HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use NAMENDA XR capsules safely and effectively. See full prescribing information for NAMENDA XR capsules.

NAMENDA  $\mathrm{XR}^8$  (memantine hydrochloride) extended-release capsules, for oral use initial U.S. Approval: 2003

AMERICAN AR: "Institution proprocesses exenues, for oral use

"NOTE ATTOMS AND USES."

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Namerican XR is a K-meth

Patients with seve once daily. (2.3)

DOSAGE FORMS AND STRENGTHS

NAMENDA XR is available as an extended-release capsule in the following strengths: 7 mg, 14 mg, 21 mg, 28 mg (3)

NAMENDA XR is contraindicated in patients with known hypersensitivity to memantine hydrochloride or to any excipients used in the formulation. (4)

Conditions that raise urine pH may decrease the urinary elimination of memantine resulting in increased plasma levels of memantine. (5.1, 7.1)

The most commonly observed adverse reactions occurring at a frequency of at least 5% and greater than placebo with administration of AMENDA XR 28 mg/day were headsche, dismrea and dizziness. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Allergan at 1-800-678-1605 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling. Revised: 11/2019

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### FULL PRESCRIBING INFORMATION

### INDICATIONS AND USAGE

NAMENDA  $XR^{\otimes}$  is indicated for the treatment of moderate to severe dementia of the Alzheimer's type.

### 2 DOSAGE AND ADMINISTRATION

### 2.1 Recommended Dosing

The dosage of NAMENDA XR shown to be effective in a controlled clinical trial is 28 mg once daily.

unce 08IV.

The recommended starting dose of NAMENDA XR is 7 mg once daily. The dose should be increased in 7 mg increments to the recommended maintenance dose of 28 mg once daily. The minimum recommended interval between dose increases is one work of the order order of the order order of the order order

Except when opened and sprinkled on applesauce, as described above, NAMENDA XR should be swallowed whole. NAMENDA XR capsules should not be divided, chewed, or crushod

If a patient misses a single dose of NAMENDA XR, that patient should not double up on the next dose. The next dose should be taken as scheduled. If a patient falls to take NAMENDA XR for several days, dosing may need to be resumed at lower doses and retrated as described above.

# 2.2 Switching from NAMENDA to NAMENDA XR Capsules

Pacients treated with NAMENDA No MANENDA XIX Capsules
plaints treated with NAMENDA may be either than NAMENDA XIX capsules as folious:
It is recommended that a patient who is on a regimen of 10 mg brice daily of
NAMENDA he without the NAMENDA XIX 22 mg more cally created the Top foliowing the
last dose of 10 mg NAMENDA. There is no study addressing the comparative efficacy of
these 2 regimens.

these 2 regmens.

In a patient with severe renal impairment, it is recommended that a patient who is o regimen of 5 mg twice daily of NAMENDA be switched to NAMENDA XR 14 mg once capsules the day following the last dose of 5 mg NAMENDA. Dosing in Patients with Renal Impairment

In patients with severe renal impairment (creatinine clearance of 5 – 29 mL/min, based on the Cockcroft-Gault equation), the recommended maintenance dose (and maximum recommended dose) is 14 mg/day [see Clinical Pharmacology (12.3)].

## DOSAGE FORMS AND STRENGTHS

- 3 DOSAGE FORMS AND STRENOTHS

  Each capsule contains 7 mg. 14 mg. 21 mg. or 28 mg of memanthe hydrochloride.

  \* The 7 mg capsules are a yellow opaque capsule, with \*FLI 7 mg black imprint.

  \* The 14 mg capsules are a yellow opa and dark green opaque body capsule, with \*FLI 14 mg\* black imprint on the yellow cap.

  \* The 21 mg capsules are a whelve of th-withe cap and dark green opaque body capsule, with \*FLI 22 mg\* black imprint on the white to off-withe cap.

  \*\*The 21 mg capsules are a white forem opaque capsule, with \*\*FLI 28 mg\* white imprint.

# CONTRAINDICATIONS

NAMENDA XR is contraindicated in patients with known hypersensitivity to memantine hydrochloride or to any excipients used in the formulation.

# 5 WARNINGS AND PRECAUTIONS

## 5.1 Genitourinary Conditions

Conditions that raise urine pH may decrease the urinary elimination of memantine resulting in increased plasma levels of memantine [see Drug Interactions (7.1)].

## 6 ADVERSE REACTIONS

## 6.1 Clinical Trials Experience

NAMENDA XR was evaluated in a double-blind placebo-controlled trial in which a total 676 patients with moderate to severe dementia of the Akheimer's type (341 patients NAMENDA XR 28 mg/day and 335 patients on placebo) were treated for up to 24 we

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

## Adverse Reactions Leading to Discontinuation

Adverse Reactions Leading to Discontinuation
In the placebo-controlled clinical trial of NAMENDA XR, the proportion of patients in the NAMENDA XR group and the placebo group who discontinued treatment due to adverse reactions was 10% and 6%, respectively. The most common adverse reaction that the treatment discontinuation in the NAMENDA XR group was disziness, at a rate of 1.5%.

## Most Common Adverse Reactions

INDEX.COMMINIOR JANKS AS REACTIONS.

The most commonly observed adverse reactions seen in patients administered NAMENDA XR in the controlled clinical trial, defined as those occurring at a frequency of at least 5% in the NAMENDA XR group and at a frequency higher than placebo, were headache, diarrhea and dizziness.

Table 1 lists adverse reactions that were observed at an incidence of  $\geq 2\%$  in the NAMENDA XR group and occurred at a rate greater than placebo.

Table 1: Adverse Reactions Observed with a Frequency of ≥

### 2% in the NAMENDA XR Group and at a Rate Greater than Placebo

Adverse Reaction	Placebo (n=335) %	NAMENDA XR 28 mg (n=341) %
Gastrointestinal Disorders		
Diarrhea	4	5
Constipation	1	3
Abdominal pain	1	2
Vomiting	1	2
Infections and Infestations		
Influenza	3	4
Investigations		
Weight, increased	1	3
Musculoskeletal and Connective Tissue Disorders		
Back pain	1	3
Nervous System Disorders		
Headache	5	6
Dizziness	1	5
Somnolence	1	3
Psychiatric Disorders		
Anxiety	3	4
Depression	1	3
Aggression	1	2
Renal and Urinary Disorders		
Urinary incontinence	1	2
Vascular Disorders		
Hypertension	2	4
Hypotension	1	2

Memantine has not been systematically evaluated in patients with a seizure disorder. In clinical trials of memantine, seizures occurred in 0.3% of patients treated with memantine and 0.6% of patients treated with placebo.

**6.2 Postmarketing Experience**The following adverse reactions have been identified during post-approval use of memantine.

Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. These reactions include:

Blood and Lymphatic System Disorders: agranulocytosis, leukopenia (including neutropenia), pancytopenia, thrombocytopenia, thrombotic thrombocytopenic purpura. Cardiac Disorders: cardiac failure congestive.

Gastrointestinal Disorders: pancreatitis. Hepatobiliary Disorders: hepatitis.

Psychiatric Disorders: suicidal ideation.

Renal and Urinary Disorders: acute renal failure (including increased creatinine and renal insufficiency).

Skin Disorders: Stevens Johnson syndrome.

### 7 DRUG INTERACTIONS

### 7.1 Drugs That Make Urine Alkaline

7.1 Drugs That Make Urnie Aukanie

The clearance of memantine was reduced by about 80% under alkaline urine conditions at pH 8. Therefore, alterations of urine pH towards the alkaline condition may lead to an at pH 8. Therefore, alterations of urine pH towards the alkaline condition may lead to an better the second to the pH 9. The second the second to the pH 9. The second the second to the pH 9. The second the second to the urinary tract). Hence, memanties should be used with caution under these conditions.

### 7.2 Use with Other N-methyl-D-aspartate (NMDA) Antagonists

The combined use of NAMENDA XR with other NMDA antagonists (amantadine, ketamine, and dextromethorphan) has not been systematically evaluated and such use should be approached with caution.

### 8 USE IN SPECIFIC POPULATIONS

### 8.1 Pregnancy

### Risk Summary

There are no adequate data on the developmental risk associated with the use of NAMENDA XR in pregnant wome

Adverse developmental effects (decreased body weight and skeletal ossification) were observed in the offspring of rats administered memantine during pregnancy at doses associated with minimal mater In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively. The background risk of major birth defects and miscarriage for the indicated population is unknown.

# Data

Animal Data

Oral administration of memorative (0, 2, 6, or 12 in grigology) to rate during the period of organogenesis resulted in decreased skeletal ossification in fetuses at the highest dose tested. The higher no effect dose for a doverse developmental effects (6 ongolds) is 2 times the maximum recommended human day dose (MRHD) of NAMENDA XR (28 mg) on a body surface area (mg/mg/m bbss.

- 20 cal administration of memantine to rabbits (0, 3, 10, or 30 mg/kg/day) during the period of organogenesis resulted in no adverse developmental effects. The highest dose tested is appr 20 times the MRHD of NAMENDA XR on a mg/m² basis.

The state of the control of the state of the

Risk Summary

There are no data on the presence of memantine in human milk, the effects on the breastfed infant, or the effects of NAMENDA XR on milk production

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for NAMENDA XR and any potential adverse effects on the breastfed infant from NAMENDA XR or from the underlying mater

Safety and effectiveness in pediatric patients have not been established.

Safety and erectiveness in pediatric patients naive hot been established.

Memanther failable to demonstrate effects, or two 12-week controlled clinical studies of 378 pediatric patients aged 6.12 years with autom spectrum disorders (ASD), including Specified (PDD-ADS). Memanther has not been studied in pediatric patients under 6 years of age or over 12 years of age. Memanther treatment was instated at 3 migriday and the dose was escalated to the turder dose (weight breased) yeared. 6.10 alloses of patients with weights < 20 kg, 20-39 kg, 40-59 kg and 2.60 kg, respectively.

puemens were new more year. See 20 kg, 20-39 kg, 30-39 kg, 30-32 k

The overall safety profile of memantine in pediatric patients was generally consistent with the known safety profile in adults [see Adverse Reactions (6.1)].

In Study A, the adverse reactions in the memantine group (n=56) that were reported in at least 5% of patients and at least twice the frequency of the placebo group (N=58) are listed in Table 2.

