COLD FLU SEVERE DAY NIGHT- acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride Harris Teeter

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

HTE - 1186 - 2019-1011

Cold + Flu Severe Day

Drug Facts

Active ingredients (in each caplet)	Purpose
Acetaminophen 325 mg	Pain reliever/fever
Acetaninophen 525 mg	reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

- for the temporary relief of the following cold/flu symptoms:
 - minor aches and pain
 - headache
 - sore throat
 - nasal congestion
 - cough
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- temporarily reduces fever

Warnings

Liver warning

This product contains acetaminophen. The maximum daily dose of this product is 10 caplets (3,250 mg acetaminophen) in 24 hours. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert

Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

Ask a doctor of pharmacist before use if you are

taking the blood thinning drug warfarin

When using this product

do not exceed recommended dosage

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts

These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Overdose warning

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

• do not take more than directed (see overdose warning)

	 take 2 caplets every 4 hours swallow whole – do not crush, chew, or
adults and children	dissolvedo not take more than 10 caplets in 24

	hours
children under 12	 ask a doctor
years	

Other information

- store between 20-25°C (68-77°F) in a dry place
- retain carton for complete product information and warnings

Inactive ingredients

acesulfame potassium, colloidal silicon dioxide, croscarmellose sodium, crospovidone, D&C yellow #10 aluminum lake, FD&C blue #2 aluminum lake, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, stearic acid, talc, titanium dioxide

Cold + Flu Severe Night Drug Facts

Active ingredients (in each caplet)	Purpose
Acetaminophen 325 mg	Pain reliever/fever
Acetaninophen 525 mg	reducer
Chlorpheniramine Maleate 2 mg	Antihistamine
Dextromethorphan HBr 10 mg	Cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

- for the temporary relief of the following cold/flu symptoms:
 - minor aches and pains
 - headache
 - sore throat
 - nasal congestion
 - cough
 - sinus congestion and pressure
 - sneezing and runny nose
- helps clear nasal passages
- relieves cough to help you sleep
- temporarily reduces fever

Warnings

Liver warning

This product contains acetaminophen. The maximum daily dose of this product is 10 caplets (3,250 mg acetaminophen) in 24 hours. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert

Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Sore throat warning

If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, or emphysema
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

- do not exceed recommended dosage
- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts

These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

Overdose warning

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

• do not use more than directed (see overdose warning)

adults and children 12 years and over	 take 2 caplets every 4 hours swallow whole – do not crush, chew, or dissolve do not take more than 10 caplets in 24 hours
children under 12 years	 ask a doctor

Other information

- store between 20-25°C (68-77°F) in a dry place
- retain carton for complete product information and warnings

Inactive ingredients

acesulfame potassium, colloidal silicon dioxide, croscarmellose sodium, FD&C blue #1 aluminum lake, flavor, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, stearic acid, talc, titanium dioxide

