Gastroenterology: Hepatitis C - Ledipasvir/Sofosbuvir Order Set

Order Set: Conceptual Structure

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Knowledge Based Systems (KBS)
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Clinical Decision Support (CDS)

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Gastroenterology: Hepatitis C - Ledipasvir/Sofosbuvir Order Set: Order Set: Conceptual Structure

by Knowledge Based Systems (KBS), Office of Informatics and Information Governance (OIIG), and Clinical Decision Support (CDS)

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Table of Contents

Preface	v
Artifact Applicability	vi
Models	vii
1. External Data Definitions	1
2. Expression Definitions	2
3. Medications	6
4. Laboratory Tests	11
5. Patient and Caregiver Education	
6. Tabular List	
7. Behavior Symbols	19
A. References	

List of Tables

1. Revision History	. V
2. Clinical White Paper Contributors	. v
3. Artifact Identifier	
4. Applicability Foci, Description and Codes	vi
5. Model References	
2.1. Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 1 refill (routine)	. 2
2.2. Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine)	2
2.3. Ribavirin 200 mg capsule oral, take 2 capsules every morning	. 2
2.4. Ribavirin 200 mg capsule oral, take 3 capsules every evening	. 2
2.5. Ribavirin 200 mg capsule oral, take 2 capsules every morning and 3 capsules every evening;	
take with food 140 capsules 2 refills (routine)	. 3
2.6. Ribavirin 200 mg capsule oral, take 3 capsules every morning and 3 capsules every evening;	
take with food 168 capsules 2 refills (routine)	3
2.7. Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 5 refills (routine)	3
2.8. Ribavirin 200 mg capsule oral, take 1 capsule every morning and 2 capsules every evening;	
take with food; increase dose by 1 capsule every 2 weeks, up to 5 pills per day as tolerated 126	
capsules 2 refills (routine)	. 3
2.9. Ribavirin 200 mg capsule oral, take 1 capsules every morning	. 4
2.10. Ribavirin 200 mg capsule oral, take 2 capsules every evening	. 4
2.11. Ribavirin 200 mg capsule oral, take 1 capsule every morning and 2 capsules every evening;	
take with food; increase dose by 1 capsule every 2 weeks, up to 6 pills per day as tolerated 140	
capsules 2 refills (routine)	. 4
2.12. Ribavirin 200 mg capsule oral, take 1 capsule every other day, alternating with 2 capsules on	
alternate days; on 2-capsule days, take 1 capsule in the morning and one capsule in the evening;	
take with food 42 capsules 2 refills (routine)	. 4
2.13. Ribavirin 200 mg capsule oral, take 1 capsule every other day (routine)	. 5
2.14. Ribavirin 200 mg capsule oral on alternate days, take 1 capsule in the morning and one	
capsule in the evening (routine)	. 5
6.1. Terminology Versions	16
6.2. Terminology References	16
7.1. Group Organizational Behavior	19
7.2. Group Selection Behavior	19
7.3. Required Behavior	19
7.4. Precheck Behavior	20
7.5. Cardinality Behavior	20
·	20
7.7. Read Only Behavior	20

Preface

Table 1. Revision History

Date	Life Cycle Event	
June 14, 2018	Published	
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May 29, 2018	Reviewed	
August 29, 2017	Pre-published	
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Table 2. Clinical White Paper Contributors

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Table 3. Artifact Identifier

Domain	Artifact ID	Name
urn:va.gov:kbs:knart:artifact:r1	51c64787-fe39-5740-b7d4-7713567d4a0e	B29

Artifact Applicability

Table 4. Applicability Foci, Description and Codes

Focus	Description	Code System	Code	Value Set	Value Set Version
TargetUser	Primary Care physicians	SNOMED CT	453231000124104 Primary care provider (occupation)	N/A	N/A
TargetUser	Gastroenterologists			N/A	N/A
PatientAgeGroup	Adult patients	SNOMED CT	133936004 Adult (person)	N/A	N/A
ClinicalFocus	Adult outpatients with chronic Hepatitis C infection			N/A	N/A
WorkflowSetting	Routine primary care and gastroenterology			N/A	N/A
ClinicalVenue	Outpatient	SNOMED CT	33022008 Hospital-based outpatient department (environment)	N/A	N/A

Models

Table 5. Model References

Referenced Model	Description
urn:solor.io:anf-model:1.0	VA Analysis Normal Form Model

Chapter 1. External Data Definitions

No externalData expression definitions and no trigger definitions are present.

Chapter 2. Expression Definitions

Table 2.1. Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 1 refill (routine)

Expression: type=elm:Instance

Annotation:

Codes: elm:value[elm:Code]: [385644000 |Requested (qualifier value)|]elm:value[elm:Code]: [[416118004 |Administration (procedure)] ->(260686004 |Method (attribute))->[129445006 |Administration - action (qualifier value)] ->(363701004 |Direct substance (attribute))->[Rx;1591943 ledipasvir 90 MG / sofosbuvir 400 MG Oral Tablet] ->(410675002 |Route of administration (attribute))->[260548002 |Oral (qualifier value)]]elm:value[elm:Code]: [421026006 |Conventional release oral tablet (dose form)|]elm:value[elm:Code]: [50811001 |Routine (qualifier value)|]elm:value[elm:Code]: [258703001 |day (qualifier value)|]elm:value[elm:Code]: [258703001 |day (qualifier value)|]

Table 2.2. Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine)

Expression: type=elm:Instance

Annotation:

Codes: elm:value[elm:Code]: [385644000 | Requested (qualifier value)|]elm:value[elm:Code]: [[416118004 | Administration (procedure)] ->(260686004 | Method (attribute))->[129445006 | Administration - action (qualifier value)] ->(363701004 | Direct substance (attribute))->[Rx;1591943 | Bedipasvir 90 MG / sofosbuvir 400 MG Oral Tablet] ->(410675002 | Route of administration (attribute))->[260548002 | Oral (qualifier value)]]elm:value[elm:Code]: [421026006 | Conventional release oral tablet (dose form)|]elm:value[elm:Code]: [50811001 | Routine (qualifier value)|]elm:value[elm:Code]: [258703001 | day (qualifier value)|]elm:value[elm:Code]: [258703001 | day (qualifier value)|]