# Table 2: Study A Commonly Reported Adverse Reactions with a Frequency ≥ 5% and Twice

That o	t Placebo	
Adverse Reaction	Memantine N=56	Placebo N=58
Cough	8.9%	3.4%
Influenza	7.1%	3.4%
Rhinorrhea	5.4%	0%
Agitation	5.4%	1.7%
Discontinuations due	to Adverse	Reactionsa
Aggression	3.6%	1.7%
Irritability	1.8%	3.4%
Reported adverse react discontinuation in more t	ions leading to han one patier	it in either

The adverse reactions that were reported in at least 5% of patients in the 12-48 week open-label study to identify responders to enroll in Study B are listed in Table 3.

# Table 3: 12-48 Week Open Label Lead-In study to Study B Commonly Reported Adverse Reactions with a Frequency ≥ 5%

Adverse Reaction	Memantine N=903
Headache	8.0%
Nasopharyngitis	6.3%
Pyrexia	5.8%
Irritability	5.4%
Discontinuations due	to Adverse Reactionsa
Irritability	1.2%
Aggression	1.0%
At least 1% incidence of	adverse reactions leading

### Juvenile Animal Study

Juvenile Animal Study.

In a Juvenile animal Study, male and female juvenile rats were administered memantine (13, 50, and 45 mg/kg/dg/s) starting on jostinatal dg/ (PMD) 14 through PMD 7.0. Body and 15 mg/kg/dg/s) starting on jostinatal dg/ (PMD) 14 through PMD 7.0. Body and female rate at closes = 3.0 mg/kg/dg/s). Bethanders induced neuronal sitesions in several areas of the brain on PMD 15 and 17 at doses = 30 mg/kg/dg/s. Behavioral toxicky (decrease percent of auditory startle habituation) was noted for animals in the 45 mg/kg/dg/s you have jorded to the start of the

Adverse-Effect-Level (NOAEL) for his study.

In a second juvenile rat toxickly study, male and female juvenile rats were administered memantine (1, 3, 8, 15, 30, and 45 mg/kg/day) starting on postnatal day (PND) 7 through PND 70. Due to early memantine-related mortality, the 30 and 45 mg/kg/day) dose groups were terminated without further evaluation. Memantine induced apoptoses and the starting of the starting

8.5 Gerattra Use
The mapirty of people with Alzheimer's disease are 65 years of age and older. In the clinical study of memantine hydrochloride extended-release, the mean age of patients was approximately 71 years; over 91% of patients were 65 years and older, 67% were 73 years and older, and 14% were at or above 85 years of age. The efficacy and safe data presented in the clinical trail sections were obtained from these patients. There were no chically meaningful differences in most adverse reactions reported by patier groups a 65 years old and < 65 years old.

### 8.6 Renal Impairment

No dosage adjustment is needed in patients with mild or moderate renal impairment. A dosage reduction is recommended in patients with severe renal impairment [see Dosage and Administration (2.3) and Clinical Pharmacology (12.3)].

### 8.7 Hepatic Impairment

No dosage adjustment is needed in patients with mild or moderate hepatic impairment Namenda XR was not studied in patients with severe hepatic impairment [see Clinical Pharmacology (12.3)].

### OVERDOSAGE

10 OVERDOSAGE
Signs and symptoms most often accompanying overdosage with other formulations of memantine in clinical trials and from worldwide marketing experience, alone or in combination with other drugs and/or achool, include aglation, asthenia, brindyaged, or combination with other drugs and/or achool, include aglation, asthenia, brindyaged, or consciousness, psychosis, resittesness, slowed movement, sommolence, stupor, unsteady gat, visual hallucantions, vertigo, vomiting, and weakness. The largest known ingestion of memantine worldwide was 2 grams in a patient who took memantine in conjunction with unspecified antidabler medications. This patient experienced coma, diplopia, and aglation, but subsequently recovered.

One patient participating in a NAMEANA XR clinical trial unintentionally took 112 mg of a serial making phosphatase, and low platetet count in the serial serial serial making phosphatase, and low platetet counts.

Fatal outcome has been very rarely reported with memantine, and the relationship to memantine was unclear.

Recause strategies for the management of overdose are continually evolving, it is advisable to contact a poison control center to determine the latest recommendation for the management of an overdose of any drug. As in any cases of overdose, get supportive measures should be utilized, and treatment should be symptomatic.

Elimination of memantine can be enhanced by acidification of urine.

### DESCRIPTION

NAMENDA XR (memantine hydrochloride) is an orally active NMDA receptor antagonist. The chemical name for memantine hydrochloride is 1-amino-3,5-dimethyladamantane hydrochloride with the following structural formula:



The molecular formula is  $C_{12}H_{21}N \cdot HCl$  and the molecular weight is 215.76. Memantine hydrochloride occurs as a fine white to off-white powder and is soluble in water. AMMENDA XR capsules are supplied for oral administration as 7 mg, 14 mg, 21 mg, and 28 mg capsules. Each capsule contains extended-release beads with the labeled amount of memantine hydrochrolride and the following inactive ingredients: sugar spheres, polyvinylyroridione, hypromelose, talc, polyethylene glycol, ethylcellulose, ammonium hydroxide, olicie acid, and medium chair triglycerides in hard gelatin capsules.

12.1. mechanism of Account Persistent activation of central nervous system N-methyl-D-aspartate (NMDA) receptors by the excitatory amino acid glutamate has been hypothesized to contribute to the symptomatology of Alzheimer's classes. Memantine is postulated to exert its therapeutic effect through its action as a low to moderate affinity uncompetitive (open-channel) NMDA receptor antagonist which binds preferentially to the NMDA receptor-operated cation channels. There is no evidence that memantine prevents or slows neurodegeneration in patients with Alzheimer's Gleesee.

## 12.2 Pharmacodynamics

Memanthe showed low to negligible affinity for GABA, benzodiazepine, dopamine, dafenergic, histamine and glycine receptors and for voltage-dependent Ca<sup>+</sup>\*, Na\*, or K\* channes. Memanthe also showed antagonistic effects at the SHTs receptor with a potency similar to that for the NMDA receptor and blocked nicotinic acetylcholine receptors with one-sixth to one-tenth the potency.

In vitro studies have shown that memantine does not affect the reversible inhibition of acetylcholinesterase by donepezil, galantamine, or tacrine.

## 12.3 Pharmacokinetics

ALS.3 Pharmacountercus, when are a substantial production and has linear pharmacokinetics over the therapeutic dose range. It is excreted predominantly unchanged in urine and has a terminal elimination half-life of boost 60-80 hours, in a study comparison to a star brain all emination half-life of boost 60-80 hours, in a study comparison 28 mg once daily NAMENDA. Xt to 10 mg twice daily NAMENDA the C<sub>max</sub> and AUC<sub>0.24</sub> values were 48% and 33% higher for the XM dosage regimen, respectively.

Absorption After multiple dose administration of NAMENDA XR, memantine peak concentrations occur around 9-12 hours post-dose. There is no difference in the absorption of NAMENDA XR when the capsule is taken intact or when the contents are sprinkled on

There is no difference in memantine exposure, based on  $C_{\text{max}}$  or AUC, for NAMENDA XR whether that drug product is administered with food or on an empty stomach. However, peak plasma concentrations are achieved about 18 hours after administration with food versus approximately 25 hours after administration on an empty stomach.

# Distribution

The mean volume of distribution of memantine is 9-11 L/kg and the plasma protein binding is low (45%).

## Elimination

Metabolism

Memantine undergoes partial hepatic metabolism. The hepatic microsomal CYP450 enzyme system does not play a significant role in the metabolism of memantine.

Excretion

Memantine is excreted predominantly unchanged in the urine and has a terminal
elimination half-life of about 60-80 hours. About 48% of administered drug is excreted
unchanged in urine, the memander is converted primary to there point reabolities
which posses minimal MMDA receptor untaggoristic activity, to there point reabolities
which posses minimal MMDA receptor untaggoristic activity, the three point reabolities
of the definite feed does in excreted as the sum of the period from the About 16 of 14%
glucuroide conjugate. Renal clearance involves active tubular secretion moderated by
pil dependent bulsular reabourption.

# Specific Populations

The pharmacokinetics of memantine in young and elderly subjects are similar.

Genter
Following multiple dose administration of memantine hydrochloride 20 mg daily, fer
had about 45% higher exposure than males, but there was no difference in exposure
when body weight was taken into account.

# Renal Impairment

Renal Impartment Memanther pharmacokinetics were evaluated following single oral administration of 20 mg memanther hydrochioride in 8 subjects with mild renal impartment (creatinine clearance, CLC; > 50.- 60 mL/min), 8 subjects with moderate renal impartment (CLC; 30 mL/min) matched as conselved as the subjects (CLC; > 80 mL/min) matched as closely as possible by age, weight and gender to the subjects with renal impartment. Mean AUC, an increased by 4%, 60%, and 115% in subjects with mail, moderate, and severe renal impairment, respectively, compared to healthy subjects. The terminal elimination half-life necessed by 18%, 41%, and 95% in subjects with mild, moderate, and severe renal impairment, respectively, compared to healthy subjects.

# Hepatic Impairment

Hepatic Impairment
Memanthe pharmacokhetics were evaluated following the administration of single oral
doses of 20 mg in 8 subjects with moderate hepatic impairment (Chit-P-ugh Class
8, score 7-9) and 8 subjects with moderate hepatic impairment (Chit-P-ugh Class
8, score 7-9) and 8 subjects with moderate hepatic impairment accompared with health
comax and AUCI is subjects with moderate hepatic impairment as compared with health
subjects. However, terminal elimination half-life increased by about 16% in subjects with
moderate hepatic impairment as compared with health subjects.

## <u>Drug-Drug Interactions</u>

Use with Cholinesterase Inhibitors

Coadministration of memantine with the AChE inhibitor donepezil did not affect the pharmacokinetics of either compound. Furthermore, memantine did not affect ACht inhibition by donepezil. In a 24-week controlled clinical study in patients with modera

severe Alzheimer's disease, the adverse reaction profile observed with a combination of memantine immediate-release and donepezil was similar to that of donepezil alone.