PRINCIPAL DISPLAY PANEL

Harris Teeter

Cold + Flu Severe

Day & Night

Compare to the Active Ingredients in Tylenol(R) Cold + Flu Severe Day and Night

For Adults

Day

Acetaminophen, Dextromethorphan HBr, Phenylephrine HCl, Guaifenesin

PAIN RELIEVER/FEVER REDUCER, COUGH SUPPRESSANT, NASAL DECONGESTANT, EXPECTORANT

Relief of

Head + Body Aches

Fever + Sore Throat

Cough, Nasal Congestion

Mucus & Chest Congestion

Night

Acetaminophen, Chlorpheniramine Maleate, Dextromethorphan HBr, Phenylephrine HCl

PAIN RELIEVER/FEVER REDUCER, ANTIHISTAMINE, COUGH SUPPRESSANT, NASAL DECONGESTANT

Relief of

Head + Body Aches

Fever + Sore Throat

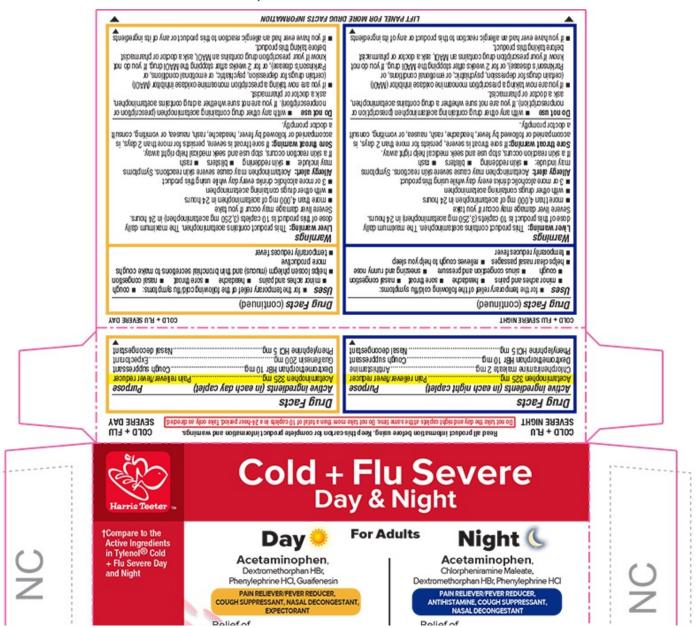
Cough

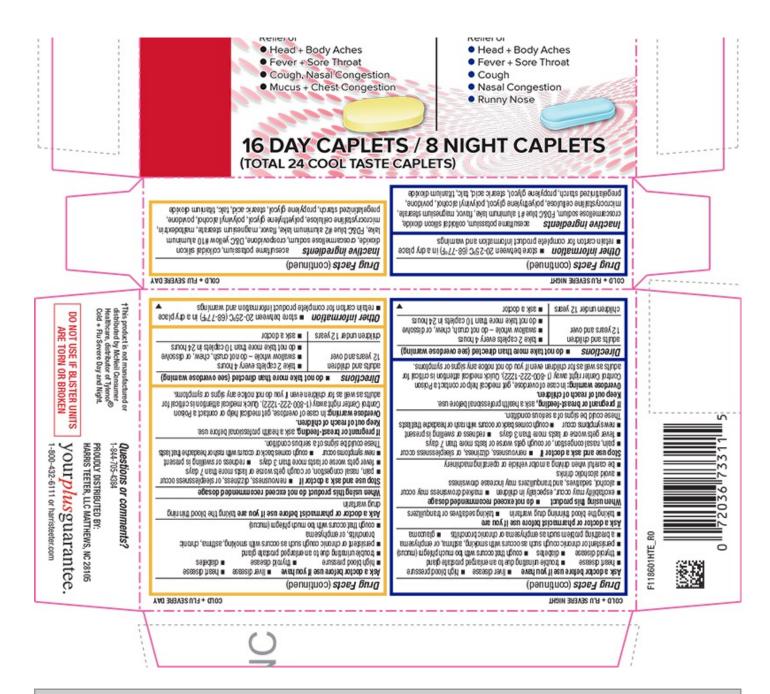
Nasal Congestion

Runny Nose

16 DAY CAPLETS / 8 NIGHT CAPLETS

(TOTAL 24 COOL TASTE CAPLETS)





COLD FLU SEVERE DAY NIGHT

acetaminophen, chlorpheniramine maleate, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride kit

Product Informat	ion				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72036-186		
Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
1 NDC:72036-186-01	1 in 1 CARTON	09/23/2019			
Quantity of Darts					
Quantity of Parts					
Part #	Package Quantity	Total Product (Quantity		

Part 1 of 2

ACETAMINOPHEN, DEXTROMETHORPHAN HYDROBROMIDE, GUAIFENESIN, AND PHENYLEPHRINE HYDROCHLORIDE

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, coated

Product Information

Route of Administration

ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6 MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

macuve ingreatents	Inactive	Ingredients
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	Ingred	lient Name	Strengtl	h
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)			
SILICON DIO XIDE (UNII: ETJ7	Z6XBU4)			
CROSCARMELLOSE SODIUM	4 (UNII: M280L1HH48)			
CROSPOVIDONE, UNSPECIFI	ED (UNII: 2S7830E561	1)		
D&C YELLOW NO. 10 (UNII: 3	35SW5USQ3G)			
ALUMINUM O XIDE (UNII: LMI	2606933)			
FD&C BLUE NO. 2 (UNII: L061	K8R7DQK)			
MAGNESIUM STEARATE (UN	II: 70097M6I30)			
MALTODEXTRIN (UNII: 7CVR	7L4A2D)			
CELLULOSE, MICROCRYSTA	ALLINE (UNII: OP1R32	D61U)		
POLYETHYLENE GLYCOL, U	UNSPECIFIED (UNII: 3)	WJQ0SDW1A)		
POLYVINYL ALCOHOL, UNS	PECIFIED (UNII: 532B	59J990)		
POVIDONE, UNSPECIFIED (U	,			
STARCH, PREGELATINIZED		/3SJ)		
PROPYLENE GLYCOL (UNII:	- /			
STEARIC ACID (UNII: 4ELV7Z6	65AP)			
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIO XIDE (UNII: 15F	FIX9 V2JP)			
Product Characteristics				
Color	yello w	Score	no score	

