Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Public Assessment Report

Decentralised Procedure

Trazodone Hydrochloride 50 mg Hard Capsules
Trazodone Hydrochloride 100 mg Hard Capsules

(Trazodone hydrochloride)

Procedure No: UK/H/6768/001-002/DC

UK Licence Numbers: PL 48278/0010-0011

Eywa Pharma Limited.

LAY SUMMARY

Trazodone Hydrochloride 50 mg Hard Capsules
Trazodone Hydrochloride 100 mg Hard Capsules

This is a summary of the Public Assessment Report (PAR) for Trazodone Hydrochloride 50 mg Hard Capsules (PL 48728/0010; UK/H/6768/001/DC) and Trazodone Hydrochloride 100 mg Hard Capsules (PL 48728/0011; UK/H/6768/002/DC). It explains how Trazodone Hydrochloride 50 mg and 100 mg Hard Capsules were assessed and their authorisation recommended, as well as their conditions of use. It is not intended to provide practical advice on how to use Trazodone Hydrochloride 50 mg and 100 mg Hard Capsules.

The products will be collectively referred to as Trazodone Hydrochloride Capsules throughout the remainder of this public assessment report (PAR).

For practical information about using Trazodone Hydrochloride Capsules, patients should read the package leaflet or contact their doctor or pharmacist.

What are Trazodone Hydrochloride Capsules and what are they used for?
Trazodone Hydrochloride Capsules are 'generic medicines'. This means that Trazodone Hydrochloride Capsules are similar to 'reference medicines' already authorised in the European Union (EU) called Molipaxin 50mg Capsules / Trazodone Hydrochloride 50mg Capsules and Molipaxin 100mg Capsules / Trazodone Hydrochloride 100mg Capsules (Winthrop Pharmaceuticals UK Limited, UK).

Trazodone Hydrochloride Capsules are used to treat anxiety and depression.

How do Trazodone Hydrochloride Capsules work?
This medicine contains a substance called trazodone hydrochloride, which belongs to a group of medicines called antidepressants. It affects the chemicals in the brain that may be unbalanced in people with depression.

How are Trazodone Hydrochloride Capsules used?
The pharmaceutical form of this medicine is a capsule (hard) and the route of administration is oral (by mouth).

The patient should always take this medicine exactly as their doctor has told them. The patient should check with their doctor or pharmacist if they are not sure.

When taking this medicine
- Take this medicine by mouth
- Swallow the capsules whole with a drink of water
- Take with or after food. This can help lower the chances of side effects
- If the patient has been told to take Trazodone Hydrochloride Capsules only once a day then they should take it before going to bed
- If the patient feels the effect of their medicine is too weak or strong, the patient should not change the dose themselves, but ask their doctor.

How much to take
Adults:
Depression
Adults usually start by taking 150mg each day. The patient's doctor may increase the dose to 300mg

each day depending on their condition.

For adults in hospital the dose may be as high as 600mg each day.

Anxiety
Adults usually start by taking 75mg each day. The patient's doctor may increase the dose to 300mg each day.

Elderly
Older people or those who are frail will usually be given a starting dose of 100mg each day.

Use in children and adolescents
This medicine is not recommended for children and adolescents under 18 years old.

Please read section 3 of the package leaflet for detailed dosing recommendations, the route of administration, and the duration of treatment.

For further information on how Trazodone Hydrochloride Capsules are used, refer to the package leaflet and Summary of Product Characteristics available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

This medicine can only be obtained with a prescription.

What benefits of Trazodone Hydrochloride Capsules have been shown in studies?
Because Trazodone Hydrochloride Capsules are generic medicines, studies in healthy volunteers have been limited to tests to determine that they are bioequivalent to the reference medicines Molipaxin 50mg Capsules / Trazodone Hydrochloride 50mg Capsules and Molipaxin 100mg Capsules / Trazodone Hydrochloride 100mg Capsules (Winthrop Pharmaceuticals UK Limited, UK). Two medicines are considered to be bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Trazodone Hydrochloride Capsules?
Because Trazodone Hydrochloride Capsules are generic medicines and are bioequivalent to the reference medicines Molipaxin 50mg Capsules / Trazodone Hydrochloride 50mg Capsules and Molipaxin 100mg Capsules / Trazodone Hydrochloride 100mg Capsules (Winthrop Pharmaceuticals UK Limited, UK), their benefits and possible side effects are taken as being similar as the reference medicines.