Effect of Memantine on the Metabolism of Other Drugs

Lines. or memoratine on the Metabolsm of Other Drugs
In vivo studies conducted with marker substrates of CIPASO encymes (CIPAS, 226, 209, 206, 221, 344) showed minimal inhibition of these encymes by memoratine. In addition, in vito subties indicate that it concentrations exceeding hose associated with efficacy, memoratine does not induce the cytochrome P450 isozymes CIPAS, 229, 225 and 34AB, to high paramockinetic interactions with drugs metabolized by these enzymes are expected.

Pharmacokinetic studies evaluated the potential of memantine for interaction with warfari and bupropion. Memantine did not affect the pharmacokinetics of the CYP2B6 substrate bupropion or its metabolise hydroxybupropion. Furthermore, memantine did not affect the pharmacokinetics or pharmacodynamics of warfarin as assessed by the protromabin INIV

Effect of Other Drugs on Memantine

Memantine is predominantly renally eliminated, and drugs that are substrates and/or inhibitors of the CYP450 system are not expected to alter the metabolism of memantine

Drugs Emmated via Renal Mechanisms
Because memantine is eliminated at part by tubular secretion, coadministration of drugs
that use the same renal cationic system, including hydrochiorchiazable (HCT2),
trainstereen (FLA), medformin, cimetiden, randisticin, qualificin, and nicotine, could
potentially result in after globs and eyes of both agents. However, coadministration of
potentially result in after globs and eyes of both agents. However, coadministration of
the bloavailability of HCT2 decreased by 29%, in addition, coadministration of memantine
with the anthyperglycemic drug Glucovance® (glyburde and medformin hydrochloride)
did not affect the pharmacokinetics of memantine, medformin and glyburde,
Furthermore, memantine did not modify the serum glucose lowering effect of
Glucovance®, indicating the absence of a pharmacokymine, interaction.

Drugs Highly Bound to Plasma Proteins

Because the plasma protein binding of memantine is low (45%), an interaction with drugs that are highly bound to plasma proteins, such as warfarin and digoxin, is unlikely.

### 13 NONCLINICAL TOXICOLOGY

### 13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

There was no evidence of carcinogenicity in a 113-week oral study in mice at doses up to 40 mgkg/dga/ (7 times the maximum recommended human dose (MRHD) on a mg/m² basis). There was also no evidence of carcinogenicity in 1sto snally dosed at 40 d mgkg/dga/ for 71 weeks followed by 20 mgkg/dga/ g/ (14 and 7 times the MRHD on a mg/m² basis, respectively) through 212 weeks.

Mutagenesis

Memanthe produced no evidence of genotoxic potential when evaluated in the in vitro 5. typhimrulum or E. col i reverse mutation assay, an in vitro chromosomal benetic test in human lymphocytes, an in vivo cytogenetic sassy for chromosome damage in rats, and the it vivo mouse micronucleus assay. The results were equivocal in an in vitro gene mutation assay using Chinese hamster VT9 cells.

Impairment of Fertility

No impairment of fertility or reproductive performance was seen in rats administers to 18 mg/kg/day (6 times the MRHD on a mg/m² basis) orally from 14 days prior to mating through gestation and lactation in females, or for 60 days prior to mating in males.

### Animal Toxicology and/or Pharmacology

Animal Toxicology allulor Final macrology

Memanthe induced neuronal lesions (scuciation and necrosis) in the multipolar and pyramidal cels in cortical layers III and IV of the posterior cingulate and retrosplenial neocortices in rats, similar to those which are known to occur in rodents administered other NNDA receptor antagonetis. Lesions were seen after a single dose of memantian for 14 days, the non-different rats were given day or all doses of memantian for 14 days, the non-different control of the new results of th

In acute and repeat-dose neurotoxicity studies in female rats, oral administration of memantine and donepezi in combination resulted in increased incidence, severity, a distribution of neurodegeneration compared with memantine alone, severity, and of the combination were associated with clinically relevant plasma memantine and donepezi exposures.

The relevance of these findings to humans is unknown

### CLINICAL STUDIES

The effectiveness of NAMENDA XR as a treatment for patients with moderate to severe Alzheimer's disease was based on the results of a double-blind, placebo-controlled trial.

24-week Study of NAMENDA XR Capsules

24-week Study of NAMENDA XR Capsules
This was a randomized double-blind clinical investigation in outpatients, with moderate to severe Arbenier's deaseae (diagnosed by DSM-V Criteria and NINCDS-ADRDA criteria severe Arbenier's deaseae (diagnosed by DSM-V Criteria and NINCDS-ADRDA criteria and Sacienie) receiving acetylcholinesterase inhibitor (ACDEI) therapy at a stable dose for 3 months prior to screening. The mean age of patients participating in the viril was 76.5 years with a range of 49-97 years. Approximately 72% of patients were female and 94% were Caucasian.

# Study Outcome Measures

The effectiveness of NAMENDA XR was evaluated in this study using the co-primary efficacy parameters of Severe Impairment Battery (SIB) and the Clinician's Interview-Based Impression of Change (CIBIC-Plus).

traces impressor for charging country ass.

The adilly of NAMERION AR (SIG) impresses the assesses of with the realized for the adilly of NAMERION AR (SIG) impresses the adilly addition of cognitive function in patients with moderate to severe dementa. The SIG examines selected aspects of cognitive performance, including elements of attention, orientation, language, memory, visuospalial ability, construction, praxis, and social conditions and additional conditions of the companion of the companion of the companion of the companion of the condition of the condit

interaction. The sills scoring range is from 10 to 100, with lower scores indicating greater cognitive impairment. At to produce an overall clinical effect was assessed using a Clinican's Interview Based Impression of Change that required the use of caregiver Clinican's Interview Based Impression of Change that required the use of caregiver standardized instrument like the ADCS-ADL or SIB. Clinical trisk for investigational drugs have used a variety of CIBIC formats, each different in terms of depth and structure, as such, results from a CIBIC-Plus reflect clinical experience from the trial or trisk in which it was used and cannot be compared directly with the results of CIBIC-Plus evaluations from other clinical trisk. The CIBIC-Plus cale in this trial was a structured instrument domains general coveral clinical status, functional trinkcling activities of clay lyingly, cognitive, and behavioral. It represents the assessment of a skiled clinician using validated scales based on his/her CIBIC-Plus is exceed as seven point categorical particle values of the compared control of the patient, in combination with information supplied by a caregiver familiar with the behavior of the patient over the interval reads. The CIBIC-Plus is covered as a seven point categorical indicating "no change" to a score of 7, indicating "marked worsening." The CIBIC-Plus has not been systematically compared directly to assessments not using information from caregivers (CIBIC) or other global methods.

In this study, 677 patients were randomized to one of the following 2 treatments: NAMENDA XR 28 mg/day or placebo while still receiving an AChEI (either donepezil, galantamine, or rivastigmine).

## Effects on Severe Impairment Battery (SIB)

Effects on Newton Impartment satters (1slat). Figure 1 shows the time course for the change from baseline in SIB score for the two treatment groups completing the 24 weeks of the study, At 24 weeks of treatment, the compared to the patient of th

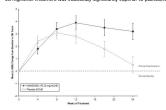


Figure 1: Time course of the change from baseline in SIB score for patients completing 24 weeks of treatment

To write the cumulative percentages of patients from each treatment group who had attained at least the measure of improvement in SIB score shown on the X axis. The curves show that both patients assigned to AMMENDA XR 28 mg/ACM and pickebiAChEI have a wide range of responses, but that the NAMENDA XR 28 mg/AChEI group is more likely to show an improvement or a smaller decline.

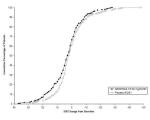


Figure 2: Cumulative percentage of patients completing 24 weeks of double-blind treatment with specified changes from baseline in SIB scores

Figure 3 shows the time course for the CIBIC-Plus score for patients in the two treatment groups completing the 24 weeks of the study, At 24 weeks of treatment, the mean difference in the CIBIC-Plus scores for the MAMERIDA AT 28 mg/AChEI-treated patients compared to the patients on place body CIBIC and Sunday Sunday

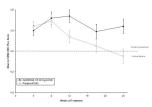


Figure 3: Time course of the CIBIC-Plus score for patients completing 24 weeks of treatment

Figure 4 is a histogram of the percentage distribution of CIBIC-Plus scores attained by patients assigned to each of the treatment groups who completed 24 weeks of treatment.

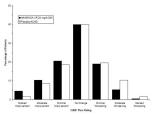


Figure 4: Distribution of CIBIC-Plus ratings at week 24

## HOW SUPPLIED/STORAGE AND HANDLING

### 7 mg Capsule

Yellow opaque capsule, with "FLI 7 mg" black imprint.

Bottle of 30: NDC# 0456-3407-33

### 14 mg Capsule

Yellow cap and dark green opaque capsule with "FLI 14 mg" black imprint on the yellow cap.

Bottle of 30: NDC# 0456-3414-33
Bottle of 90: NDC# 0456-3414-90

White to off-white cap and dark green opaque capsule, with "FLI 21 mg" black imprint on the white to off-white cap. Bottle of 30: NDC# 0456-3421-33

# 28 mg Capsule

Dark green opaque capsule, with "FLI 28 mg" white imprint.

Bottle of 30: NDC# 0456-3428-33
Bottle of 90: NDC# 0456-3428-90
<u>Titration Pack</u> NDC# 0456-3400-29

Contains 28 capsules (7 x 7 mg, 7 x 14 mg, 7 x 21 mg, 7 x 28 mg)

Store NAMENDA XR at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature].

- Advise the patient to read the FDA-approved patient labeling (Patient Information).

   To assure safe and effective use of NAMENDA XP, the information and instructions provided in the patient information section should be discussed with patients and caregivers.

   Instruct patients and caregivers to take NAMENDA XR only once per day, as
- Instruct patients and caregivers to take NAMENDA XR only once per day, as prescribed.
   Instruct patients and caregivers the NAMENDA XR popules the swidness with patients and the structure patients.
   Instruct patients are consistent to the patients of the patients are patients.
   Instructure patients are contents should be consumed. The capsules should not be divided, chewed or crushed.
   Warn patients not to use any capsules of NAMENDA XR that are damaged or show sights of farmpering.
   Instructure patients of the patients of the patients should not doubted by on the next does. The next does enough the patient should not doubted to take NAMENDA XR for several days, dosing should not be resumed without consulting that patient's heabtrace professional.
   Advise patients and caregivers that NAMENDA XR may cause headache, diarrhea, and dizzeness.

