LUVENTA XL 8 MG, 16 MG AND 24 MG PROLONGED-RELEASE CAPSULES, HARD
(galantamine hydrobromide)

PL 42924/0001-0003

UKPAR

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LAY SUMMARY

Luventa XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard
(galantamine hydrobromide)

This is a summary of the public assessment report (PAR) for Luventa XL 8 mg, 16 mg and Luventa XL 24 mg prolonged-release Capsules, hard (PL 42924/0001 - 0003). It explains how Luventa XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard were assessed and their authorisations recommended, as well as their conditions of use. It is not intended to provide practical advice on how to use Luventa XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard.

For practical information about using Luventa XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard, patients should read the Patient Information Leaflet or contact their doctor or pharmacist.

What are Luventa XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard and what are they used for?

Luventa XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard contain the active ingredient galantamine (as hydrobromide). These medicines are used to treat the symptoms of mild to moderately severe dementia of the Alzheimer type, a disease that alters the brain function.

These medicines are identical to Consion XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard (PL 17277/0254 - 0256), which were authorised in the UK to Pharmathen SA on 15 February 2013. Pharmathen SA have agreed that scientific data presented for Consion XL 8 mg, 16 mg and 24 mg prolonged-release capsules, hard can be used for these applications (Luventa XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard).

How do Luventa XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard work?

Luventa XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard are anti-dementia medicines. These medicines are indicated for the symptomatic treatment of mild to moderately severe dementia of the Alzheimer type. Alzheimer's disease is a type of disease that alters brain function resulting in increasing memory loss, confusion and behavioural changes. These symptoms are believed to be due to a lack of acetylcholine, a substance responsible for sending messages between brain cells. These medicines work by increasing the amount of acetylcholine in the brain and therefore improving the symptoms of the disease.

How are Luventa XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard used?

Luventa XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard, are for oral use and can only be obtained with a prescription from a doctor. Luventa XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard are started at a low dose. The doctor will recommend increasing the dose slowly in order to find the most suitable dose. Treatment is started with 8 mg taken once daily. The dose is increased after four weeks to 16 mg

once daily. After four weeks the doctor may decide to increase the dose to 24 mg once daily. The doctor will decide on the most appropriate dose to begin treatment with and when to increase the dose.

Please read Section 3 of the Patient Information Leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment

What benefits of Luventa XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard have been shown in studies?

These applications are identical to the previously granted Marketing Authorisations for Consion XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard (PL 17277/0254-0256) held by Pharmathen SA. The applicant (Fontus Health Ltd) referred to data submitted by Pharmathen SA as a basis for the grant of identical licences for Luventa XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard.

What are the possible side effects of Luventa XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard?

The very common side effects (which may affect more than 1 in 10 people) are feeling sick and or vomiting.

The common side effects (which may affect up to 1 in 10 people) are weight loss, loss of appetite, decreased appetite, slow heartbeat, feeling faint, dizziness, trembling, headache, drowsiness, abnormally tired, stomach pain or discomfort, diarrhoea, indigestion, increased sweating, muscle spasms, falling, high blood pressure, feeling weak, general feeling of discomfort, seeing, feeling or hearing things that are not real and feeling sad.

For the full list of all side effects reported with Luventa XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard, see section 4 of the Patient Information Leaflet.

Why are Luventa XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard approved?

No new or unexpected safety concerns arose from these applications. It was, therefore, considered that the benefits of Luventa XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard outweigh their risks; and the grant of Marketing Authorisations were recommended.

What measures are being taken to ensure the safe and effective use of Luventa XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard?

A risk management plan has been developed to ensure that Luventa XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard are used as safely as possible. Based on this plan, safety information has been included in the Summary of Product Characteristics and the Patient Information Leaflet for Luventa XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard, including the appropriate precautions to be followed by healthcare professionals and patients.

Other information about Luventa XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard.