For the full list of restrictions, see the package leaflet.

For the full list of all side effects reported with Trazodone Hydrochloride Capsules, see section 4 of the package leaflet available on the MHRA website.

Why were Trazodone Hydrochloride Capsules approved?
It was concluded that, in accordance with EU requirements, Trazodone Hydrochloride Capsules have been shown to have comparable quality and to be bioequivalent to Molipaxin 50mg Capsules / Trazodone Hydrochloride 50mg Capsules and Molipaxin 100mg Capsules / Trazodone Hydrochloride 100mg Capsules (Winthrop Pharmaceuticals UK Limited, UK). Therefore, the MHRA decided that, as for Molipaxin 50mg Capsules / Trazodone Hydrochloride 50mg Capsules and Molipaxin 100mg Capsules / Trazodone Hydrochloride 100mg Capsules (Winthrop Pharmaceuticals UK Limited, UK); the benefits are greater than the risks and recommended that they can be approved for use.

What measures are being taken to ensure the safe and effective use of Trazodone Hydrochloride Capsules?

A risk management plan (RMP) has been developed to ensure that Trazodone Hydrochloride Capsules are used as safely as possible. Based on this plan, safety information has been included in the Summaries of Product Characteristics (SmPCs) and the package leaflet for Trazodone Hydrochloride Capsules including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored and reviewed continuously.

Other information about Trazodone Hydrochloride Capsules

Ireland and the UK agreed to grant Marketing Authorisations for Trazodone Hydrochloride Capsules on 13 September 2018.

Marketing Authorisations were granted in the UK on 27 September 2018.

The full PAR for Trazodone Hydrochloride Capsules follows this summary.

For more information about treatment with Trazodone Hydrochloride Capsules read the package leaflet, or contact your doctor or pharmacist.

This summary was last updated in October 2018.

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I INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) granted Eywa Pharma Limited, marketing authorisations for the medicinal products Trazodone Hydrochloride Capsules ((PL 48728/0010-0011; UK/H/6768/001-002/DC). The products are prescription-only medicines (POM) indicated for anxiety, depression, mixed anxiety and depression.

The applications were submitted using the Decentralised Procedure (DCP), with the UK as Reference Member State and Ireland as Concerned Member State (CMS).

The applications were submitted under Article 10(1) of Directive 2001/83/EC, as amended, as generic applications. The reference medicinal products for these applications are Molipaxin 50mg Capsules / Trazodone Hydrochloride 50mg Capsules and Molipaxin 100mg Capsules / Trazodone Hydrochloride 100mg Capsules which were first authorised in the UK to Roussel Laboratories Limited on 11 July 1980 (PL 00109/0045-46) The reference products (PL 00109/0045-46) subsequently underwent several changes of ownership procedures, the most recent of which was to Winthrop Pharmaceuticals UK Limited (PL 17780/0617-618) on 17 September 2012.

Trazodone hydrochloride is a potent antidepressant. It also has anxiety reducing activity. Trazodone hydrochloride is a triazolopyridine derivative chemically unrelated to known tricyclic, tetracyclic and other antidepressant agents. It has negligible effect on noradrenaline re-uptake mechanisms. Whilst the mode of action of trazodone hydrochloride is not known precisely, its antidepressant activity may concern noradrenergic potentiation by mechanisms other than uptake blockade. A central antiserotonin effect may account for the drug's anxiety reducing properties.

One bioequivalence study (conducted under fed conditions) was submitted to support these applications. The applicant has stated that the bioequivalence study was conducted in accordance with Good Clinical practice (GCP).

With the exception of the bioequivalence study, no new non-clinical or clinical data were submitted, which is acceptable given that this is a generic medicinal product of an originator product that has been in clinical use for over 10 years.