Distributed by: Allergan USA, Inc. Madison, NJ 07940

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# NAMENDA XR® [Nuh-MEN-dah Eks-Are]

## (memantine hydrochloride) Extended-Release Capsules

(Internatione Injuriocinate) Extended-neteable Capsules
Read this Patient Information that comes with NAMENDA KR® before you start taking it
and each time you get a refill. There may be new information. This information does not
take the place of taking to your doctor about your medical condition or your treatment.
What is NAMENDA XR?

NAMENDA XR is a prescription medicine used for the treatment of moderate to severe dementia in people with Alzheimer's disease. NAMENDA XR belongs to a class of medicines called N-methyl-D-aspartate (NMDA) inhibitory.

# It is not known if NAMENDA XR is safe and effective in children. Who should not take NAMENDA XR?

# **Do not take NAMENDA XR if you** are allergic to memantine or any of the other ingredients in NAMENDA XR. See the end of this leaflet for a complete list of ingredients in NAMENDA XR.

prescription medicines, vitamins, and herbal supplements

Taking NAMENDA XR with certain other medicines may affect each other. Taking NAMENDA XR with other medicines can cause serious side effects.

Especially tell your doctor if you take:

• other MMDA antagonists such as amantadine, ketamine, and dextromethorphan

• medicines that make your urine alkaline such as carbonic anhydrase inhibitors and sodium bicarbonate

Ask your doctor or pharmacist for a list of these medicines, if you are not sure Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

- Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

  How should I take NAMENDA XR?

  Four doctor may change your dose if needed.

  Your doctor may change your dose if needed.

  Now the control of the con

## What are the possible side effects of NAMENDA XR?

### NAMENDA XR may cause side effects, including:

The most common side effects of NAMENDA XR include:

• headache
• diarrhea
• dizziness

These are not all the possible side effects of NAMENDA XR. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1.088.

FOM at 1-900F-100-1000.

How should I store NAMENDA XR?

Store NAMENDA XR at room temperature between 68°F to 77°F (20°C to 25°C).

What are the ingredients in NAMENDA XR?

Active ingredient: memantine hydrochloride

Inactive ingredients: sugar spheres, polyvinylpyrrolidone, hypromellose, tak, polyethylene glycol, ethylcellulose, ammonium hydroxide, oleic acid, and medium chain triglycerides

### Keep NAMENDA XR and all medicines out of the reach of children.

General information about the safe and effective use of NAMENDA XR: Medicines are sometimes prescribed for purposes other than those listed in a Patien Information leafle. Do not take NAMENDA XR for a condition for which it was not prescribed. Do not give NAMENDA XR to other people, even if they have the same condition. It may harm them.

Contains It may narm unems.

This Patient Information leaflet summarizes the most important information about NAMENDA XR. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about NAMENDA XR that was written for healthcare professionals.

For more information about NAMENDA XR, go to www.namendaxr.com, or call Allergan at 1-800-678-1605.

This Patient Information has been approved by the U.S. Food and Drug Administration.

Made in Ireland

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Revised: 11/2019

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NDC 0456-3407-33
30 capsules
Rx only
Once-Daily
Namenda XR®
(memantine HCI) extended release capsules
7 mg



PRINCIPAL DISPLAY PANEL
NDC 0456-3414-33
30 capsules
Rx only
Once-Daily
Namenda XR®
(memantine HCI) extended rele

tended release capsules



## PRINCIPAL DISPLAY PANEL

PRINCIPAL DISPLAY PANEL

NDC 0456-3414-90
90 capsules
Rx only
Once-Daily
Namenda XR ⊗
(memantine HCI) extended release capsules
14 mg



# PRINCIPAL DISPLAY PANEL

PRINCIPAL DISPLAY PANEL
NDC 0456-3421-33
30 capsules
Rx only
Once-Daily
Namenda XR®
(memantine HCI) extended release capsules
21 mg



PRINCIPAL DISPLAY PANEL

NDC 0456-3428-33
30 capsules
Rx only
Once-Daily
Homewid XR ⊕ (
(manantine HCI) extended release capsules
28 mg



PRINCIPAL DISPLAY PANEL
NDC 01456-3428-90
90 capsules
Once-Daly
Namenda XR ⊗
(memantine HCI) extended release capsules
28 mg



### PRINCIPAL DISPLAY PANEL

NDC 0456-3400-29 Titration Pack Once-Daily

Namenda XR ® (memantine HCI) extended release capsules



Product Inform	nation					
Product Type		HUMAN PRESCRIPTION DRUG	Item	Code (Source)	) NO	C:0456-3407
Route of Adminis		ORAL		(	,	
Koute of Adminis	tration	UNAL				
Active Ingredie	ent/Active	Moiety				
	Ingre	dient Name		Basis of S	Strenat	h Strengt
MEMANTINE HYDRO UNII:WB017SJF3T)	OCHLORIDE (	UNII: JYOWDOUA60) (memantine -		MEMANTINE HYDROCHLORI	DE	7 mg
Inactive Ingred	dients					
		Ingredient Name				Strength
sucrose (UNI: C151)						
povidone K30 (UNI						
hypromellose 2910		(UNII: 36SFW2JZ0W)				
talc (UNII: 7SEV7)4R1						
polyethylene glyco						
POLYETHYLENE GL						
AMMONIA (UNI: 513		(UNII: 47MLB0F1MV)				
OLEIC ACID (UNI: 2	UMI9U37CP)					
OLEIC ACID (UNI: 2) MEDIUM-CHAIN TRI	UMI9U37CP)					
OLEIC ACID (UNI: 2	UMI9U37CP)					
OLEIC ACID (UNI: 2) MEDIUM-CHAIN TRI	UMI9U37CP)					
OLEIC ACID (UNI: 2) MEDIUM-CHAIN TRI GELATIN, UNSPECII	UMI9U37CP) IGLYCERIDES FIED (UNI: 2G					
OLEIC ACID (UNI: 21 MEDIUM-CHAIN TRI GELATIN, UNSPECII Product Chara	UMI9U37CP) IGLYCERIDES FIED (UNI: 26	86QN327L)				
OLEIC ACID (UNI: 2) MEDIUM-CHAIN TRI GELATIN, UNSPECII Product Chara- Color	UMI9U37CP) IGLYCERIDES FIED (UNI: 20  cteristics yellow (yello	86QN327L) ow (opaque))	Score			o score
OLEIC ACID (UNI: 2) MEDIUM-CHAIN TRI GELATIN, UNSPECII  Product Chara- Color Shape	UMI9U37CP) IGLYCERIDES FIED (UNI: 26	86QN327L) ow (opaque))	Size		4	mm
OLEIC ACID (UNI: 2) MEDIUM-CHAIN TRI GELATIN, UNSPECII  Product Chara- Color Shape Flavor	UMI9U37CP) IGLYCERIDES FIED (UNI: 20  cteristics yellow (yello	86QN327L) ow (opaque))	Size	nt Code	4	
OLEIC ACID (UNI: 2) MEDIUM-CHAIN TRI GELATIN, UNSPECII  Product Chara- Color Shape	UMI9U37CP) IGLYCERIDES FIED (UNI: 20  cteristics yellow (yello	86QN327L) ow (opaque))	Size		4	mm
OLEIC ACID (UNI: 2) MEDIUM-CHAIN TRI GELATIN, UNSPECII  Product Chara- Color Shape Flavor Contains	UMI9U37CP) IGLYCERIDES FIED (UNI: 20  cteristics yellow (yello	86QN327L) w (opaque))	Size		4	mm
OLEIC ACID (UNIC 2) MEDIUM-CHAIN TRI GELATIN, UNSPECII Product Chara- Color Shape Flavor Contains  Packaging	UNISU37CP) IGLYCERIDES FIED (UNI: 2G  CTERISTICS  yellow (yello  CAPSULE (C	86QN327L) w (opaque))	Size Impri		4i Fi	mm
OLEIC ACID (UNIL 2) MEDIUM-CHAIN TRI GELATIN, UNSPECII  Product Chara- Color Shape Flavor Contains  Packaging # Item Code	UNISUSTEP) IGLYCERIDES FIED (UNI: 20  CTERISTICS yellow (yell CAPSULE (C	- w (οραφω)) ΑΡSULE)	Size Impri	nt Code keting Start Date	4i Fi	nm J;7;mg keting End Date
OLEIC ACID (UNIL 2) MEDIUM-CHAIN TRI GELATIN, UNSPECII  Product Chara- Color Shape Flavor Contains  Packaging # Item Code	UMI9U37CP) IGLYCERIDES FIED (UNI: 2C  CTEFISTICS  yellow (yello  CAPSULE (C	(REGUN327L)  W (opaque))  APSULE)  ckage Description	Size Imprii	nt Code keting Start Date	44 FI	nm J;7;mg ceting End Date
OLEIC ACID (UNR) 24 MEDIUM-CHAIN TRI GELATIN, UNSPECIA Product Chara- Color Shape Flavor Contains  Packaging # Item Code 1 33 MOC.0456-3407	UMI9U37CP) IGLYCERIDES FIED (UNI: 2C  CEEriStics  yellow (yelk  CAPSULE (C  Pa  30 in 1 BOTTI  Product	ive (opaque)) APSULE)  ckage Description  £: Type 0: Not a Combination	Size Imprii	nt Code keting Start Date	44 FI	nm J;7;mg ceting End Date
OLEIC ACID (UNIL: 2t MEDIUM-CHAIN TRI GELATIN, UNSPECII  Product Chara- Color Shape Flavor Contains  Packaging # Item Code , NOC:0455-3407-	UMI9U37CP) IGLYCERIDES FIED (UNI: 2G  CEETISTICS  yellow (yello  CAPSULE (C  Pa  30 in 1 BOTTI  Product	ive (opaque)) APSULE)  ckage Description  £: Type 0: Not a Combination	Mari 10/31/2	nt Code keting Start Date	44 FI Mari	nm J;7;mg keting End Date

memantine	hydrochloride c	apsule, extended release				
Product	Information					
		HUMAN PRESCRIPTION DRIES		ode (Source)	MDC	1456-3414
Product Ty			Item C	.ode (Source)	NDC:	3420-3414
Route of A	dministration	ORAL				
Active In	aredient/Activ	e Moietv				
	Ina	redient Name		Basis of Str	enath	Streng
MEMANTINE UNII:WB017S	HYDROCHLORIDE	(UNI: JYOWDOUA60) (memantine -		MEMANTINE HYDROCHLORIDE		14 mg
Inactive I	ngredients					
		Ingredient Name			St	rength
	II: C151H8M554)					
	30 (UNI: U725QW/3					
talc (UNII: 75		S) (UNII: 36SFW2JZ0W)				
	e alvoi 400 (UNII:					
		(UNI: 06620K8M3B)				
		(UNI: 47MLB0F1MV)				
	INI: 5138019F1X)	(Unit. 47 PEDUI 2PIV)				
	SPECIFIED (UNI:	2G86ON327L)				
MEDIUM-CH	AIN TRIGLYCERIDI	ES (UNII: C9H2L21V7U)				
OLEIC ACID	(UNII: 2UMI9U37CP)					
Product (	Characteristic	s				
Color	yellow (yellow) ,	green (dark green (opaque))		Score	r	io score
Shape	CAPSULE (CAPS	ULE)		Size	4	lmm
Flavor				Imprint Code	F	Ll;14;mg
Contains						