Marketing Authorisations were granted in the UK on 15 August 2014. For more information about treatment with Luventa XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard, read the Patient Information Leaflet, or contact your doctor or pharmacist.

This summary was last updated in October 2014.

The full PAR for Luventa XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard follows this summary.

LUVENTA XL 8 MG, 16 MG AND 24 MG PROLONGED-RELEASE CAPSULES, HARD

PL 42924/0001-0003

SCIENTIFIC DISCUSSION

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INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the UK granted Marketing Authorisations for the medicinal products Luventa XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard (PL 42924/0001-0003) on 15 August 2014 to Fontus Health Ltd.

These applications for Luventa XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard were submitted as abridged simple applications according to Article 10c of Directive 2001/83/EC, as amended, cross-referring to Consion XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard (PL 17277/0254 -0256), which were granted Marketing Authorisations to Pharmathen SA on 15 February 2013.

Luventa XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard can only be obtained with a prescription from a doctor (legal status POM) and is indicated for the symptomatic treatment of mild to moderately severe dementia of the Alzheimer type.

Luventa XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard contain the active ingredient galantamine (as hydrobromide). Galantamine, a tertiary alkaloid is a selective, competitive and reversible inhibitor of acetylcholinesterase. In addition, galantamine enhances the intrinsic action of acetylcholine on nicotinic receptors, probably through binding to an allosteric site of the receptor. As a consequence, an increased activity in the cholinergic system associated with improved cognitive function can be achieved in patients with dementia of the Alzheimer type.

PHARMACEUTICAL ASSESSMENT

LICENCE NOs:	PL 42924/0001-3
PROPRIETARY NAMES:	Luventa XL 8 mg, 16 mg, 24 mg prolonged-release Capsules, hard
ACTIVE(S):	Galantamine hydrobromide
COMPANY NAME:	Fontus Health Ltd
E.C. ARTICLE:	Article 10c
LEGAL STATUS:	POM

1. INTRODUCTION

These are simple, piggyback applications for Luventa XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard submitted under Article 10c of Directive 2001/83/EC, as amended. The proposed Marketing Authorisation Holder is Fontus Health Ltd, 1 Butts Street, Walsall WS4 2BJ.

These applications cross-refer to Consion XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard (PL 17277/0254-0256), which were granted Marketing Authorisations to Pharmathen SA on 15 February 2013.

The current applications are considered valid.

2. MARKETING AUTHORISATION APPLICATION FORM

2.1 NAME(S)

The proposed names of the products are Luventa XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard. The products have been named in-line with current requirements.

2.2 Strength, pharmaceutical form, route of administration, container and pack sizes

Each capsule contains the active substance galantamine (as hydrobromide) as follows:

Each Luventa XL 8 mg prolonged-release Capsules contains 8 mg galantamine (as hydrobromide).

Each Luventa XL 16 mg prolonged-release Capsules contains 16 mg galantamine (as hydrobromide).

Each Luventa XL 24 mg prolonged-release Capsules contains 24 mg galantamine (as hydrobromide).

The finished products are packaged in transparent polyvinylchloride (PVC)/ polyethylene (PE)/polyvinylidene chloride (PVDC) aluminium blister packs containing 7, 28, 30, 56, 84, 98 or 100 prolonged release capsules.

The Marketing Authorisation Holder has stated that not all pack sizes are intended for marketing, at present. However, they have committed to providing the relevant licensing authority with the mock-ups for any pack size before marketing them.

The proposed shelf-life of 2 years is consistent with the details registered for the cross-reference products. Luventa XL 8 mg, 16 mg, 24 mg prolonged-release Capsules, hard does not require any special storage conditons.

2.3 Legal status
On approval, the products will only be available with a prescription from a doctor (legal status POM).

2.4 Marketing authorisation holder/Contact Persons/Company
Fontus Health Ltd, 1 Butts Street, Walsall WS4 2BJ.

The QP responsible for pharmacovigilance is stated and his CV is included.