The RMS has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place at all sites responsible for the manufacture, assembly and batch release of these products.

For manufacturing sites within the Community, the RMS has accepted copies of current manufacturing authorisations issued by inspection services of the competent authorities as certification that acceptable standards of GMP are in place at those sites.

For all other manufacturing sites outside the Community, the RMS has accepted copies of current GMP Certificates of satisfactory inspection summary reports, ‘close-out letters’ or ‘exchange of information’ issued by the inspection services of the competent authorities (or those countries with which the EEA has a Mutual Recognition Agreement for their own territories) as certification that acceptable standards of GMP are in place at those non-Community sites.

The RMS and CMS considered that the applications could be approved at the end of procedure on 13 September 2018. After a subsequent national phase, a licence was granted in the UK on 27 September 2018.

II QUALITY ASPECTS

II.1 Introduction

Each hard capsule contains 50 mg or 100 mg trazodone hydrochloride as the active ingredient. Other ingredients consist of the pharmaceutical excipients:

Capsule contents:

Lactose monohydrate and magnesium stearate.

Capsule body and shell:

Brilliant Blue (E133), erythrosine (E127), yellow iron oxide (E172), red iron oxide (E172) titanium dioxide (E171) and gelatin.

Printing ink:

Shellac, black iron oxide (E172) and propylene glycol.

Both strengths (50 mg and 100 mg) of the finished product are packed into:

- Opaque polyvinyl chloride (PVC)/polyethylene (PE)/ polyvinylidene chloride (PVdC)/aluminium (Al) blisters in pack sizes of 28, 56, 84 and 100 capsules.
- Opaque PVC/PVdC/Al blisters in pack sizes of 28,56, 84 and 100 capsules.

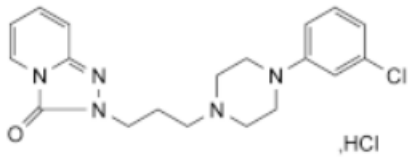
Not all pack sizes may be marketed.

Satisfactory specifications and Certificates of Analysis have been provided for all packaging components for both the capsule and tablet presentations.

II.2 Drug Substance

INN:	Trazodone hydrochloride
Chemical name:	2,3-[4-(3-chloro)phenylpiperazin-1-yl]propyl-1,2,4-triazolo[4,3-*a*]pyridin-3(*2H*)-one hydrochloride

Structural formula:



Molecular formula:	$C_{19}H_{22}ClN_5O$,HCl
Molecular mass:	408.3 g/mol
Appearance:	White or almost white, crystalline powder.
Solubility:	Soluble in water; sparingly soluble in ethanol (96%) and practically insoluble in ether.

The drug substance is the subject of an active substance master file (ASMF).

Synthesis of the active substance from the designated starting materials has been adequately described and appropriate in-process controls and intermediate specifications are applied. Satisfactory specification tests are in place for all starting materials and reagents, and these are supported by relevant Certificates of Analysis.

Appropriate proof-of-structure data have been supplied for the active substance. All potential known impurities have been identified and characterised.

An appropriate specification is provided for the active substance. Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications. Batch analyses data are provided that comply with the proposed specification.
Satisfactory certificates of analysis have been provided for all working standards.

Suitable specifications have been provided for all packaging used. The primary packaging has been shown to comply with current guidelines concerning contact with food.

Appropriate stability data have been generated supporting a suitable retest period when stored in the proposed packaging.

II.3. Medicinal Product

Pharmaceutical Development

The objective of the development programme was to formulate safe, efficacious capsules containing 50 mg or 100 mg trazodone hydrochloride per capsule that are generic versions of the reference products Molipaxin 50mg Capsules / Trazodone Hydrochloride 50mg Capsules and Molipaxin 100mg Capsules / Trazodone Hydrochloride 100mg Capsules (Winthrop Pharmaceuticals UK Limited, UK). A satisfactory account of the pharmaceutical development has been provided.