		Marketine Stan	Marketing 5
# Item Code 1 NDC:0456-		Marketing Start Date	Date Date
1 NDC:0456- 3414-33 2 NDC:0456- 3414-90	Product  90 in 1 BOTTLE; Type 0: Not a Combination Product	10/31/2011	03/31/2023
3 NDC:0456- 3414-63	10 in 1 BOX, UNIT-DOSE	10/31/2011	09/06/2016
3 NDC:0456- 3414-11	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
Marketing	Information		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing E Date
	'	20/31/2011	
NAMENDA memantine hyd	XR rochloride capsule, extended release		
Product Info	rmation		
Product Type	HUMAN PRESCRIPTION DRUG  ORAL	Item Code (Source)	NDC:0456-34
Active Incom	lient/Active Molety		
	Ingredient Name ROCHLORIDE (UNI: )YOWCOUA60) (memantine -	Basis of S	
UNII:WB017SJF3T)		HYDROCHLORI	DE 21 mg
Inactive Ingr	Ingredient Name		Strength
sucrose (UNI: C1 povidone K30 (U	51H8M554) NII: U725QW/32X)		
talc (UNII: 7SEV7)4	10 (15 MPA.S) (UNII: 36SFW2;ZOW) IR1U) col 400 (UNII: 8697894SGQ)		
POLYETHYLENE (	SLYCOL 8000 (UNI: Q662QK8M3B) E (100 MPA.S) (UNI: 47MLB0F1MV)		
AMMONIA (UNI: 5 OLEIC ACID (UNI:	138Q19F1X) 2UMI9U37CP)		
MEDIUM-CHAIN T	PRIGLYCERIDES (UNII: C9H2L21V7U) CIFIED (UNII: 2G86QN327L)		
Product Chai	acteristics		
Color whi Shape CA	te (white to off-white) , green (dark green (opaque)	Score Size	no scor
Flavor Contains			Code FLU:21:r
Packaging # Item Code	Package Description	Marketing Start	Marketing E
1 NDC:0456-3421		Date 10/31/2011	Date
Marketing Marketing	Information Application Number or Monograph Citation	Marketing Start	Marketing E
Category	Citation NDA022525	Date 10/31/2011	Date
NAMENDA	XR		
memantine hyd	rochloride capsule, extended release		
Product Info		Item Code (Source)	NDC:0456-34
	olistration ORAL		
Active Ingred	lient/Active Moiety		
	Ingredient Name ROCHLORIDE (UNI: )YOWDOUA60) (memantine -	Basis of S MEMANTINE HYDROCHLORIC	Strength Strength
UNII:W8017SJF3T)		HYDROCHLORI	DE 28 mg
Inactive Ingr	edients		
sucrose (UNI: C1	Ingredient Name		Strength
povidone K30 /11			
tale (UNII: 7SEV7)	NI: U725QW/32X) 10 (15 MPA.S) (UNII: 365FW2/ZOW)		
talc (UNII: 7SEV7)- polyethylene gly POLYETHYLENE	NI: U725QW/32X) 10 (15 MPA.5) (UNII: 365FW2/ZOW) IRIU) ERU) 501 400 (UNII: 86978945GQ) SLYCOL 8000 (UNII: Q662QK8M3B)		
talc (UNII: 7SEV7)4 polyethylene gly POLYETHYLENE ( ETHYLCELLULOS AMMONIA (UNII: 5	NIE U725QWY32X) 10 (15 MPA.S) (UNIE: 365FV2/JZOW) RRIU)  col 400 (UNIE: 86978945GQ) SLYCOL 8000 (UNIE: Q662QKSM3B) E (100 MPA.S) (UNIE: 47MLB0F1MV) 133Q19F1X)		
talc (UNI: 7SEV7): polyethylene gly POLYETHYLENE ( ETHYLCELLULOS AMMONIA (UNI: S OLEIC ACID (UNI: MEDIUM-CHAIN 1	NIE U725QWY32X) 10 (15 MPA.S) (UNIE: 365FV2/JZOW) RRIU)  col 400 (UNIE: 86978945GQ) SLYCOL 8000 (UNIE: Q662QKSM3B) E (100 MPA.S) (UNIE: 47MLB0F1MV) 133Q19F1X)		
talc (UNI: 75EV7)- polyethylene gly polyethylene ETHYLCELULOS AMMONIA (UNI: 5 OLEIC ACID (UNI: MEDIUM-CHAIN 1 GELATIN, UNSPE	NIL U7350WTZXX 10(13 MPA.3) (UNIL 365YU)Z-DW  NELU)  NELU)  NELU SUNI 869789456(0)  NELYCOL 8000 (UNIL 565YU)Z-DW  NELYCOL 8000 (UNIL 565Z06M38)  E DOO MPA.5) (UNIL 47ME.80F1M4)  1380(1911)  NELWORNSTOP()  FORGELYCEROPS (UNIL CSHC2.21YVU)  CEPIED (UNIL 2086CM2271)		
tale (UNI: 75EV7)- polyethylene gly POLYETHYLENE ETHYLCELLULOS AMMONIA (UNI: 5 OLEIC ACID (UNI: MEDIUM-CHAIN 1 GELATIN, UNSPE	NE U725/00/1202 10.15 MPA-33 (UNE: 365/V0/2/2004 NELU) 10.15 MPA-33 (UNE: 365/V0/2/2004 NELU) 10.15 MPA-34 (UNE: 365/V0/2/2004 NEVCOL 8000 (UNE: 0662/00/8016)	Score Size	no score
tale (UNI: 75EV7)- polyethylene gly POLYETHYLENE ETHYLCELLULOS AMMONIA (UNI: 5 OLEIC ACID (UNI: MEDIUM-CHAIN 1 GELATIN, UNSPE	NIL U7350WTZXX 10(13 MPA.3) (UNIL 365YU)Z-DW  NELU)  NELU)  NELU SUNI 869789456(0)  NELYCOL 8000 (UNIL 565YU)Z-DW  NELYCOL 8000 (UNIL 565Z06M38)  E DOO MPA.5) (UNIL 47ME.80F1M4)  1380(1911)  NELWORNSTOP()  FORGELYCEROPS (UNIL CSHC2.21YVU)  CEPIED (UNIL 2086CM2271)	Score Size Imprint Code	no score 3mm
tale (UNII: 75EV7) polyethylene gly POLYETHYLENE : ETHYLERLUGELUGE AMMONIA (UNI: 5 OLEIC ACID (UNI: MEDIUM-CHAIN 1 GELATIN, UNSPE- Product Chai Color Shape Flavor Contains	NE U725/00/1202 10.15 MPA-33 (UNE: 365/V0/2/2004 NELU) 10.15 MPA-33 (UNE: 365/V0/2/2004 NELU) 10.15 MPA-34 (UNE: 365/V0/2/2004 NEVCOL 8000 (UNE: 0662/00/8016)	Size	no score 3mm
take (MNI: 75EVP) polyethylene gly POLYETHYLENE ETHYLCELLULOS OLEIC ACID (UNIE BOLEIC ACID (UNIE FOLIALITY GELATIN, UNSPE- Product Chair Color Shape Flavor Contains Packaging	INI U752/07200 10.15 MPA.3 (JUNI MISERY/02/09) 10.15 MPA.3 (JUNI MISERY/02/09) 10.16 MPA.3 (JUNI MISERY/02/09) 10.16 MPA.3 (JUNI MISERY/02/09) 10.16 MPA.3 (JUNI MISERY/04/09) 10.16 MPA.3 (JU	Size Imprint Code	no score 3mm FLt28;mg
take (MNIE: PSEVY) polysthylene gly polysthylene gly polysthylene gly polysthylene gly polysthylene gly polysthylene gly menium-Chain t GELATIN, UNIS S  Product Chair Color Shape Flavor Contains  Packaging # Item Code 1 NOC:0456-	THE UTS/GROWN TO THE UTS/GROWN TO THE THE UTS/GROWN TO THE THE UTS/GROWN TO THE UTS/GROWN T	Size	no score 3mm FLt28;mg
tate (UMI: 75EV)/ polysthytene (polysthytene) polysthytene (polysthytene) polysthytene) polysthytene) polysthytene) polysthytene) polysthytene (polysthytene) polysthytene) polysthytene	THE UTS/GROWN TO THE UTS/GROWN TO THE THE UTS/GROWN TO THE THE UTS/GROWN TO THE UTS/GROWN T	Imprint Code  Marketing Start Date	no score 3mm FLt28;mg
tate (UMI: 75EV)/ polysthylene gly polysthylene gly polythyruse is privately polythyruse is privately polythyruse polythylene	IN UTS/GRAPIZO  10.15 SPACE, SI DINI JESPINZZONO  ILLU  Illu	Imprint Code   Impr	no score 3mm FL128/mg Marketing E Date
tate (UMI: 75EV)/ polysthytene (polysthytene) polysthytene (polysthytene) polysthytene) polysthytene) polysthytene) polysthytene) polysthytene (polysthytene) polysthytene) polysthytene	INCLUSION DE SERVICION DE SERVI	Imprint Code   Impr	no score 3mm FL128:mg Marketing E Date 03/31/2023
tate (UMI 75EV)/ populythipiene gip polythythene gip polythythene gip polythythene gip polythythene gip polythythene gip polythythene polythythene polythythene polythythene polythythene polythene polythythene polythythene polythythene polythythene polythene polythythene polythy	INCLUSION DE LOS DE LA COMBINACION DEL LA COMBINACION DE LA COMBINACION DE LA COMBINACION DE LA COMBINACION DEL LA COMBIN	Imprint Code   Impr	no score 3mm FL128:mg Marketing E Date 03/31/2023
tate (JURI 75EV/J) polyethylene jop poly	IN UTS/GROWING THE	Marketing Start Date  10/31/2011  10/31/2011  Marketing Start Date  Marketing Start Date	no score Jame FLIZE.mg  Marketing E Date 03/01/2021  Marketing E Date
tate (JURI 75EV/J) polyethylene jop poly	IN UTS/GRAPIZO  10.15 SPACE, 3 (IDM. SERVING/COR)  THAN 10.15 SPACE, 3 (IDM. SERVING/C	Marketing Start   Date   10/31/2011   10/3	no score Jame FLIZE.mg  Marketing E Date 03/01/2021  Marketing E Date
Tate (JUNE TSEVI)  proposition of the proposition o	INCLUSION DE LOS DE LA COMBINACION DEL LA COMBINACION DE LA COMBINACION DE LA COMBINACION DEL LA C	Marketing Start Date  10/31/2011  10/31/2011  Marketing Start Date  Marketing Start Date	no score Jame FL128:mg Marketing E Date 03/01/2023
tate (JUNE / SEV/)  population of the control of th	THE UTSTANDAY DIVISION TO THE UTSTANDAY DIVISION THE UTSTANDAY DIVISION TO THE UTSTANDAY DIVISION TO THE UTSTANDAY DIVISION TO THE UTSTANDAY DIVISION TO THE UTSTANDAY DIVISION THE UTSTANDAY DIVISION TO THE UTSTANDAY DIVISION T	Marketing Start Date  10/31/2011  10/31/2011  Marketing Start Date  Marketing Start Date	no score Jame FLIZE.mg  Marketing E Date 03/01/2021  Marketing E Date
Late (JUNE 1755V)  polythylenes (June 1755V)  polythylenes (June 1755V)  polythylenes (June 1755V)  product Chaic  Color  Shape  Flavor  Contains  Packaging  # Rem Code  1 MCC 0556  1 MC	THE UTSTANDAY DIVISION TO THE UTSTANDAY DIVISION THE UTSTANDAY DIVISION TO THE UTSTANDAY DIVISION TO THE UTSTANDAY DIVISION TO THE UTSTANDAY DIVISION TO THE UTSTANDAY DIVISION THE UTSTANDAY DIVISION TO THE UTSTANDAY DIVISION T	Marketing Start Date 1001/2011 1001/2011 1001/2011 Marketing Start Edge 1001/2011	no score Jam FL128.mg Marketing E Date  03/31/2023 09/06/2016
tate (June 17527)  product Chair  product Type	THE UTS/GROUPSON  10.15 SPACES, DIVIN SERVING/CORE  THAT  THE UTS SPACES, DIVIN SERVING/CORE  THAT SPACES AND SERVING/CORES  EL 10.0 SPACES, DIVIN CHARGOTISMS  SERVING/CORES  THAT SPACES AND SERVING/CORES  THAT SPACES	Marketing Start Date 1001/2011 1001/2011 1001/2011 Marketing Start Edge 1001/2011	no score Jam FL128:mg FL128:mg Marketing E Date 03/31/2022 09/06/2016