2.5 Manufacturers
The proposed manufacturing sites are consistent with that registered for the cross-reference products and evidence of Good Manufacturing Practice (GMP) compliance has been provided.

2.6 Qualitative and quantitative composition
The proposed compositions are consistent with the details registered for the cross-reference products.

2.7 Manufacturing process
The proposed manufacturing process is consistent with the details registered for the cross-reference products and the maximum batch sizes are stated.

2.8 Finished product/shelf-life specification
The proposed finished product specifications are in line with the details registered for the cross-reference products.

2.9 Drug substance specification
The proposed drug substance specifications are consistent with the details registered for the cross-reference products.

2.10 TSE Compliance
With the exception of gelatine, none of the excipients contain materials of animal or human origin. This is consistent with the cross-reference products.

The suppliers of gelatine have provided Certificates of Suitability from the European Directorate for the Quality of Medicines and Healthcare (EDQM) to show that it is manufactured in line with the current European guidelines concerning the minimising of risk of transmission of Bovine Spongiform Encephalopathy/Transmissible Spongiform Encephalopathies (BSE/TSE).

3. EXPERT REPORTS
The applicant has included detailed expert reports in Module 2 of the application. Signed declarations and copies of the experts' CVs are enclosed in Module 1.4 for the quality, non-clinical and clinical experts. All are considered to have sufficient experience for their responsibilities.

4. PRODUCT NAME & APPEARANCE
See 2.1 for details of the proposed product names. The appearances of the products are identical to the cross-reference products.

5. SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

The proposed SmPCs are consistent with the details registered for the cross-reference products.

6. PATIENT INFORMATION LEAFLET (PIL) AND LABELLING

PIL

The Patient Information Leaflet has been prepared in-line with the details registered for the cross-reference products.

Labelling

The proposed artwork for the cartons and blisters complies with statutory requirements. In-line with current legislation, the applicant has also included the name of the products in Braille on the outer packaging and has included sufficient space for a standard UK pharmacy dispensing label.

7. CONCLUSIONS

The data submitted with these applications is acceptable. From a quality perspective, Marketing Authorisations can be granted.

NON-CLINICAL ASSESSMENT

No new non-clinical data have been supplied with these applications and none are required for applications of this type.

CLINICAL ASSESSMENT

No new clinical data have been supplied with these applications and none are required for applications of this type.

OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

QUALITY

The important quality characteristics of Luventa XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard are identical to those of the already granted reference products. There are no outstanding quality issues that would have a negative impact on the benefit/risk balance.

NON-CLINICAL

No new non-clinical data were submitted and none are required for applications of this type.

CLINICAL PHARMACOLOGY/EFFICACY

No new clinical pharmacology/efficacy data have been submitted with these applications and none are required for applications of this type.

SAFETY

No new safety data have been submitted with these applications and none are required for applications of this type.

No new or unexpected safety concerns arose from these applications.

PRODUCT LITERATURE

The SmPCs, PIL and labelling are satisfactory.

PHARMACOVIGILANCE SYSTEM AND RISK MANAGEMENT PLAN

The Pharmacovigilance System, as described by the applicant, fulfils the requirements and provides adequate evidence that the applicant has the services of a qualified person responsible for pharmacovigilance, and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

A risk management plan has been developed to ensure that Luventa XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard are used as safely as possible. Based on this plan, safety information has been included in the Summary of Product Characteristics and the Package Information Leaflet for Luventa XL 8 mg, 16 mg and 24 mg prolonged-release Capsules, hard, including the appropriate precautions to be followed by healthcare professionals and patients.

BENEFIT-RISK ASSESSMENT

The quality of the products is acceptable, and no new non-clinical or clinical safety concerns have been identified. Extensive clinical experience with galantamine hydrobromide is considered to have demonstrated the therapeutic value of the product. The benefit/risk assessment is, therefore, considered to be positive.