Table 2.3. Ribavirin 200 mg capsule oral, take 2 capsules every morning

Expression: type=elm:Instance

Annotation:

Codes: elm:value[elm:Code]: [385644000 |Requested (qualifier value)|]elm:value[elm:Code]: [[416118004 |Administration (procedure)] ->(260686004 |Method (attribute))->[129445006 | Administration - action (qualifier value)] ->(363701004 |Direct substance (attribute))->[Rx;312817 Ribavirin 200 MG Oral Capsule] ->(410675002 |Route of administration (attribute))->[260548002 | Oral (qualifier value)]]elm:value[elm:Code]: [420692007 |Conventional release oral capsule (dose form)|]elm:value[elm:Code]: [50811001 |Routine (qualifier value)|]elm:value[elm:Code]: [73775008 | Morning (qualifier value)|]

Table 2.4. Ribavirin 200 mg capsule oral, take 3 capsules every evening

Expression: type=elm:Instance

Annotation:

Codes: elm:value[elm:Code]: [385644000 |Requested (qualifier value)|]elm:value[elm:Code]: [[416118004 |Administration (procedure)] ->(260686004 |Method (attribute))->[129445006 | Administration - action (qualifier value)] ->(363701004 |Direct substance (attribute))->[Rx;312817]

Ribavirin 200 MG Oral Capsule] ->(410675002 | Route of administration (attribute))->[260548002 | Oral (qualifier value)]]elm:value[elm:Code]: [420692007 | Conventional release oral capsule (dose form)|]elm:value[elm:Code]: [50811001 | Routine (qualifier value)|]elm:value[elm:Code]: [3157002 | Evening (qualifier value)|]

Table 2.5. Ribavirin 200 mg capsule oral, take 2 capsules every morning and 3 capsules every evening; take with food 140 capsules 2 refills (routine)

Expression: type=elm:Instance

Annotation:

Codes: elm:value[elm:Code]: [385644000 |Requested (qualifier value)|]elm:value[elm:Code]: [[416118004 |Administration (procedure)] ->(260686004 |Method (attribute))->[129445006 | Administration - action (qualifier value)] ->(363701004 |Direct substance (attribute))->[Rx;312817 Ribavirin 200 MG Oral Capsule] ->(410675002 |Route of administration (attribute))->[260548002 | Oral (qualifier value)]]elm:value[elm:Code]: [258703001 |day (qualifier value)|]

Table 2.6. Ribavirin 200 mg capsule oral, take 3 capsules every morning and 3 capsules every evening; take with food 168 capsules 2 refills (routine)

Expression: type=elm:Instance

Annotation:

Codes: elm:value[elm:Code]: [385644000 | Requested (qualifier value)|]elm:value[elm:Code]: [[416118004 | Administration (procedure)] ->(260686004 | Method (attribute))->[129445006 | Administration - action (qualifier value)] ->(363701004 | Direct substance (attribute))->[Rx;312817 Ribavirin 200 MG Oral Capsule] ->(410675002 | Route of administration (attribute))->[260548002 | Oral (qualifier value)]]elm:value[elm:Code]: [420692007 | Conventional release oral capsule (dose form)|]elm:value[elm:Code]: [50811001 | Routine (qualifier value)|]elm:value[elm:Code]: [258703001 | day (qualifier value)|]elm:value[elm:Code]: [73775008 | Morning (qualifier value)|]elm:value[elm:Code]: [3157002 | Evening (qualifier value)|]

Table 2.7. Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 5 refills (routine)

Expression: type=elm:Instance

Annotation:

Codes: elm:value[elm:Code]: [385644000 |Requested (qualifier value)|]elm:value[elm:Code]: [[416118004 |Administration (procedure)] ->(260686004 |Method (attribute))->[129445006 |Administration - action (qualifier value)] ->(363701004 |Direct substance (attribute))->[Rx;1591943 | ledipasvir 90 MG / sofosbuvir 400 MG Oral Tablet] ->(410675002 |Route of administration (attribute))->[260548002 |Oral (qualifier value)]]elm:value[elm:Code]: [421026006 |Conventional release oral tablet (dose form)|]elm:value[elm:Code]: [50811001 |Routine (qualifier value)|]elm:value[elm:Code]: [258703001 | day (qualifier value)|]

Table 2.8. Ribavirin 200 mg capsule oral, take 1 capsule every morning and 2 capsules every evening; take with food; increase dose by 1 capsule every 2 weeks, up to 5 pills per day as tolerated 126 capsules 2 refills (routine)

Expression: type=elm:Instance

Annotation:

Codes: elm:value[elm:Code]: [385644000 | Requested (qualifier value)|]elm:value[elm:Code]: [[416118004 | Administration (procedure)] ->(260686004 | Method (attribute))->[129445006 | Administration - action (qualifier value)] ->(363701004 | Direct substance (attribute))->[Rx;312817 Ribavirin 200 MG Oral Capsule] ->(410675002 | Route of administration (attribute))->[260548002 | Oral (qualifier value)]]

Table 2.9. Ribavirin 200 mg capsule oral, take 1 capsules every morning

Expression: type=elm:Instance

Annotation:

Codes: elm:value[elm:Code]: [385644000 |Requested (qualifier value)|]elm:value[elm:Code]: [[416118004 |Administration (procedure)] ->(260686004 |Method (attribute))->[129445006 | Administration - action (qualifier value)] ->(363701004 |Direct substance (attribute))->[Rx;312817 Ribavirin 200 MG Oral Capsule] ->(410675002 |Route of administration (attribute))->[260548002 | Oral (qualifier value)]]elm:value[elm:Code]: [420692007 |Conventional release oral capsule (dose form)|]elm:value[elm:Code]: [50811001 |Routine (qualifier value)|]elm:value[elm:Code]: [73775008 | Morning (qualifier value)|]

Table 2.10. Ribavirin 200 mg capsule oral, take 2 capsules every evening

Expression: type=elm:Instance

Annotation:

Codes: elm:value[elm:Code]: [385644000 | Requested (qualifier value)|]elm:value[elm:Code]: [[416118004 | Administration (procedure)] ->(260686004 | Method (attribute))->[129445006 | Administration - action (qualifier value)] ->(363701004 | Direct substance (attribute))->[Rx;312817 Ribavirin 200 MG Oral Capsule] ->(410675002 | Route of administration (attribute))->[260548002 | Oral (qualifier value)]]elm:value[elm:Code]: [420692007 | Conventional release oral capsule (dose form)|]elm:value[elm:Code]: [50811001 | Routine (qualifier value)|]elm:value[elm:Code]: [3157002 | Evening (qualifier value)|]

Table 2.11. Ribavirin 200 mg capsule oral, take 1 capsule every morning and 2 capsules every evening; take with food; increase dose by 1 capsule every 2 weeks, up to 6 pills per day as tolerated 140 capsules 2 refills (routine)

Expression: type=elm:Instance

Annotation:

Codes: elm:value[elm:Code]: [385644000 | Requested (qualifier value)|]elm:value[elm:Code]: [[416118004 | Administration (procedure)] ->(260686004 | Method (attribute))->[129445006 | Administration - action (qualifier value)] ->(363701004 | Direct substance (attribute))->[Rx;312817 Ribavirin 200 MG Oral Capsule] ->(410675002 | Route of administration (attribute))->[260548002 | Oral (qualifier value)]]

Table 2.12. Ribavirin 200 mg capsule oral, take 1 capsule every other day, alternating with 2 capsules on alternate days; on 2-capsule days, take 1 capsule in the morning and one capsule in the evening; take with food 42 capsules 2 refills (routine)

Expression: type=elm:Instance

Annotation:

Codes: elm:value[elm:Code]: [385644000 | Requested (qualifier value)|]elm:value[elm:Code]: [[416118004 | Administration (procedure)] ->(260686004 | Method (attribute))->[129445006 | Administration - action (qualifier value)] ->(363701004 | Direct substance (attribute))->[Rx;312817 Ribavirin 200 MG Oral Capsule] ->(410675002 | Route of administration (attribute))->[260548002 | Oral (qualifier value)]]

Table 2.13. Ribayirin 200 mg capsule oral, take 1 capsule every other day (routine)

Expression: type=elm:Instance

Annotation:

 $\label{lem:code:elm$

Table 2.14. Ribavirin 200 mg capsule oral on alternate days, take 1 capsule in the morning and one capsule in the evening (routine)

Expression: type=elm:Instance

Annotation:

Codes: elm:value[elm:Code]: [385644000 |Requested (qualifier value)|]elm:value[elm:Code]: [[416118004 |Administration (procedure)] ->(260686004 |Method (attribute))->[129445006 | Administration - action (qualifier value)] ->(363701004 |Direct substance (attribute))->[Rx;312817 Ribavirin 200 MG Oral Capsule] ->(410675002 |Route of administration (attribute))->[260548002 | Oral (qualifier value)]]elm:value[elm:Code]: [420692007 |Conventional release oral capsule (dose form)|]elm:value[elm:Code]: [50811001 |Routine (qualifier value)|]elm:value[elm:Code]: [73775008 | Morning (qualifier value)|]

Chapter 3. Medications

Ledipasvir/sofosbuvir should not be used in patients with severe renal impairment (eGFR<30mL/min/1.73 m^2), with end-stage-renal disease, or on hemodialysis. Ledipasvir/sofosbuvir should not be used in combination with amiodarone, carbamazepine, oxcarbazepine, phenobarbital, phenytoin, rifabutin, rifampin, rifapentine, rosuvastatin, St. John's wort, elvitegravir/cobicistat/emtricitabine/tenofovir, tipranavir/ritonavir, or simeprevir. Ledipasvir/sofosbuvir should not used in patients who require twice-daily proton pump inhibitor therapy for esophageal disease. Providers should check http://www.hep-druginteractions.org, https://www.hepatitis.va.gov/provider/guidelines/hcv-treatment-considerations.asp, and/or a pharmacist for additional drug interactions or contraindications before starting ledipasvir/sofosbuvir.

Hep Drug Interactions link [https://www.hep-druginteractions.org/.]

([VA 2017i]) Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations from the Department of Veterans Affairs National Hepatitis C Resource Center Program and the HIV, Hepatitis, and Related Conditions Program in the Office of Specialty Care Services link [https://www.hepatitis.va.gov/provider/guidelines/hcv-treatment-considerations.asp]

Non-African-Americans with Genotype 1, Treatment-Naïve, without Cirrhosis, HCV RNA < 6 Million IU/mL

Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 1 refill (routine) actionSentence[type=elm:ExpressionRef, classType=]

Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 1 refill (routine)

African-Americans with Genotype 1, Treatment-Naïve, without Cirrhosis, HCV RNA < 6 Million IU/mL

Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine) actionSentence[type=elm:ExpressionRef, classType=]

Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine)

Genotype 1, Treatment-Naïve, without Cirrhosis, HCV RNA >= 6 Million IU/mL.

Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine) actionSentence[type=elm:ExpressionRef, classType=]

Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine)

Genotype 1, Treatment-Naïve, without Cirrhosis, with HIV Coinfection.

Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine) actionSentence[type=elm:ExpressionRef, classType=]

Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine)

Genotype 1, Treatment-Naïve, with Compensated Cirrhosis.

Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine) actionSentence[type=elm:ExpressionRef, classType=]

Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine)

Genotype 1, Treatment-Experienced (PEG-RBV with or without Protease Inhibitor), without Cirrhosis

Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine) actionSentence[type=elm:ExpressionRef, classType=]

Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine)

Genotype 1, Treatment-Experienced (PEG-RBV with or without Protease Inhibitor), with Compensated Cirrhosis (CTP A).

Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine) actionSentence[type=elm:ExpressionRef, classType=]

Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine)

Ribavirin 200 mg capsule oral, take 2 capsules every morning and 3 capsules every evening; take with food 140 capsules 2 refills (routine)

actionSentence[type=elm:ExpressionRef, classType=]

Ribavirin 200 mg capsule oral, take 2 capsules every morning and 3 capsules every evening; take with food 140 capsules 2 refills (routine)

Ribavirin 200 mg capsule oral, take 3 capsules every morning and 3 capsules every evening; take with food 168 capsules 2 refills (routine)

actionSentence[type=elm:ExpressionRef, classType=]

Ribavirin 200 mg capsule oral, take 3 capsules every morning and 3 capsules every evening; take with food 168 capsules 2 refills (routine)

Genotype 1, Treatment-Experienced (PEG-RBV with or without Protease Inhibitor), Ribavirin Intolerant, with Compensated Cirrhosis (CTP A).

Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 5 refills (routine) actionSentence[type=elm:ExpressionRef, classType=]

Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 5 refills (routine)

Genotype 1 with Decompensated Cirrhosis (CTP B or C).

Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine) actionSentence[type=elm:ExpressionRef, classType=]

Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine)

Ribavirin 200 mg capsule oral, take 1 capsule every morning and 2 capsules every evening; take with food; increase dose by 1 capsule every 2 weeks, up to 5 pills per day as tolerated 126 capsules 2 refills (routine)

actionSentence[type=elm:ExpressionRef, classType=]

Ribavirin 200 mg capsule oral, take 1 capsule every morning and 2 capsules every evening; take with food; increase dose by 1 capsule every 2 weeks, up to 5 pills per day as tolerated 126 capsules 2 refills (routine)

Ribavirin 200 mg capsule oral, take 1 capsule every morning and 2 capsules every evening; take with food; increase dose by 1 capsule every 2 weeks, up to 6 pills per day as tolerated 140 capsules 2 refills (routine)

actionSentence[type=elm:ExpressionRef, classType=]

Ribavirin 200 mg capsule oral, take 1 capsule every morning and 2 capsules every evening; take with food; increase dose by 1 capsule every 2 weeks, up to 6 pills per day as tolerated 140 capsules 2 refills (routine)

Genotype 1, Ribavirin Intolerant, with Decompensated Cirrhosis (CTP B or C).

Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 5 refills (routine) actionSentence[type=elm:ExpressionRef, classType=]

Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 5 refills (routine)

Genotype 1, Pre- or Post-Liver Transplant (Including CTP A, B, or C or Suitable Candidate with Hepatocellular Carcinoma).

Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine) actionSentence[type=elm:ExpressionRef, classType=]

Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine)

Ribavirin 200 mg capsule oral, take 1 capsule every morning and 2 capsules every evening; take with food; increase dose by 1 capsule every 2 weeks, up to 5 pills per day as tolerated 126 capsules 2 refills (routine)

actionSentence[type=elm:ExpressionRef, classType=]

Ribavirin 200 mg capsule oral, take 1 capsule every morning and 2 capsules every evening; take with food; increase dose by 1 capsule every 2 weeks, up to 5 pills per day as tolerated 126 capsules 2 refills (routine)

Ribavirin 200 mg capsule oral, take 1 capsule every morning and 2 capsules every evening; take with food; increase dose by 1 capsule every 2 weeks, up to 6 pills per day as tolerated 140 capsules 2 refills (routine)

actionSentence[type=elm:ExpressionRef, classType=]

Ribavirin 200 mg capsule oral, take 1 capsule every morning and 2 capsules every evening; take with food; increase dose by 1 capsule every 2 weeks, up to 6 pills per day as tolerated 140 capsules 2 refills (routine)

Ribavirin 200 mg capsule oral, take 2 capsules every morning and 3 capsules every evening; take with food 140 capsules 2 refills (routine)

actionSentence[type=elm:ExpressionRef, classType=]

Ribavirin 200 mg capsule oral, take 2 capsules every morning and 3 capsules every evening; take with food 140 capsules 2 refills (routine)

Ribavirin 200 mg capsule oral, take 3 capsules every morning and 3 capsules every evening; take with food 168 capsules 2 refills (routine)

actionSentence[type=elm:ExpressionRef, classType=]

Ribavirin 200 mg capsule oral, take 3 capsules every morning and 3 capsules every evening; take with food 168 capsules 2 refills (routine)

Genotype 4, 5, or 6 without Cirrhosis or with Compensated Cirrhosis (CTP A).

Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine) actionSentence[type=elm:ExpressionRef, classType=]

Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine)

Genotype 4, 5, or 6 with Decompensated Cirrhosis (CTP B or C).

Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine) actionSentence[type=elm:ExpressionRef, classType=]

Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine)

Ribavirin 200 mg capsule oral, take 1 capsule every morning and 2 capsules every evening; take with food; increase dose by 1 capsule every 2 weeks, up to 5 pills per day as tolerated 126 capsules 2 refills (routine)

actionSentence[type=elm:ExpressionRef, classType=]

Ribavirin 200 mg capsule oral, take 1 capsule every morning and 2 capsules every evening; take with food; increase dose by 1 capsule every 2 weeks, up to 5 pills per day as tolerated 126 capsules 2 refills (routine)

Ribavirin 200 mg capsule oral, take 1 capsule every morning and 2 capsules every evening; take with food; increase dose by 1 capsule every 2 weeks, up to 6 pills per day as tolerated 140 capsules 2 refills (routine)

actionSentence[type=elm:ExpressionRef, classType=]

Ribavirin 200 mg capsule oral, take 1 capsule every morning and 2 capsules every evening; take with food; increase dose by 1 capsule every 2 weeks, up to 6 pills per day as tolerated 140 capsules 2 refills (routine)

Genotype 4, Post-Liver Transplant.

Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine) actionSentence[type=elm:ExpressionRef, classType=]

Ledipasvir/sofosbuvir (90 mg/400 mg) 1 tablet oral, daily, 28 tablets 2 refills (routine)

Ribavirin 200 mg capsule oral, take 1 capsule every morning and 2 capsules every evening; take with food; increase dose by 1 capsule every 2 weeks, up to 5 pills per day as tolerated 126 capsules 2 refills (routine)

actionSentence[type=elm:ExpressionRef, classType=]

Ribavirin 200 mg capsule oral, take 1 capsule every morning and 2 capsules every evening; take with food; increase dose by 1 capsule every 2 weeks, up to 5 pills per day as tolerated 126 capsules 2 refills (routine)

Ribavirin 200 mg capsule oral, take 1 capsule every morning and 2 capsules every evening; take with food; increase dose by 1 capsule every 2 weeks, up to 6 pills per day as tolerated 140 capsules 2 refills (routine)

actionSentence[type=elm:ExpressionRef, classType=]

Ribavirin 200 mg capsule oral, take 1 capsule every morning and 2 capsules every evening; take with food; increase dose by 1 capsule every 2 weeks, up to 6 pills per day as tolerated 140 capsules 2 refills (routine)

Ribavirin 200 mg capsule oral, take 2 capsules every morning and 3 capsules every evening; take with food 140 capsules 2 refills (routine)

actionSentence[type=elm:ExpressionRef, classType=]

Ribavirin 200 mg capsule oral, take 2 capsules every morning and 3 capsules every evening; take with food 140 capsules 2 refills (routine)

Ribavirin 200 mg capsule oral, take 3 capsules every morning and 3 capsules every evening; take with food 168 capsules 2 refills (routine)

actionSentence[type=elm:ExpressionRef, classType=]

Ribavirin 200 mg capsule oral, take 3 capsules every morning and 3 capsules every evening; take with food 168 capsules 2 refills (routine)

Reduced-Dose Ribavirin for Patients with Renal Impairment (Creatinine Clearance 30–50 mL/min/1.73 m^2)

Ribavirin 200 mg capsule oral, take 1 capsule every other day, alternating with 2 capsules on alternate days; on 2-capsule days, take 1 capsule in the morning and one capsule in the evening; take with food 42 capsules 2 refills (routine)

actionSentence[type=elm:ExpressionRef, classType=]

Ribavirin 200 mg capsule oral, take 1 capsule every other day, alternating with 2 capsules on alternate days; on 2-capsule days, take 1 capsule in the morning and one capsule in the evening; take with food 42 capsules 2 refills (routine)

Chapter 4. Laboratory Tests

Routine tests in referrals for management of hepatitis C # Complete blood count 1 time (routine) actionSentence[type=elm:Instance, classType=anf:ClinicalStatement] statementType: Precoordinated Expression 385644000 | Requested (qualifier value) topic: Precoordinated Expression 26604007 | Complete blood count (procedure)| priority: Precoordinated Expression 50811001 | Routine (qualifier value) # Hepatic function panel 1 time (routine) actionSentence[type=elm:Instance, classType=anf:ClinicalStatement] statementType: Precoordinated Expression 385644000 | Requested (qualifier value) topic: Precoordinated Expression T26958001 | Hepatic function panel (procedure) priority: Precoordinated Expression 50811001 | Routine (qualifier value) # International normalized ratio 1 time (routine) actionSentence[type=elm:Instance, classType=anf:ClinicalStatement] statementType: Precoordinated Expression 385644000 | Requested (qualifier value) topic: Precoordinated Expression 440685005 | Calculation of international normalized ratio (procedure) # Basic metabolic panel 1 time (routine) actionSentence[type=elm:Instance, classType=anf:ClinicalStatement] statementType: Precoordinated Expression 385644000 | Requested (qualifier value) topic: Precoordinated Expression 1421000205106 |Basic metabolic panel (procedure) priority: Precoordinated Expression 50811001 | Routine (qualifier value) # Glomerular Filtration rate 1 time (routine) actionSentence[type=elm:Instance, classType=anf:ClinicalStatement] statementType: Precoordinated Expression 385644000 | Requested (qualifier value) topic: Precoordinated Expression 167181009 | Measurement of renal clearance of creatinine (procedure) priority: Precoordinated Expression 50811001 | Routine (qualifier value) The following lab is recommended if not performed within the previous 5 years.

HCV genotype 1 time (routine)

