE TYPE:Non-adherence CERTAINTY:Certain OUTCOME:Worsen Preexist Cond		Entered by:XXANR-91 2020-02-20	2020-02-20
Adverse event			VENLAFAXINE HCL TEVA CANADA LI 150 MG CAP ER 24H	2275058	ADE SYMPTOMS: ANXIETY,VOMITING,INSOMNIA TYPE:Drug Withdrawal CERTAINTY:Probable OUTCOME:Emergency Visit		Entered by:XXANR-91 2020-02-20	2020-02-20
Adverse event			LORAZEPAM APOTEX INC 0.5 MG TAB SUBL	2410745	ADE SYMPTOMS: SEIZURE,ANXIETY,HYPERTHERMIA TYPE:Drug Withdrawal CERTAINTY:Certain OUTCOME:Hospitalization		Entered by:XXANR-91 2020-02-20	2020-02-20
Rx filled	2020-08-21	100	PENICILLIN G POTASSIUM NOVOPHARM LTD 312.5MG TABLET	151432	TAKE.	1	ALCOVE [XXAWE-91]	
Rx filled	2020-07-09	26	ACETYLSALICYLIC ACID BAYER CONSUMER 81 MG TABLET DR	2237726	1 TAB DAILY	.929	ALCOVE [XXAWE-91]	

Legend: Another Store Severe Warning Click on item to display detail

### PharmaNet Drug Utilization Evaluation (DUE) Screen

Alerts for ADE are denoted as Adverse Event and coloured orange to differentiate from prior ADR.

WinRx v.9.080 BETA - Test Pharmacy  
 Applied Robotics Inc.

Dispense results

Adjudication results.  
 ACCEPTED WITH PRICE ADJUSTMENTS  
 CD: PATIENT NOT ENTITLED TO DRUG CLAIMED

GOOLEYS, SKIFFED PENICILLIN G-500 (NOVO) Rx# 11251  
 Cost 5.46 [0.00] + Upchrg 1.09 [0.00] + Fee 8.00 [0.00] = Total 14.55  
 Insurance pays: PNET=0.00 COPAY=14.55  
 PLAN= S/A=N EXP= DRUG=0000.00  
 ACC EXP=0000000.00 RBP=N LCA=N BEN=N  
 RESTRICTION= FEE=000.00

Current patient: GOOLEYS, SKIFFED  
 Sex: F Age: 0 Phone: 5552401734 Cell:    
 Diagnosis:   
 Allergies:

Reason for returning:  How was consult done:

N/R	Source	Date	Rx	Drug	Alg	Net	DTP	Final	Consult	Note
N		21 Aug 08:30	11251	PENICILLIN G-500 (NOVO)						
R		05 Jun 11:38	11176	MEVACOR 20MG (LOVASTATIN)						

[Enter] Net Profile [Space] Adjudication Results [Esc] Return to Search

**Severity Unspecified** Drug to Prior Adverse Reaction Grp All to PENICILLIN G POTASSIUM  
 DIN 00151432 on 2020/03/31 by PA  
 21 Aug 2020 100 PENICILLIN G POTASSIUM Daily dose: 1 DIN: 151432  
 Filled Id: XXAWE [91]  
 TAKE.

**Severity ADVERSE EVENT** Drug to Prior Adverse Reaction Grp All to PENICILLIN V  
 POTASSIUM DIN 00642215 on 2020/02/20 by AE  
 21 Aug 2020 100 PENICILLIN G POTASSIUM Daily dose: 1 DIN: 151432  
 Filled Id: XXAWE [91]  
 TAKE.

**Severity Unspecified** Drug to Prior Adverse Reaction Grp All to AMOXICILLIN  
 DIN 00628115 on 2019/12/01 by PA  
 21 Aug 2020 100 PENICILLIN G POTASSIUM Daily dose: 1 DIN: 151432  
 Filled Id: XXAWE [91]  
 TAKE.

## Display of ADE information in WinRx (Applied Robotics) – previous software versions

### Patient's PharmaNet Profile

The details of the ADE will be present in the patient profile screen. Note that this information is separated into the Condition section and the Reaction section. To match the information you must match the \*ADE\_hhmm together. In this case there are two ADEs. The black bracket matches \*ADE\_2310, and the blue bracket matches \*ADE\_1323. In most cases patients will not have more than one \*ADE on their profile.

In the DUE screen, ADEs will flag as Prior ADRs. You must review the patient profile to assess the ADE details and determine the most appropriate clinical action.