LUVENTA XL 8 MG, 16 MGAND 24 MG PROLONGED-RELEASE CAPSULES, HARD

(PL 42924/0001-0003)

STEPS TAKEN FOR ASSESMENT

1	The MHRA received the marketing authorisation applications on 16 January 2104.
2	Following standard checks and communication with the applicant, the MHRA considered the applications valid on 28 January 2014.
3	Following assessment of the applications, the MHRA requested further information relating to the dossiers on 08 April 2014, 16 May 2014 and 22 June 2014.
4	The applicant responded to the MHRA's requests, providing further information on 30 April 2014, 10 June 2014 and 04 August 2014.
5	The applications were determined on 15 August 2014.

LUVENTA XL 8 MG, 16 MG AND 24 MG PROLONGED-RELEASE CAPSULES, HARD

(PL 42924/0001-0003)

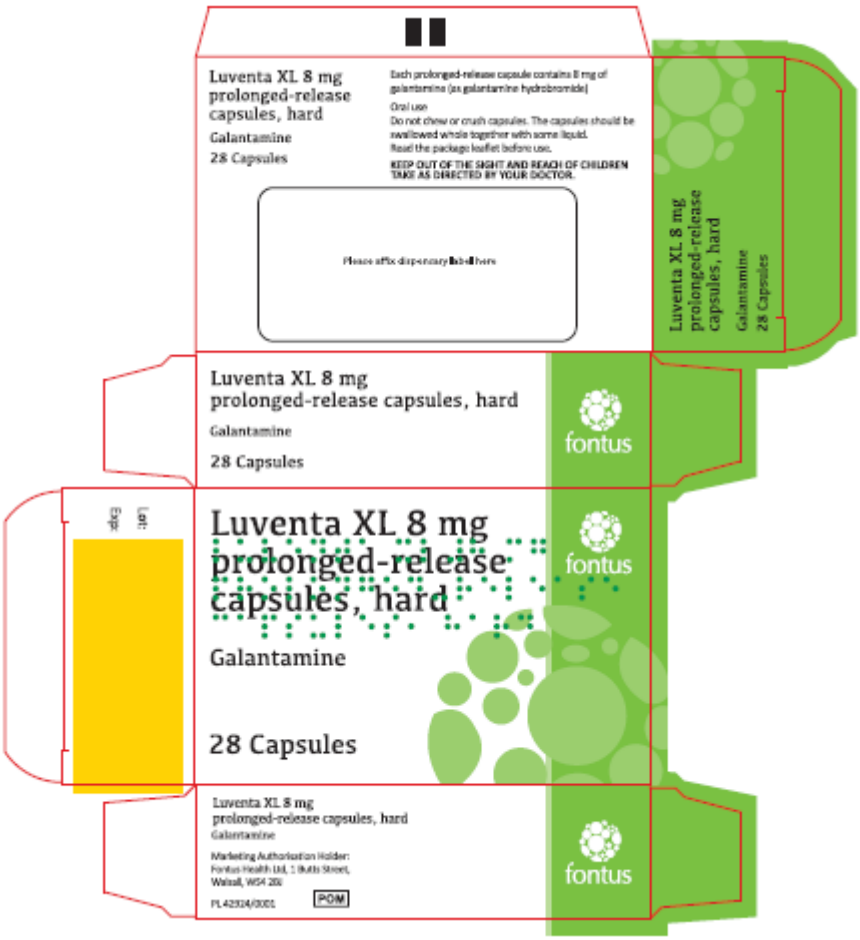
STEPS TAKEN AFTER AUTHORISATION - SUMMARY

Date submitted	Application type	Scope	Outcome

Summary of Product Characteristics and Patient Information Leaflet

The current approved UK versions of the Summary of Product Characteristics (SmPCs) and Patient Information Leaflet (PIL) for these products is available on the MHRA website.