statementType: Precoordinated Expression 385644000 |

actionSentence[type=elm:Instance, classType=anf:ClinicalStatement]

```
Requested (qualifier value)
                               topic: Precoordinated Expression 397662006 | Hepatitis C virus
                               genotype determination (procedure)
                               priority: Precoordinated Expression 50811001 | Routine
                               (qualifier value)
The following labs are recommended if not performed within the previous 10 years.
# Hepatitis B surface antigen (HBsAg) 1 time (routine)
actionSentence[type=elm:Instance, classType=anf:ClinicalStatement]
                               statementType: Precoordinated Expression 385644000 |
                               Requested (qualifier value)
                               topic: Precoordinated Expression 47758006 | Hepatitis B
                               surface antigen measurement (procedure)
                               priority: Precoordinated Expression 50811001 | Routine
                               (qualifier value)
# Hepatitis B core antibody (HBcAb) 1 time (routine)
actionSentence[type=elm:Instance, classType=anf:ClinicalStatement]
                               statementType: Precoordinated Expression 385644000 |
                               Requested (qualifier value)
                               topic: Precoordinated Expression 59582004 |Hepatitis B core
                               antibody measurement (procedure)
                               priority: Precoordinated Expression 50811001 | Routine
                               (qualifier value)
# Hepatitis B surface antibody (HBsAb) 1 time (routine)
actionSentence[type=elm:Instance, classType=anf:ClinicalStatement]
                               statementType: Precoordinated Expression 385644000 |
                               Requested (qualifier value)
                               topic: Precoordinated Expression 65911000 | Hepatitis B
                               surface antibody measurement (procedure)
                               priority: Precoordinated Expression 50811001 | Routine
                               (qualifier value)
# Hepatitis A antibody (HAVAb) 1 time (routine)
actionSentence[type=elm:Instance, classType=anf:ClinicalStatement]
                               statementType: Precoordinated Expression 385644000 |
                               Requested (qualifier value)
                               topic: Precoordinated Expression 697001 |Hepatitis A virus
                               antibody measurement (procedure)
                               priority: Precoordinated Expression 50811001 | Routine
                               (qualifier value)
The following lab is recommended if not performed within the previous 6 months.
# HCV viral load (quantitative HCV RNA) 1 time (routine)
actionSentence[type=elm:Instance, classType=anf:ClinicalStatement]
```

statementType: Precoordinated Expression 385644000 |

Requested (qualifier value)

topic: Precoordinated Expression 395197008 |Hepatitis C viral

load (procedure)

priority: Precoordinated Expression 50811001 |Routine (qualifier value)|

The following lab is recommended if not performed within the previous 5 years.

HIV test 1 time (routine)

actionSentence[type=elm:Instance, classType=anf:ClinicalStatement]

statementType: Precoordinated Expression 385644000 |

Requested (qualifier value)

topic: Precoordinated Expression 359796005 | Measurement of both Human immunodeficiency virus 1 antibody and Human

immunodeficiency virus 2 antibody (procedure)|

priority: Precoordinated Expression 50811001 |Routine

(qualifier value)|

The following lab is recommended if not performed within the previous 2 weeks.

Qualitative human chorionic gonadotropin 1 time (routine)

actionSentence[type=elm:Instance, classType=anf:ClinicalStatement]

statementType: Precoordinated Expression 385644000 |

Requested (qualifier value)

topic: Precoordinated Expression 386558001 |Chorionic gonadotropin, beta-subunit measurement (procedure)|

Chapter 5. Patient and Caregiver Education

This section should be available to users in gastroenterology settings and for primary care providers who are referring a patient to gastroenterology for management of hepatitis C

Hepatitis C Information for Veterans

actionSentence[type=elm:Instance, classType=anf:ClinicalStatement]

statementType: Precoordinated Expression 385644000 |

Requested (qualifier value)

topic: Precoordinated Expression TSR-NoCode

([VA 2017b]) Hepatitis C Information for Veterans link [https://

www.hepatitis.va.gov/pdf/Hepatitis-C-Factsheet-Veterans.pdf]

Chronic Hepatitis C and Alcohol Use

actionSentence[type=elm:Instance, classType=anf:ClinicalStatement]

statementType: Precoordinated Expression 385644000 |

Requested (qualifier value)

topic: Precoordinated Expression TSR-NoCode

([VA 2017c]) Chronic Hepatitis C and Alcohol Use link [https://

www.hepatitis.va.gov/products/patient/hepatitisC-alcohol-

brochure.asp]

What to Expect Before Your Treatment for Hepatitis C Virus

actionSentence[type=elm:Instance, classType=anf:ClinicalStatement]

statementType: Precoordinated Expression 385644000 |

Requested (qualifier value)

topic: Precoordinated Expression TSR-NoCode

([VA 2017d]) What to Expect Before Your Treatment for Hepatitis C Virus

link [https://www.hepatitis.va.gov/products/patient/hepatitisC-

pretreatment.asp]

Ribavirin: Information for Patients

actionSentence[type=elm:Instance, classType=anf:ClinicalStatement]

statementType: Precoordinated Expression 385644000 |

Requested (qualifier value)

topic: Precoordinated Expression TSR-NoCode

([VA 2017e]) Ribavirin: Information for Patients link [https://

www.hepatitis.va.gov/pdf/patient-ribavirin.pdf]

Taking Your Hepatitis C Therapy: Harvoni(R) with or without Ribavirin

actionSentence[type=elm:Instance, classType=anf:ClinicalStatement]

statementType: Precoordinated Expression 385644000 |

Requested (qualifier value)

topic: Precoordinated Expression TSR-NoCode

([VA 2017f]) Taking Your Hepatitis C Therapy: Harvoni(R) with or without

Ribavirin link [https://www.hepatitis.va.gov/products/patient/

sofosbuvir-simeprevir-handouts.asp]

Managing Side Effects of Harvoni(R)

actionSentence[type=elm:Instance, classType=anf:ClinicalStatement]

statementType: Precoordinated Expression 385644000 |

Requested (qualifier value)

topic: Precoordinated Expression TSR-NoCode

([VA 2015a]) Managing Side Effects of Harvoni® link [https://

www.hepatitis.va.gov/pdf/side-effects-harvoni.pdf]

Managing Side Effects of Harvoni(R) and Ribavirin

actionSentence[type=elm:Instance, classType=anf:ClinicalStatement]

statementType: Precoordinated Expression 385644000 |

Requested (qualifier value)

topic: Precoordinated Expression TSR-NoCode

([VA 2015b]) Managing Side Effects of Harvoni(R) and Ribavirin link

[https://www.hepatitis.va.gov/pdf/side-effects-harvoni-

ribavirin.pdf]