tate (JUNI 75EV)  populyshipiene jun  populysh	THE UTS/GROUPSON  10.15 SPACES, DIVIN SERVING/CORE  THAT  THE UTS SPACES, DIVIN SERVING/CORE  THAT SPACES AND SERVING/CORES  EL 10.0 SPACES, DIVIN CHARGOTISMS  SERVING/CORES  THAT SPACES AND SERVING/CORES  THAT SPACES	Size imprint Code	no score 3mm FL128-mg Marketing E Date  Marketing E Date  Marketing E Date
tate (JMM 75EV)  product Charles  produc	INCLUSION DE LA COMBINATION DEL COMBINATION DE LA COMBINATION DE L	Marketing Start Local Local Marketing Start Local Local Local Local Marketing Start Local Local Marketing Start	Marketing E Date  NOC.0456-3400  Marketing E Date  Marketing E Date  NOC.0456-3400
tate (JMR 175EV)  product The Contrains  Product Char Contrains  Product The Contrains  Marketing  Ma	INTO 15 SPACE, 3 (INC. 15 SPACE) SPACE OF SPACE	Marketing Start Local Local Marketing Start Local Local Local Local Marketing Start Local Local Marketing Start	ms sore  mm Fal28.mg Fal28.mg  Marketing E 03/01/02/2 09/06/2016  Marketing E Date  NOC.0456-3400  Marketing E Date
tate (JMM TSEVI)  population of the control of the	INC. 1975/00/2070  10.15 1894-3.3 IDMS INSERVIÇUON  10.15 1894-3.3 IDMS INSERVIÇUON  10.15 1894-3.3 IDMS INSERVIÇUON  10.15 18.0 IDM	Marketing Start Local Local Marketing Start Local Local Local Local Marketing Start Local Local Marketing Start	no score Jamin Fischering Fischering Date 03/01/2023 00/06/2016 Marketing E Date 12/2/2018
Late (JUNI 75EV)  product Charles  Color Charles  product	TO 15 18 MAS 19 MIN SERVICE/ORD  TO 15 MAS 19 MIN SERVICE/ORD  TO 15 MAS 19 MIN SERVICE/ORD  TO 16 MIN SERV	Marketing Start Local Local Marketing Start Local Local Local Local Marketing Start Local Local Marketing Start	no score Jamin Fischering Fischering Date 03/01/2023 00/06/2016 Marketing E Date 12/2/2018
tate (JMM 75EV)  population of the population of	TO 15 SPACE, 3 DIVIN 1567962709  101.5 SPACE, 3 DIVIN 1567962709	Marketing Start Local Local Marketing Start Local Local Local Local Marketing Start Local Local Marketing Start	no score Jamin Fischering Fischering Date 03/01/2023 00/06/2016 Marketing E Date 12/2/2018
tate (JUNE 755-77)  tate (JUNE 755-77)  product Char  tate (JUNE 755-77)  product Char  tate (JUNE 755-77)  product Char  tate (JUNE 755-77)  product Info	TO 15 SPACE, 3 DIVIN 1567962 DIVIN 1667962 DIVIN 1667962 DIVIN 1667962 DIVIN 1667962 DIVIN 1667962 DIVIN 166796 DIVIN 1667	Marketing Start Local Local Marketing Start Local Local Local Local Marketing Start Local Local Marketing Start	no score Jamin Fischering Fischering Date 03/01/2023 00/06/2016 Marketing E Date 12/2/2018
tate (JMM 75EV)  product Ton Colors  product Char  color Char  product Char	TO 15 18 MAS 19 MIN SERVICE/DOWN  TO 15 18 MAS 19 MIN SERVICE/DOWN  THE SERVICE SERVICE SERVICE SERVICE SERVICE  EL ROS MAS 19 MIN STANDARD SERVICE  EL ROS MAS 19 MIN STANDARD SERVICE  EL ROS MAS 19 MIN STANDARD SERVICE  MAS 19 MIN STANDARD SERVICE  PROCESSED SERVICE SERVICE SERVICE  PROCESSED SERVICE SERVICE  PROCESSED SERVICE SERVICE SERVICE SERVICE SERVICE  PROCESSED SERVICE SE	Marketing Start Local Local Marketing Start Local Local Local Local Marketing Start Local Local Marketing Start	no score Jami Fs22amg Fs22amg Marketing t O3/01/02/016  Marketing t Date  NoC-0456-3400  Marketing t Date
tate (JMM 75EV)  product Ton Colors  product Char  color Char  product Char	TO 15 1994.3   DIN 15 1994.2   DIN 15 1994.3	Marketing Start Local Local Marketing Start Local Local Local Local Marketing Start Local Local Marketing Start	no score Jamin Fischering Fischering Date 03/01/2023 00/06/2016 Marketing E Date 12/2/2018
tate (JUNI 75EV)  product Char  Contains  Removed  Remove	TO 15 1994.3 JUNI SECTION TO 15 1994.5 JUNI	Marketing Start Local Local Marketing Start Local Local Local Local Marketing Start Local Local Marketing Start	no score Jami Fs22amg Fs22amg Marketing t O3/01/02/016  Marketing t Date  NoC-0456-3400  Marketing t Date
tate (JMM 75EV)  product Char	TO 15 1994.3 JUNI SECTION TO 15 1994.5 JUNI	Marketing Start Local Local Marketing Start Local Local Local Local Marketing Start Local Local Marketing Start	no score Jami Fs22amg Fs22amg Marketing t O3/01/02/016  Marketing t Date  NoC-0456-3400  Marketing t Date
tate (JMT 75EV)  product Char  Color  Product Char  Color  Flavor  Contains  Packaging  # Item Code  1 MCC 4556  3 3028-315  Marketing  Favor  Category  NAMENDA  Memantine hyd  Product Info  Packaginy  # Item Code  1 MCC 4556-3400  Quantity of F  Part 2  Part 3  Part 3  Part 1  Part 1  Part 1 Of 4  NAMENDA  Remandine hyd  NAMENDA  Remandine hyd  Product Info  Product Info  Route of Admin	TOTS IN A TOTS I	Marketing Start Local Local Marketing Start Local Local Local Local Marketing Start Local Local Marketing Start	no score Jami Fs22amg Fs22amg Marketing t O3/01/02/016  Marketing t Date  NoC-0456-3400  Marketing t Date
tate (JMM 75EV)  product Total (JMM 75EV)  product Char Color (JMM 75EV)  product Info (JMM	IN 1975/09/09/10/10/10/10/10/10/10/10/10/10/10/10/10/	Marketing Start Institute Star	no score Dam Filipling Filipling Filipling Marketing t Oxid12023 05/06/2016  Marketing t Date 12/31/2028  Marketing t Date 12/31/2028
tate (JMM 75EV)  product Total (JMM 75EV)  product Char Color (JMM 75EV)  product Info (JMM	TO 15 19 MAS 10 MIN SERVICE/DOWN  10 15 19 MAS 10 MIN SERVICE/DOWN  10 15 19 MAS 10 MIN SERVICE/DOWN  10 16 10 10 MIN SERVICE/DOWN	Marketing Start Institute Star	no score Dam Filipling Filipling Filipling Marketing t Oxid12023 05/06/2016  Marketing t Date 12/31/2028  Marketing t Date 12/31/2028
tate (JMM 75EV)  product Total (JMM 75EV)  product Char Color (JMM 75EV)  product Info (JMM	TO 15 18 MAS 19 MIN SERVICE/DON  10.15 18 MAS 19 MIN SERVICE/DON	Marketing Start  Marketing Start  Marketing Start  Marketing Start  Marketing Start  Date  Marketing Start  Outs Out (1971)  Marketing Start  Out (2071)  Marketi	no score Jamm FLUZerng FLUZerng FLUZerng FLUZerng Marketing E Osciol2016  Marketing E Oste 12/31/2018  Marketing E Oste 12/31/2018  Marketing E Oste 12/31/2018
tate (JMM 75EV)  product Charles  Finance Category  From Code  Finance Category  From Code  Finance Category  Finance Ca	TO 15 SPACE, 3 DIVIN 1567962 POR  TO 1	Marketing Start  Marketing Start  Marketing Start  Marketing Start  Marketing Start  Date  Marketing Start  Outs Out (1971)  Marketing Start  Out (2071)  Marketi	no score Jamm FLUZerng FLUZerng FLUZerng FLUZerng Marketing E Osciol2016  Marketing E Oste 12/31/2018  Marketing E Oste 12/31/2018  Marketing E Oste 12/31/2018
tate (JMIT 25EV)  product Type  Product Info  Product Info	TO 15 1994.3 JUNI SECTION TO 10 15 1994.5 JUN	Marketing Start  Marketing Start  Marketing Start  Marketing Start  Marketing Start  Date  Marketing Start  Outs Out (1971)  Marketing Start  Out (2071)  Marketi	no score Jamm FLUZerng FLUZerng FLUZerng FLUZerng Marketing E Osciol2016  Marketing E Oste 12/31/2018  Marketing E Oste 12/31/2018  Marketing E Oste 12/31/2018
tate (JMR 75EV)  product Total  product Char  color  product Char  product Info  Route of Admin  Active Ingree  sucress (JMR CL  product Info  product Info  Route of Admin  Active Ingree  sucress (JMR CL  product Ingree  product Info  product Info  Route of Admin  Active Ingree  sucress (JMR CL  product Ingree  sucress (JMR CL  propriedors 120 (JMR CR  product Info  p	TOTS 1994-33 DINI SERVING TORS  TOTS 1994-33 DINI SERVING TORS  TOTS 1994-33 DINI SERVING TORS  TOTS 1994-34 DINI SERVING TORS	Marketing Start  Marketing Start  Marketing Start  Marketing Start  Marketing Start  Date  Marketing Start  Outs Out (1971)  Marketing Start  Out (2071)  Marketi	no score Jamm FLUZerng FLUZerng FLUZerng FLUZerng Marketing E Osciol2016  Marketing E Oste 12/31/2018  Marketing E Oste 12/31/2018  Marketing E Oste 12/31/2018
tate (JMI 75EV)  product Top  Product Chai  Contains  Flavor  Contains  Packaging  # tem Code  1 34CC 2035  1 34CC 2035  1 34CC 2035  3 30CC 2045  3 30CC 2045  3 30CC 2045  3 30CC 2045  4 30CC 2045  5 3 30CC 2045  7 700  Marketing	TO 15 1994.3 JUNI SERVICE/DON  10.15 1994.3 JUNI SERVICE/DON	Marketing Start  Marketing Start  Marketing Start  Marketing Start  Marketing Start  Date  Marketing Start  Outs Out (1971)  Marketing Start  Out (2071)  Marketi	no score Jamin Fischering Fischering Date 03/01/2023 00/06/2016 Marketing E Date 12/2/2018
Table (July 2007)  The Control of th	TO 15 1994.3 pilos Miscretigo (19 15 1994.3) pilos Miscretigo	Marketing Start  Marketing Start  Marketing Start  Marketing Start  Marketing Start  Date  Marketing Start  Outs Out (1971)  Marketing Start  Out (2071)  Marketi	no score Jamm FLUZEINg FLUZEINg FLUZEINg FLUZEINg ADC-0456-3400 Marketing E Date  Marketing E Date  Marketing E J2/31/2018  Marketing E J2/31/2018