Shape					
	OVAL	Size		mm	
Flavor	MINT	Imprint Code	A	AA;1136	
Contains					
Packaging					
# Item Code	Package	Description N	larketing Start Dat	e Marketing	End Date
1 8 in 1 BL	ISTER PACK; Type	0: Not a Combination Product			
Marketing Infor	mation				
Marketing Category	Application Nu	mber or Monograph Citation	Marketing Start Dat	e Marketing	End Date
OTC monograph final	bart341				
Part 2 of 2					
Product Information					
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Route of Administration		L			
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Route of Administration	n ORA	L			
Route of Administration	n ORA		Basis of	Strength	Strengt
Route of Administration Active Ingredient/A	n ORA ctive Moiety Ingredien			U	Strengt 325 mg
Route of Administration Active Ingredient/A ACETAMINOPHEN (UNII: CHLORPHENIRAMINE M	n ORA Ctive Moiety Ingredien 36209ITL9D) (AC	t Name	ACETAMINOPH	U	325 mg
Route of Administration Active Ingredient/A ACETAMINOPHEN (UNII: CHLORPHENIRAMINE M UNII:3U6 IO 1965U) DEXTROMETHO RPHAN	n ORA Ctive Moiety Ingredien 36209ITL9D) (AC ALEATE (UNII: V14 HYDROBRO MIDE	t Name ETAMINOPHEN - UNII:36209ITL9D) Q0090J9Z) (CHLORPHENIRAMINE - E (UNII: 9D2RTI9KYH)	ACETAMINOPH	EN MINE MALEATE ORPHAN	325 mg
Route of Administration Active Ingredient/A ACETAMINOPHEN (UNII: CHLORPHENIRAMINE M UNII:3U6 IO 1965U) DEXTROMETHORPHAN (DEXTROMETHORPHAN - PHENYLEPHRINE HYDRO	n ORA Ctive Moiety Ingredien 36209ITL9D) (AC ALEATE (UNII: V14 HYDROBRO MIDE UNII:7355X3ROTS)	t Name ETAMINOPHEN - UNII:36209ITL9D) Q0090J9Z) (CHLORPHENIRAMINE - E (UNII: 9D2RTI9KYH)	ACETAMINOPH CHLORPHENIRA DEXTROMETHO	EN MINE MALEATE PRPHAN E E	325 mg 2 mg
Route of Administration Active Ingredient/A ACETAMINOPHEN (UNII: CHLORPHENIRAMINE M UNII:3U6 IO 1965U) DEXTROMETHORPHAN (DEXTROMETHORPHAN - PHENYLEPHRINE HYDRO	n ORA Ctive Moiety Ingredien 36209ITL9D) (AC ALEATE (UNII: V14 HYDROBRO MIDE UNII:7355X3ROTS)	t Name ETAMINOPHEN - UNII:36209ITL9D) Q009OJ9Z) (CHLORPHENIRAMINE - E (UNII: 9D2RTI9KYH))	ACETAMINOPH CHLORPHENIRA DEXTROMETHO HYDROBROMID PHENYLEPHRIN	EN MINE MALEATE PRPHAN E E	325 mg 2 mg 10 mg
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Route of Administration Active Ingredient/A ACETAMINOPHEN (UNII: CHLORPHENIRAMINE M UNII:3U6 IO 1965U) DEXTROMETHORPHAN - PHENYLEPHRINE HYDRO UNII:1WS 297W6 MV)	n ORA Ctive Moiety Ingredien 36209ITL9D) (AC ALEATE (UNII: V14 HYDROBRO MIDE UNII:7355X3ROTS) OCHLORIDE (UNII	t Name ETAMINOPHEN - UNII:36209ITL9D) Q009OJ9Z) (CHLORPHENIRAMINE - E (UNII: 9D2RTI9KYH))	ACETAMINOPH CHLORPHENIRA DEXTROMETHO HYDROBROMID PHENYLEPHRIN	EN MINE MALEATE ORPHAN E E DE	325 mg 2 mg 10 mg
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SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)