Tracking My Hepatitis C Treatment Results

actionSentence[type=elm:Instance, classType=anf:ClinicalStatement]

statementType: Precoordinated Expression 385644000 |

Requested (qualifier value)

topic: Precoordinated Expression TSR-NoCode

([VA 2017g]) Tracking My Hepatitis C Treatment Results link [https://

www.hepatitis.va.gov/pdf/HCV-tracking-chart.pdf]

FAQs about Sustained Virologic Response to Treatment for Hepatitis C

actionSentence[type=elm:Instance, classType=anf:ClinicalStatement]

statementType: Precoordinated Expression 385644000 |

Requested (qualifier value)|

topic: Precoordinated Expression TSR-NoCode

([VA 2017h]) FAQs about Sustained Virologic Response to Treatment for

Hepatitis C link [https://www.hepatitis.va.gov/products/patient/

sustained-virological-response.asp]

Chapter 6. Tabular List

Terminology Service Request (TSR) Mappings

Table 6.1. Terminology Versions

Name	Identifer	Version
SNOMED CT	2.16.840.1.113883.6.96	United States Edition 20180301

Table 6.2. Terminology References

System	Code	Display Text ^a	References ^b
SNOMED CT	133936004 Adult (person)	Adult patients	1
SNOMED CT	1421000205106 Basic metabolic panel (procedure)	Precoordinated Expression	1
SNOMED CT	167181009 Measurement of renal clearance of creatinine (procedure)	Precoordinated Expression	1
SNOMED CT	258703001 day (qualifier value)	Precoordinated Expression	9
SNOMED CT	26604007 Complete blood count (procedure)	Precoordinated Expression	1
SNOMED CT	3157002 Evening (qualifier value)	Precoordinated Expression	3
SNOMED CT	33022008 Hospital-based outpatient department (environment)	Outpatient	1
SNOMED CT	359796005 Measurement of both Human immunodeficiency virus 1 antibody and Human immunodeficiency virus 2 antibody (procedure)	Precoordinated Expression	1
SNOMED CT	385644000 Requested (qualifier value)	Precoordinated Expression	36
SNOMED CT	386558001 Chorionic gonadotropin, beta-subunit measurement (procedure)	Precoordinated Expression	1
SNOMED CT	395197008 Hepatitis C viral load (procedure)	Precoordinated Expression	1
SNOMED CT	397662006 Hepatitis C virus genotype determination (procedure)	Precoordinated Expression	1

System	Code	Display Text ^a	References ^b
SNOMED CT	420692007 Conventional release oral capsule (dose form)	Precoordinated Expression	7
SNOMED CT	421026006 Conventional release oral tablet (dose form)	Precoordinated Expression	3
SNOMED CT	440685005 Calculation of international normalized ratio (procedure)	Precoordinated Expression	1
SNOMED CT	453231000124104 Primary care provider (occupation)	Primary Care physicians	1
SNOMED CT	47758006 Hepatitis B surface antigen measurement (procedure)	Precoordinated Expression	1
SNOMED CT	50811001 Routine (qualifier value)	Precoordinated Expression	21
SNOMED CT	59582004 Hepatitis B core antibody measurement (procedure)	Precoordinated Expression	1
SNOMED CT	65911000 Hepatitis B surface antibody measurement (procedure)	Precoordinated Expression	1
SNOMED CT	697001 Hepatitis A virus antibody measurement (procedure)	Precoordinated Expression	1
SNOMED CT	73775008 Morning (qualifier value)	Precoordinated Expression	4
SNOMED CT	T26958001 Hepatic function panel (procedure)	Precoordinated Expression	1
SNOMED CT	TSR-NoCode ^c	Precoordinated Expression	9
SNOMED CT	[416118004 Administration (procedure)] ->(260686004 Method (attribute))- >[129445006 Administration - action (qualifier value)] - >(363701004 Direct substance (attribute))- >[Rx;1591943 ledipasvir 90 MG / sofosbuvir 400 MG Oral Tablet] - >(410675002 Route of administration (attribute))- >[260548002 Oral (qualifier value)]	Postcoordinated Expression	3

System	Code	Display Text ^a	References ^b
SNOMED CT	[416118004 Administration (procedure)] ->(260686004 Method (attribute))- >[129445006 Administration - action (qualifier value)] -	Postcoordinated Expression	11
	>(363701004 Direct substance (attribute))- >[Rx;312817 Ribavirin 200 MG Oral Capsule] - >(410675002 Route of administration (attribute))- >[260548002 Oral (qualifier value)]		

^aIf a code is used multiple times in the KNART, only the display text of the first instance is shown.

^bCount of the number of times the given code system and code pair is used in the KNART.

^cTSR-NoCode is a placeholder indicating a code was requested, but was not provided.

Chapter 7. Behavior Symbols

Table 7.1. Group Organizational Behavior

Symbol	Name	Definition
#	Sentence Group	A group of related alternative actions is a sentence group if the item referenced by the action is the same in all the actions, and each action simply constitutes a different variation on how to specify the details for that item. For example, two actions that could be in a SentenceGroup are "aspirin, 500 mg, 2 times per day" and "aspirin, 300 mg, 3 times per day". In both cases, aspirin is the item referenced by the action, and the two actions represent two different options for how aspirin might be ordered for the patient. Note that a SentenceGroup would almost always have an associated selection behavior of "AtMostOne", unless it's a required action, in which case, it would be "ExactlyOne".
#	Logical Group	A group with this behavior logically groups its sub-elements, and may be shown as a visual group to the end user, but it is not required to do so.
>	Visual Group	Any group marked with this behavior should be displayed as a visual group to the end user.

Table 7.2. Group Selection Behavior

Symbol	Name	Definition
#	Any	Any number of the items in the group may be chosen, from zero to all.
#	All	All the items in the group must be selected as a single unit.
#	AllOrNone	All the items in the group are meant to be chosen as a single unit: either all must be selected by the end user, or none may be selected.
#	ExactlyOne	The end user must choose one and only one of the selectable items in the group. The user may not choose none of the items in the group.
0	AtMostOne	The end user may choose zero or at most one of the items in the group.
*	OneOrMore	The end user must choose a minimum of one, and as many additional as desired.