Color Shape		cteristics yellow (YELLOW (OPAQUE)) CAPSULE (CAPSULE)	Score Size	no score
Flavor Contains		CA JULE (CA JULE)	Imprint Code	FLI;7;mg
Contains				
Market	ing l	nformation		
Marke Categ	ting ory	Application Number or Monograph Citation	Marketing Start Date 09/15/2011	Marketing En Date
NDA		NDA022525	0W15/2011	
Part 2	of 4			
NAMEN	IDA 2	(R		
memanun	e ilyulu	chloride capsule, extended release		
Product	Inforn	nation		
Route of	Adminis	tration ORAL		
Active In	gredie	nt/Active Moiety		
		Ingredient Name Moride (UNI: JYOWDOUA60) (memantine -	Basis of S memantine hydrochloride	trength Streng
UNII:WBO17S	(JF3T)		hydrochloride	14 1119
Inactive	Ingred	lients		
sucrose (U)				Strength
hypromello talc (UNII: 7:	se 2910	U725QW/32X) (15 MPA.S) (UNII: 36SFW2JZ0W)		
polyethyles	ne glyco	I 400 (UNII: B697894SGQ) I 8000 (UNII: Q662QKBM3B)		
ethylcelluk ammonia (l	se (100 JNII: 5138	MPA.S) (UNII: 47MLB0F1MV) 8Q19F1X)		
OLEIC ACID MEDIUM-CH	(UNI: 20	JMI9U37CP) GLYCERIDES (UNII: C9H2L21V7U)		
GELATIN, U	NSPECIF	HED (UNI: 2G86QN327L)		
Product	Charae	cteristics		
Color Shape	yello	w (YELLOW) , green (DARK GREEN (OPAQUE)) ULE (CAPSULE)	Score Size	no score 14mm
Flavor Contains			Imprint Co	de FU;14;mg
		nformation	Marketing Str.	Marketing
Categ	ory	Application Number or Monograph Citation NDA022525	Date 09/15/2011	Date Date
Part 3				
NAMEN memantin	IDA 2 e hydro	KR chloride capsule, extended release		
Product				
Route of	Adminis	tration ORAL		
Active In	gredie	nt/Active Moiety		
		nt/Active Moiety Ingredient Name Noride (UNI: YOWDOUASO) (memantine -		trength Stren
		nt/Active Moiety Ingredient Name Moride (UNI: )YOWDOUA60) (memantine -		trength Streng
memantine UNI:WBO17S	hydroci (F3T)	Ingredient Name  Noride (UNI: )YOWDOUA60) (memantine -		
memantine UNI:W8017S	hydroci (F3T)	Ingredient Name  Moride (UNI: )YOWOOUA60) (memantine -  lients  Ingredient Name	memantine hydrochloride	
memantine UNIEW8017S Inactive sucrose (UNIEW8017S	hydroci (F3T) Ingred	Ingredient Name Moride (UNI: y/0WD0UA60) (memantine -  Illents Ingredient Name  188554)	memantine hydrochloride	21 mg
memantine UNI:W80175  Inactive sucrose (UI) povidone K hypromello talc (UNI: 7:	Ingred	Ingredient Name Moride (UNI: )YOVIDOUA60) (memantine -  lients Ingredient Name  18M554) U725(WW32X) U725(WM32X) (LS MPA.5) (UNI: 365FW2/20W)	memantine hydrochloride	21 mg
inactive sucrose (UNIE 7: polyethyles polyethyles polyethyles ethylcelluke	hydroci (F3T) Ingred II: C151E 30 (UNI: se 2910 SEV7/4R1 ne glyco ne glyco se (100	Ingredient Name  Meride (JNH: )FOMCOUAGO) (memantine -  Illents  Ingredient Name  8040554) (123 9MrA; 50, UMH: 365790/2709) (123 9MrA; 50, UMH: 365790/2709)  14 9000 (JUH: 96620/381488)  14 9000 (JUH: 96620/381488)	memantine hydrochloride	21 mg
Inactive sucrose (UI) polyathyler polyathyler polyathyler ethyleriluk ammonia (L OLEIC ACID)	hydroci (F3T) Ingred II: C151: 30 (UNI: 5e 2910 5e 2910 5e 2910 6e glyco 6e glyco 6e (106 6uni: 5138	Ingredient Name Merde (JNB) (PORCOUAGO) (meneration - Indress	memantine hydrochloride	21 mg
Inactive sucrose (UP povidone K hypromello tate (UNI: 7: polyethyler ethylcellule ammonia (L OLEIC ACID MEDIUM-CE MEDIUM-CE	hydroci (F3T) Ingred II: C151: 30 (UNI: 5e 2910 SEV7)4R1 ne glyco ose (108: 0 (UNI: 21	Ingredient Name Meride (JMB: (POVDOUAGO) (Imematice - Idents Ingredient Name MINISTER (Impredient Name MINISTER (Impredien	memantine hydrochloride	21 mg
memantine UNIL-W80175  Inactive sucrose (UI) povidone K hypromello talc (UNIL: 7: polyathyles polyathyles ethylcellule ammonia (L OLIEC ACIB MEDIUM-C: GELATIN, U	Ingred II: C1518 30 (UNI: Se 2910 See 2910 See glyco se (100 INI: 5138 (UNI: 21 HAIN TRI	Ingredient Name  Wester Street (1997-1997-1997-1997-1997-1997-1997-1997	memantine hydrochloride	21 mg
memantine UNIEW80175  Inactive sucrose (UNIE Providence K hypromello tale (UNIE Prophythyler polyethyler polyethyler ethyleelluk ammonia (UNIE Product)  Product	Ingred III C1518	Ingredient Name  Herital State (DIOCCOULGO) (Immensation -  Herital Ingredient Name  Herital Ingredient Name  HOSSIN STATE (INGREDIENT NAME  HOSSIN STATE (	memantine hydrochloride	21 mg
memantine UNIL-W80175  Inactive sucrose (UI) povidone K hypromello tale (UNIL-7: polyethyler ethylcelluk ammonia (L OLEIC ACID MEDIANCIA GELATIN, U  Product Color Flavor	hydrocic (151)  Ingred  II: (151)  II: (151)  II: (152)	Ingredient Name  Wester Street (1997-1997-1997-1997-1997-1997-1997-1997	memantine hydrochloride	21 mg
memantine UNIL-W60175  Inactive sucrose (UP povidone K hypromello tale (UNIL-7 polyethyler polyethyler thylcellula ammonia (t OLEIC ACID MEDIUM-C: GELATIN, U  Product Color Shape	hydrocic (151)  Ingred  II: (151)  II: (151)  II: (152)	Ingredient Name  Herital State (DIOCCOULGO) (Immensation -  Herital Ingredient Name  Herital Ingredient Name  HOSSIN STATE (INGREDIENT NAME  HOSSIN STATE (	memantine hydrochloride	Strength
memantine UNIF-W60175  Inactive sucrose (UN povidone K hypromello tale (UNIF-7 polyethyler polyethyler ethyler	hydroci je31) Ingred all: C1511 all: C1513 all: C1513 a	Integration Name  Wester State (1997-1997-1997-1997-1997-1997-1997-1997	memarine   hydrachloride   hydrachloride   score   size   Imprin	Strength  Strength  no score  44mm  RU21;m
memantine UNIF-W60175  Inactive sucrose (UP povidone K hypromello tac (UNIF-7 polyethyles	hydroci je31) Ingred  iii (151) iii (251) iii	Ingredient Name  Warded SNIB (PORCOUND) (Immension -  Idents  Ingredient Name  WARDED (Immension -  Immension -  I	memarica	Strength  Strength  no score  44mm  RU21;m
memantine UNIF-W60175  Inactive sucrose (UN povidone K hypromello tale (UNIF-7 polyethyler polyethyler ethyler	hydroci je31) Ingred  iii (151) iii (251) iii	Integration Name  Wester State (1997-1997-1997-1997-1997-1997-1997-1997	memarine   hydrachloride   hydrachloride   score   size   Imprin	Strength  Strength  no score  44mm  RU21;m
memantine  Inactive  sucress (I/I with the sucress of the sucress	Ingred III. Ingred III. III. III. III. III. III. III. III	Ingredient Name  Warded SNIB (PORCOUND) (Immension -  Idents  Ingredient Name  WARDED (Immension -  Immension -  I	memarica	Strength  Strength  no score  44mm  RU21;m
memantine Inactive sucrose (JI of the State	Ingred  III. (151)	Ingredient Name  Weeted SIME (PORCOUAGE) (premaratine -  Idents Ingredient Name  100554 (premaratine -  100554 (pr	memarica	Strength  Strength  no score  44mm  RU21;m