 FD&C BLUE NO. 1 (UNII: H3R47K3TBD)

 ALUMINUM OXIDE (UNII: LMI26O6933)

 MAGNESIUM STEARATE (UNII: 70097M6I30)

CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)

POLVETHYLENE GLYCOL, UNSPECIFIED (UNE 32320531990) Image: State in the stat	MICRO CRYSTALLINE	CELLULOSE (UNII: OP1R3	32D61U)				
PV UBONE, UNSPECIFIED (UNII: F2989GF94E) Image: Second Secon	POLYETHYLENE GLYC	POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)					
STARCH, PREGELATINIZED CORN (UNII: 08232N/35.) Image: Constant of the stant	POLYVINYL ALCOHO	L, UNSPECIFIED (UNII: 53	2B59J990)				
PROPYLENE GLYCOL (UNI: 6DC90167V3) Image: Starl CACID (UNI: 4ELV7265AP) Image: Starl CACID (UNI: 4ELV7265AP) TALC (UNI: 75EV7JARIU) Image: Starl CACID (UNI: 4ELV7265AP) Image: Starl CACID (UNI: 4ELV7265AP) TTANUM DIO XIDE (UNI: 75EV7JARIU) Image: Starl CACID (UNI: 4ELV7265AP) Image: Starl CACID (UNI: 4ELV7265AP) TTANUM DIO XIDE (UNI: 15FIX9V2JP) Image: Starl CACID (UNI: 4ELV7265AP) Image: Starl CACID (UNI: 4ELV7265AP) Product Characteristics Image: Starl CACID (UNI: 4ELV7265AP) Image: Starl CACID (UNI: 4ELV7265AP) Shape V Starl CACID (UNI: 4ELV7265AP) Image: Starl CACID (UNI: 4ELV7265AP) Shape VAL Starl CACID (UNI: 4ELV7265AP) Image: Starl CACID (UNI: 4ELV7265AP) Shape VAL Starl CACID (UNI: 4ELV7265AP) Image: Starl CACID (UNI: 4ELV7265AP) Shape VAL Starl CACID (UNI: 4ELV7265AP) Image: Starl CACID (UNI: 4ELV726AP) Shape VAL Starl CACID (UNI: 4ELV726AP) Image: Starl CACID (UNI: 4ELV726AP) Shape VAL Starl CACID (UNI: 4ELV726AP) Marketing Starl CACID (UNI: 4ELV726AP) Packaging Application Number or Monograph Citation Marketing Starl CACID (UNI: 4ELV726AP)	POVIDONE, UNSPECIFI	IED (UNII: FZ989GH94E)					
STEARIC ACID (UNII: 4ELV7265AP) TALC (UNII: 7SEV7J4RIU) TITANUM DIO XIDE (UNII: 15FIX3 V2JP) Product Characteristics Color blue Score no score Shape OVAL Size 17mm Flavor MINT Ontains MINT Packaging # Item Code Package Description Marketing Start Date Narketing End Date Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date	STARCH, PREGELATIN	IZED CORN (UNII: 08232	NY3SJ)				
TALC (UNIE: 75E V7J4R1U) Image: Second	PROPYLENE GLYCOL	(UNII: 6DC9Q167V3)					
TITANIUM DIO XIDE (UNIE: 15FIX9 Y2JP) Product Characteristics Color blue Score noscore Shape OVAL Size noscore OVAL Size 17mm Tamm Flavor OVAL MINT Imprint Code AAA;139 Contains Flavor OTA MINT Imprint Code Package Description Marketing Start Date Marketing End Date Packaging I tem Code 8 in 1 BLISTER PACK; Type 0; Not a Combination Product Marketing Category Application Number or Monograph Citation Marketing Start Date Application Start Date Marketing End Date Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date	STEARIC ACID (UNII: 4E	ELV7Z65AP)					
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Marketing Information Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date	Marketing Category	Marketing Category Application Number or Monograph Citation		Marketing Start Date	Marketing End Date		
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Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date							
	Marketing Information						
OTC monograph final part341 09/23/2019	Marketing Category	Application Number	or Monograph Citation	Marketing Start Date	Marketing End Date		
	OTC monograph final	part341		09/23/2019			

Labeler - Harris Teeter (047279351)

Revised: 10/2019

Harris Teeter