Pharmanet profile containing All Rxs - 0 Operation successful

**CHAPBOOK MARTYR** PHN: 9735355666 Sex: F Birth: Jun 24 1944 Age: 74 Ph: 555 8703607 May 24, 2019 - 1:58 PM  
 Address: 8387 FRONTANA PLACE CORBY SOHO BC CAN V5E4Y2 Net ID: BC000001AB  
 Pharmacy: Helpcomputer Pharmacy Practitioner: MONTHABSORPTION [XXBKR-P1] Total Rxs found: 32

Print Exit [Esc]  
 From Date: 24/01/2018 To Date: 24/05/2019  
 Summarized by DIN

Description	Prev Date	Qty	Drug	DIN	Practitioner	SIG/Comments	MaxDaily	Created
Condition						*ADE_2310_BACK PAIN Reported by:AE Chronic:N		2019-05-03
Condition					Entered by XXANV-91 2019-04-03	*ADE_1323_GASTRIC HAEMORRHAGE ABDOMINAL DISTENSION Reported by:AE Chronic:N INTL NORMALIZED RATIO INCREASED OSTEOARTHRITIS Reported by:PH Chronic:Y		2019-04-03
Condition						ATRIAL FIBRILLATION Reported by:PH Chronic:Y		2019-04-02
Condition						HYPERTENSION Reported by:PH Chronic:Y		2019-04-01
Reaction			OXYCODONE HCL SANDOZ CANADA 5 MG TA...	789739	Entered by XXANV-91 2019-05-03	Reported by:AE *ADE_2310_DRUG MISUSE_POSSIBLE_EMERGENCY VISIT_5MG_BID		2019-05-03
Reaction			ACETAMINOPHEN/CODEINE/CAFFEINEJANS...	2163926	Entered by XXALD-91 2019-04-03	Reported by:PA NAUSEA		2019-04-03
Reaction			CELECOXIB PHARMASCIENCE 200 MG CAPS...	2355450	Entered by XXANV-91 2019-04-03	Reported by:AE *ADE_1323_ADVERSE DRUG REACTION_LIKELY_HOSPITALIZATION_400MG_BID		2019-04-03
Rx filled	2019-05-04	90	HYDROCHLOROTHIAZIDE TEVA CANADA LI 2...	21474	ALCOVE [XXAWE-91]	TAKE 1 TAB DAILY	1	
Rx filled	2019-03-29	7	PANTOPRAZOLE MAGNESIUM TEVA CANAD...	2440628	ALCOVE [XXAWE-91]	TAKE 1 TABLET DAILY		
Rx filled	2019-03-29	7	ACETYSALICYLIC ACID PHARMASCIENCE 81...	2433044	ALCOVE [XXAWE-91]	TAKE 1 TABLET ONCE DAILY		
Rx filled	2019-03-29	14	WARFARIN SODIUM TARO PHARM 2.5 MG T...	2242682	ALCOVE [XXAWE-91]	TAKE 2 TABLETS DAILY OR AS PER INR		
Rx filled	2019-03-29	15	INSULIN GLARGINE.HUM.REC.ANLOGSANOFI...	2245689	ABSORPTION [XXANA-P1]	INJECT 20 UNITS SUBCUTANEOUSLY EVERY NIGHT AT BEDTIME	0.2	
Rx filled	2019-03-29	28	GLYBURIDE SANDOZ CANADA 5 MG TABLET	2248009	ALCOVE [XXAWE-91]	TAKE 2 TABLETS TWICE DAILY	4	
Rx filled	2019-03-29	7	ATORVASTATIN CALCIUM APOTEX INC 40 M...	2295296	ALCOVE [XXAWE-91]	TAKE 1 TABLET AT BEDTIME	1	
Rx filled	2019-03-29	28	METFORMIN HCL MYLAN PHARMACE 500 MG...	2148765	ALCOVE [XXAWE-91]	TAKE 2 TABLETS TWICE DAILY	4	
Rx filled	2019-03-29	14	FUROSEMIDE TEVA CANADA LI 20 MG TABLET	337730	ALCOVE [XXAWE-91]	TAKE 1 TABLET TWICE DAILY	2	
Rx filled	2019-03-29	14	METOPROLOL TARTRATE TEVA CANADA LI ...	648035	ALCOVE [XXAWE-91]	TAKE 1 TABLET TWICE DAILY	2	
Rx filled	2019-03-29	7	HYDROCHLOROTHIAZIDE TEVA CANADA LI 2...	21474	ALCOVE [XXAWE-91]	TAKE 1 TABLET DAILY	1	
Rx filled	2019-03-29	7	AMLODIPINE BESYLATE MYLAN PHARMACE ...	2272121	ALCOVE [XXAWE-91]	TAKE 1 TABLET DAILY	1	
Rx filled	2019-03-29	14	RAMIPRIL PHARMASCIENCE 2.5 MG CAPSULE	2247917	ABSORPTION [XXANA-P1]	(ADAPTED) TAKE 1 CAPSULE TWICE DAILY	2	
Rx filled	2019-03-21	14	RAMIPRIL PHARMASCIENCE 2.5 MG CAPSULE	2247917	ALCOVE [XXAWE-91]	TAKE 1 CAPSULE TWICE DAILY	2	
Rx filled	2019-03-19	60	CELECOXIB PHARMASCIENCE 200 MG CAPS...	2355450	ALCOVE [XXAWE-91]	TAKE 1 CAPSULE TWICE DAILY	2	
Rx filled	2019-03-19	60	CELECOXIB APOTEX INC 200 MG CAPSULE	2418940	ALCOVE [XXAWE-91]	TAKE 1 CAPSULE TWICE DAILY	2	

Legend: Another store Severe warning Click on item to display detail

**Look for the \*ADE**