Table 7.3. Required Behavior

Symbol	Name	Definition
*	Must	An action with this behavior must be included in the actions processed by the end user; the end user may not choose not to include this action.
\$	Could	An action with this behavior may be included in the set of actions processed by the end user.

Symbol	Name	Definition
>	MustUnlessDocumented	An action with this behavior must be included in the set of actions processed by the end user, unless the end user provides documentation as to why the action was not included.

Table 7.4. Precheck Behavior

Symbol	Name	Definition
•	Yes	An action with this behavior is one of the most frequent actions that is, or should be, included by an end user, for the particular context in which the action occurs. The system displaying the action to the end user should consider "prechecking" such an action as a convenience for the user.
#	No	An action with this behavior is one of the less frequent actions included by the end user, for the particular context in which the action occurs. The system displaying the actions to the end user would typically not "pre-check" such an action.

Table 7.5. Cardinality Behavior

	Symbol	Name	Definition
ĺ	♦	Single	An action with this behavior may only be completed once.
Ì	*	Multiple	An action with this behavior may be repeated multiple times.

Table 7.6. Item Flags

Symbol	Name	Definition
4	fillIn	This item, in a list entry, allows the user to enter a fill in value
		that is not present in the set of presented choices.

Table 7.7. Read Only Behavior

Symbol	Name	Definition
#		For a particular action or action group, specifies whether the elements are read only.

Appendix A. References

This appendix contains the list of related resources and supporting documents used in creating this KNART.

List of References

Related Resources

[CCWP] Gastroenterology: Hepatitis C Clinical Content White Paper

[CSD] Gastroenterology: Hepatitis C - Ledipasvir/Sofosbuvir Order Set Conceptual Structure Document

 $[KVRpt] \ \textit{Gastroenterology: Hepatitis C-Ledipasvir/Sofosbuvir Order Set KNART \ Validation \ Report$

- [UL 2018] University of Liverpool. 2018. Hep Drug Interactions. Accessed April 25, 2018 from https://www.hep-druginteractions.org/. (link [https://www.hep-druginteractions.org/.])
- [VA 2017b] US Dept of Veterans Affairs. 2017. Hepatitis C Information for Veterans. Accessed April 25, 2018 from https://www.hepatitis.va.gov/pdf/Hepatitis-C-Factsheet-Veterans.pdf. (link [https://www.hepatitis.va.gov/pdf/Hepatitis-C-Factsheet-Veterans.pdf])
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- [VA 2017e] Department of Veterans Affairs. Ribavirin information for patients. 2017. [Internet]. Accessed April 22, 2018 from https://www.hepatitis.va.gov/pdf/patient-ribavirin.pdf (link [https://www.hepatitis.va.gov/pdf/patient-ribavirin.pdf])
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- [VA 2017g] Department of Veterans Affairs. Tracking my hepatitis C treatment results. 2017. [Internet]. Accessed Apr 22, 2018, from https://www.hepatitis.va.gov/pdf/HCV-tracking-chart.pdf (link [https://www.hepatitis.va.gov/pdf/HCV-tracking-chart.pdf])
- [VA 2017h] Department of Veterans Affairs. FAQs about Sustained Virologic Response to Treatment for Hepatitis C. 2017. [Internet]. Accessed Apr 22, 2018, from https://www.hepatitis.va.gov/products/

patient/sustained-virological-response.asp (link [https://www.hepatitis.va.gov/products/patient/sustained-virological-response.asp])

Supporting Evidence

- [AASLD 2017] American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C. Updated September 2017 (link [https://doi.org/10.1002/hep.27950])
- [Fox 2017] Fox RK. Summary of FDA Approval for Mavyret. Published August 2017 (link [https://www.hepatitis.va.gov/provider/hcv/mavyret-approval.asp])
- [VA 2017a] U.S. Department of Veterans Affairs. After the Initial Diagnosis of HCV: Overview of Next Steps. Published May 2017 (link [https://www.hepatitis.va.gov/products/next-steps.asp])
- [VA 2017i] U.S. Department of Veterans Affairs National Hepatitis C Resource Center Program and the National Viral Hepatitis Program. Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations from the Department of Veterans Affairs National Hepatitis C Resource Center Program and the HIV, Hepatitis, and Related Conditions Program in the Office of Specialty Care Services. Updated March 2017 (link [https://www.hepatitis.va.gov/provider/guidelines/hcv-treatment-considerations.asp])
- [NLM 2017a] U.S. National Library of Medicine. HARVONI- ledipasvir and sofosbuvir tablet, film coated [Gilead Sciences, Inc]. Updated April 2017 (link [https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm? setid=f4ec77e4-bae8-4db0-b3d5-bde09c5fa075])
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- [NLM 2016] U.S. National Library of Medicine. REBETOL- ribavirin capsule; REBETOL- ribavirin liquid [Merck Sharp & Dohme Corp.]. Updated January 2016 (link [https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm? setid=04d2b6f4-bd9b-4871-9527-92c81aa2d4d0])
- [NLM 2017c] U.S. National Library of Medicine. ZEPATIER- elbasvir and grazoprevir tablet, film coated [Merck Sharp & Dohme Corp.]. Updated February 2017 (link [https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=164dc02a-9180-426a-b8b5-04ab39d2bbd4])
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- [VA 2016b] VA Pharmacy Benefits Management Services, Medical Advisory Panel, VISN Pharmacist Executives and Office of Public Health. Ledipasvir/Sofosbuvir (Harvoni®) and Sofosbuvir/Velpatasvir (Epclusa®) Criteria for Use. Published September 2016 (link [https://www.pbm.va.gov/apps/VANationalFormulary/])