Labelling


Luventa XL 8 mg
prolonged-release
capsules, hard
Galantamine
28 Capsules
Each prolonged-release capsule contains 8 mg of galantamine (as galantamine hydrobromide)
Oral use
Do not chew or crush capsules. The capsules should be swallowed whole together with some liquid.
Read the package leaflet before use.
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN
TAKE AS DIRECTED BY YOUR DOCTOR.
Please affix dispensary label here
Luventa XL 8 mg
prolonged-release
capsules, hard
Galantamine
28 Capsules
fontus
Luventa XL 8 mg
prolonged-release
capsules, hard
Galantamine
28 Capsules
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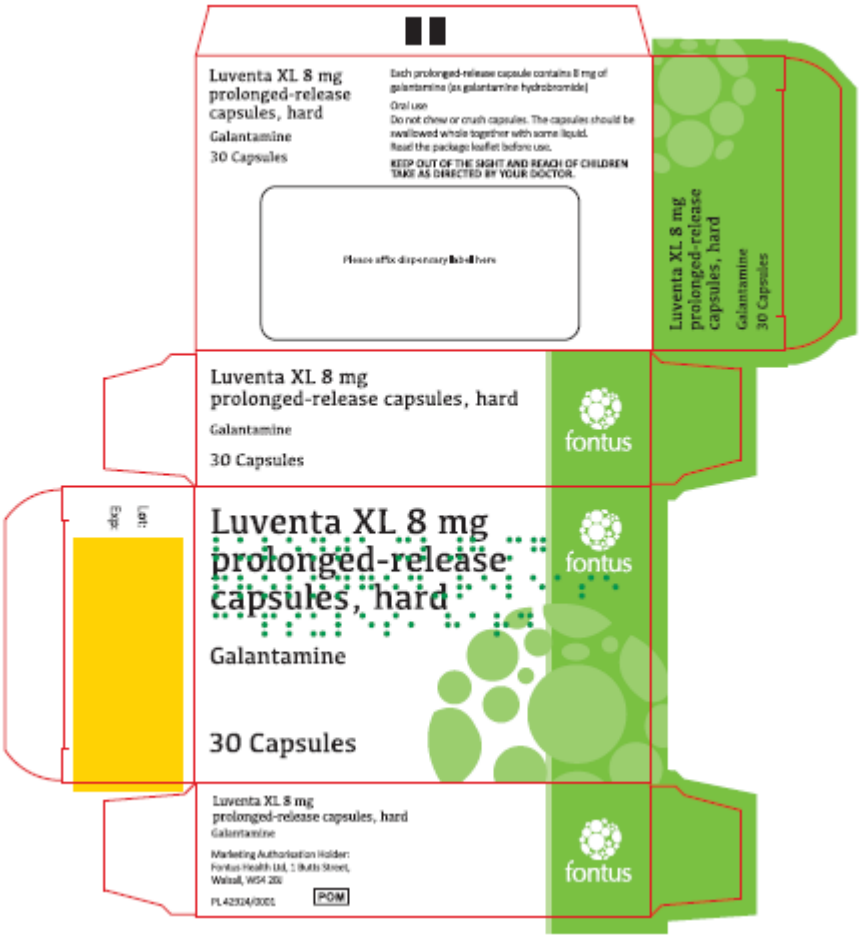
Luventa XL 8 mg
prolonged-release capsules, hard
Galantamine
28 Capsules
fontus
Marketing Authorisation Holder:
Fontus Health Ltd, 1 Butts Street,
Walsall, WS4 2BJ
PL 42924/0001
POM