memantine Inactive sucrose (JI of the State	Ingred  III. (151)	Ingredient Name  Warded SNIP (PORCOUND) (Immunition -  Ilients Ingredient Name  Biogradient Name  Biog	memarica	Strength  Strength  no score  44mm  RU21;m
memantine unit Web 175  Inactive sucrose (JI of the	hydroci  #37)  Ingred #30 (UNE: C151)  Be glyco  Be glyco  GUNE: 20  CAPSU  Charac  white ( CAPSU  CAPSU  CAPSU  De hydro  de hydro	Ingredient Name  Warded SNIP (PORCOUND) (Immunition -  Illents  Ingredient Name  Ingredient	memarica	Strength  Strength  no score  44mm  RU21;m
memantine  Inactive  sucrose (JI   Inactive  sucrose (	hydroci  #37)  Ingred #I. C1513 30 (UNE 26 2910  E. G1513  MIL C1513 30 (UNE 26 2910  MIL C1513  WHILD (MIL C1514  WHILD	Ingredient Name  Warded SNIP (PORCOUND) (Immunition -  Illents  Ingredient Name  Ingredient	memarica	Strength  Strength  no score  44mm  RU21;m
memantine unit veol 175 Inactive success (II) projection in the success (III) projection in th	hydrocide #31)  Ingred  #: C151)  30 (UNIE 330	Ingredient Name  Warded JNN: [PORCOUND) (premaratine -  Idents Ingredient Name  BINS: Ingre	memarica	Strength  Strength  no score  44mm  RU21;m
memantine memant	hydrocile #37)  Ingred  #: C151)  30 (UNIE 330	Interested SIME (PORCEAUMO) (Immensation - Immensation - I	Institution (hydrochloride hydrochloride hyd	21 mg Strength  no score 14mm t Code Fu 21m Date
memantine memant	hydrocile #37)  Ingred  #: C151)  30 (UNIE 330	Ingredient Name  strette SIME (PORCOUND) (Immension -  lients  Ingredient Name  stretts  Ingredient  Ingre	Institution of the control of the co	21 mg Strength  no storength  tense tense pulling
memantine with the control of the co	hydrocide hydroc	Ingredient Name  Warded SNIB (PORCOUND) (Immunition -  Idents Ingredient Name  Biogradient Name  KR Chibride Capsule, extended release  Pation  Total Operation Name  KR Chibride Capsule, extended release  Pation  Total Operation Name  KR Chibride Capsule, extended release  Pation  Total Operation Name  KR Chibride Capsule, extended release  Pation  Total Operation Name  KR Chibride Capsule, extended release  Pation  Total Operation Name  KR Chibride Capsule, extended release  Pation  Total Operation Name  Market District Name  Mar	Institution (hydrochloride hydrochloride hyd	21 mg Strength  no storength  tense tense pulling
memantine work of the control of the	hydrocide hydroc	Ingredient Name  Warted SIME (PORCOUND) (Immunition -  Idents  Ingredient Name	Desire of Service State Service Servic	21 mg Strength  no storength  tense tense pulling
memantine memant	hydroctory  iii C1511  iii C1512  iii C1513  ii C1513	Ingredient Name  Interest   Ingredient Name  Interest   Ingredient Name  I	Desire of Service State Service Servic	21 mg Strength an according to the strength Marketing Ed Date Date trength Strength
memantinement of the control of the	hydroctostal ingred  iii: C1511  iii: C151	Interested SIME (PORCOUND) (Immension - Immension - Im	Desire of Service State Service Servic	21 mg Strength an according to the strength Marketing Ed Date Date trength Strength
Inactive Ina	hydrocic see 2910 (Ingred winter a control of the c	Ingredient Name  Warted SIME (PORCOUND) (Immunition -  Illents  Ingredient Name  MISS (IMPURISH NAME  MISS (IMPURI	Desire of Service State Service Servic	21 mg Strength an according to the strength Marketing Ed Date Date trength Strength
memantime Inactive  Learning III Inactive  Le	hydroctopy in gred iii C1511 iii g li ii c2511 iii g li ii c3511 iii g li ii c4511 iii g li ii c5511 ii ii c551	Interested Name  Weeter State (1907-2004-200) (Immensation -  Illients Impredient Name  Imp	Desire of Service State Service Servic	21 mg Strength an according to the strength Marketing Ed Date Date trength Strength
memanation of the control of the con	Ingred  III Cape	Ingredient Name  Warted SIME (PORCOUND) (Immunition -  Idents Ingredient Name  100553	Desire of Service State Service Servic	Strength  as a code  Admin  E Code  F1121.n  Marketing Er  bate  trength Strength  Strength Strength
memantime manual material mate	hydrocic (153) and (153) a	Ingredient Name  Warted SIME (PORCOUND) (Immunition -  Idents Ingredient Name  100505   Ingredie	Desire of Service State Service Servic	21 mg Strength an according to the strength Marketing Ed Date Date trength Strength
memantime manuatime manuat	hydrocipes  Ingred  In	Interested SIME (PORCOLAND) (Immension - Immension - I	Desire of Service Serv	Strength  As score  As score  And recting E  Marketing E  trength  Strength  Strength
memanatine memanatine sucrose (II in active sucrose (II in active) memanatine meman	hydroctopy	Ingredient Name  Warted SIME (PORCOUND) (Immunition -  Idents Ingredient Name  100505   Ingredie	Provided Score Size Score Size Size Size Size Size Size Size Siz	Strength   Strength   No score
memanatine memanatine sucrose (II in active sucrose (II in active) memanatine meman	hydroctopy	Interested SIME (PORCOLAND) (Immension - Immension - I	Production (National Control of C	Strength   Strength   No score
mammatine manual	hydrocic property of the prope	Ingredient Name  Warted SIME (PORCOUND) (Immunition -  Idents Ingredient Name  10550, 105700, 105700, 105700, 105700, 105700, 10	Provided Score Size Score Size Size Size Size Size Size Size Siz	Strength   Strength   No score
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memantime memant	hydrocic hyd	Ingredient Name  Warted SIME (PORCOUND) (Immunition -  Idents Ingredient Name  10550, 105700, 105700, 105700, 105700, 105700, 10	Source   S	Strength  As score  An accord  An
memorations and the second of	hydrocic hyd	Ingredient Name  Warted SINE (PORCOUND) (Immension -  Idents Ingredient Name  Ingredient Na	Instruction Start  Size Start  Marketing Start  Start  Marketing Start  Start  Marketing St	Strength  As score  An accord  An
memoration with the control of the c	hydraci hydroci post post post post post post post post	Ingredient Name  Warted SINE (PORCOUND) (Immension -  Idents Ingredient Name  Ingredient Na	Marketing Start Optional Start Date Score Size Import Code  Marketing Start Optional Start Optio	21 mg Strength  no score 14mm Length Strength Strength Strength Strength Strength Aurketing En Date  No score 16mm PLL20mg  Marketing En Date

Labeler - Allergan, Inc. (144796497)

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