Luventa XL 8 mg
prolonged-release
capsules, hard
Galantamine
30 Capsules
Each prolonged-release capsule contains 8 mg of galantamine (as galantamine hydrobromide)
Oral use
Do not chew or crush capsules. The capsules should be swallowed whole together with some liquid.
Read the package leaflet before use.
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN
TAKE AS DIRECTED BY YOUR DOCTOR.
Please affix dispensary label here
Luventa XL 8 mg prolonged-release capsules, hard
Galantamine
30 Capsules
Luventa XL 8 mg
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prolonged-release capsules, hard
Galantamine
Marketing Authorisation Holder:
Fontus Health Ltd, 1 Butts Street,
Walsall, WS4 2BE
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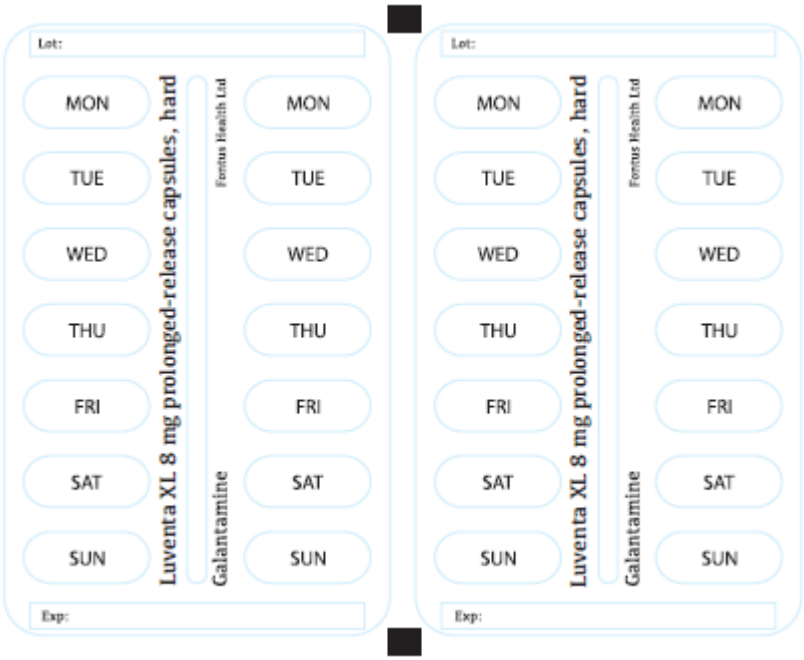
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Luventa XL 8 mg prolonged-release capsules, hard
Fontus Health Ltd
Galantamine
Exp:


Luventa XL 16 mg
prolonged-release
capsules, hard
Galantamine
28 Capsules
Each prolonged-release capsule contains 16 mg of galantamine (as galantamine hydrobromide)
Oral use
Do not chew or crush capsules. The capsules should be swallowed whole together with some liquid.
Read the package leaflet before use.
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN
TAKE AS DIRECTED BY YOUR DOCTOR.
Please affix dispensary label here
Luventa XL 16 mg
prolonged-release capsules, hard
Galantamine
28 Capsules
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Luventa XL 16 mg
prolonged-release
capsules, hard
Galantamine
28 Capsules
Luventa XL 16 mg
prolonged-release capsules, hard
Galantamine
Marketing Authorisation Holder:
Fontus Health Ltd, 1 Butts Street,
Walsall, WS4 2BJ
PL 42924/0002
POM


Luventa XL 16 mg prolonged-release capsules, hard
Galantamine
30 Capsules
Each prolonged-release capsule contains 16 mg of galantamine (as galantamine hydrobromide)
Oral use
Do not chew or crush capsules. The capsules should be swallowed whole together with some liquid.
Read the package leaflet before use.
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN
TAKE AS DIRECTED BY YOUR DOCTOR.
Please affix dispensary label here
Luventa XL 16 mg prolonged-release capsules, hard
Galantamine
30 Capsules
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Luventa XL 16 mg prolonged-release capsules, hard
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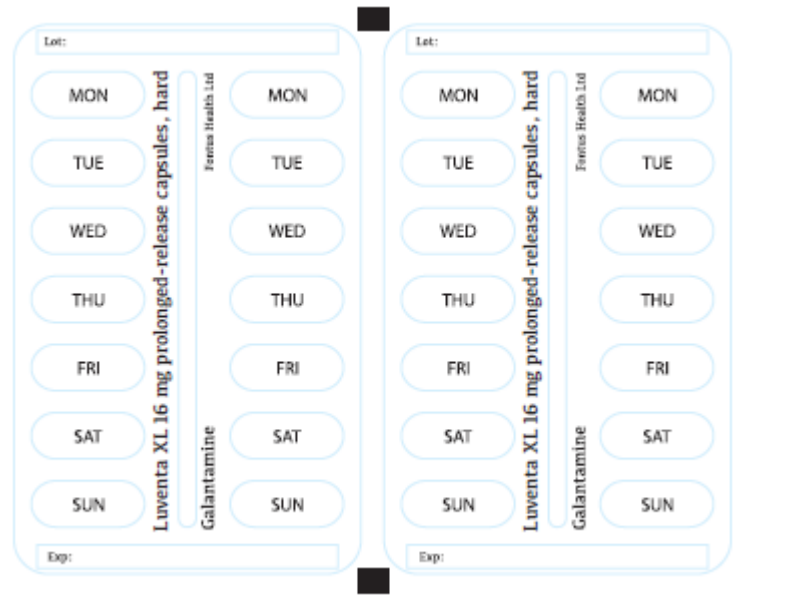
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Luventa XL 16 mg prolonged-release capsules, hard
Fontus Health Ltd
Galantamine
Exp:


Luventa XL 24 mg prolonged-release capsules, hard
Galantamine
28 Capsules
Each prolonged-release capsule contains 24 mg of galantamine (as galantamine hydrobromide)
Oral use
Do not chew or crush capsules. The capsules should be swallowed whole together with some liquid.
Read the package leaflet before use.
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN
TAKE AS DIRECTED BY YOUR DOCTOR.
Please affix dispensary label here
Luventa XL 24 mg prolonged-release capsules, hard
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Luventa XL 24 mg prolonged-release capsules, hard
Galantamine
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Luventa XL 24 mg prolonged-release capsules, hard
Galantamine
Marketing Authorisation Holder:
Fontus Health Ltd, 1 Butts Street,
Walsall, WS4 2BJ
PL 42924/0003
POM


Luventa XL 24 mg prolonged-release capsules, hard
Galantamine
30 Capsules
Each prolonged-release capsule contains 24 mg of galantamine (as galantamine hydrobromide)
Oral use
Do not chew or crush capsules. The capsules should be swallowed whole together with some liquid.
Read the package leaflet before use.
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN
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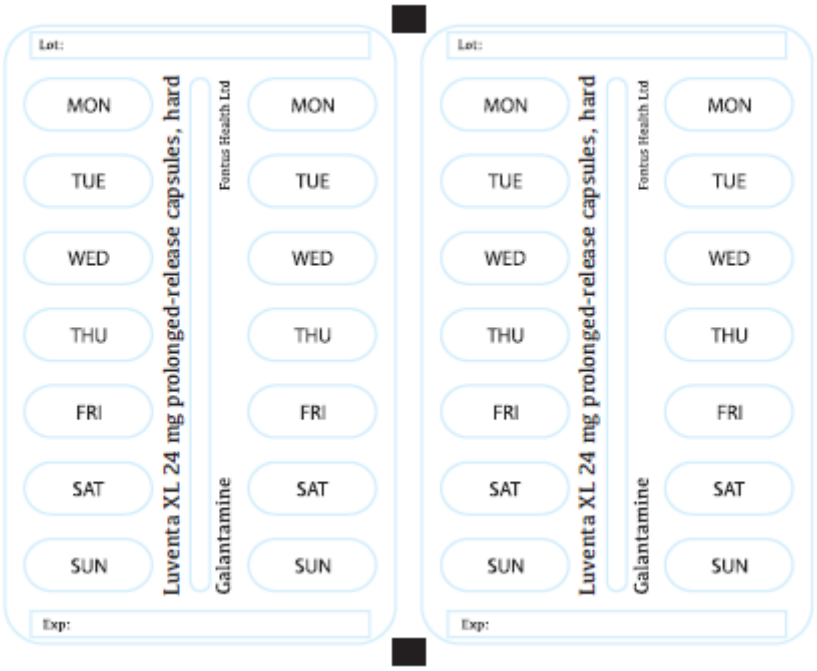
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