Comparative *in-vitro* dissolution profiles have been provided for the proposed and originator products.

All excipients comply with their respective European Pharmacopoeia monographs with the exception of the empty hard gelatin capsules which are controlled to suitable in-house specifications. Satisfactory Certificates of Analysis have been provided for all excipients. Suitable batch analysis data have been provided for each excipient.

With the exception of lactose monohydrate and gelatin none of the excipients used contain material of animal or human origin. The supplier of lactose monohydrate has confirmed that it is sourced from healthy animals under the same conditions as milk for human consumption. The suppliers of gelatin have provided Certificates of Suitability from the European Directorate for the Quality of Medicines (EDQM) to show that they are manufactured in-line with current European guidelines concerning the minimising of risk of transmission of Bovine Spongiform Encephalopathy/transmissible Spongiform Encephalopathies (BSE/TSE).

No genetically modified organisms (GMO) have been used in the preparation of this product.

Manufacture of the product

Satisfactory batch formulae have been provided for the manufacture of the product, along with an appropriate account of the manufacturing process. The manufacturing processes have been validated at commercial scale batch sizes and have shown satisfactory results.

Finished Product Specifications

The finished product specifications proposed are acceptable. Test methods have been described that have been adequately validated. Batch data have been provided which comply with the release specifications. Certificates of Analysis have been provided for all working standards used.

Stability of the product

Finished product stability studies were performed in accordance with current guidelines on batches of the finished product in the packaging proposed for marketing. The data from these studies support a shelf-life of 2 years with the storage conditions ‘Store in the original package, in order to protect from moisture.’

Suitable post approval stability commitments have been provided to continue stability testing on batches of finished product.

II.4 Discussion on chemical, pharmaceutical and biological aspects

There are no objections to the approval of these applications from a pharmaceutical viewpoint.

III NON-CLINICAL ASPECTS

III.1 Introduction

As the pharmacodynamic, pharmacokinetic and toxicological properties of trazodone hydrochloride are well-known, no new non-clinical studies are required and none have been provided. An overview based on the literature review is, thus, appropriate.

The applicant's non-clinical expert report has been written by an appropriately qualified person and is satisfactory, providing an appropriate review of the relevant non-clinical pharmacology, pharmacokinetics and toxicology.

III.2 Pharmacology

Not applicable for this product type. Refer to section 'III.1; Introduction' detailed above.

III.3 Pharmacokinetics

Not applicable for this product type. Refer to section 'III.1; Introduction' detailed above.

III.4 Toxicology

Not applicable for this product type. Refer to section 'III.1; Introduction' detailed above.

III.5 Ecotoxicity/environmental risk assessment (ERA)

Since Trazodone Hydrochloride Capsules are intended for generic substitution, this will not lead to an increase in environmental exposure. An environmental risk assessment is therefore not deemed necessary**.**

III.6 Discussion on the non-clinical aspects

There are no objections to the approval of these applications from a non-clinical viewpoint.

IV CLINICAL ASPECTS

IV.1 Introduction

The clinical pharmacology of trazodone hydrochloride is well-known. With the exception of data from the bioequivalence study detailed below, no new pharmacodynamic or pharmacokinetic data are provided or required for this type of application.

No new efficacy or safety studies have been performed and none are required for this type of application. A comprehensive review of the published literature has been provided by the applicant, citing the well-established clinical pharmacology, efficacy and safety of trazodone hydrochloride.

Based on the data provided, Trazodone Hydrochloride Capsules can be considered bioequivalent to Molipaxin 50mg Capsules / Trazodone Hydrochloride 50mg Capsules and Molipaxin 100mg Capsules / Trazodone Hydrochloride 100mg Capsules (Winthrop Pharmaceuticals UK Limited, UK).

IV.2 Pharmacokinetics

In support of these applications, the applicant submitted the following bioequivalence study:

STUDY
An open-label, balanced, randomised, single-dose, two-treatment, two-sequence, two-period, crossover, oral, bioequivalence study of the applicant's test product Trazodone Hydrochloride 100 mg Capsules (Eywa Pharma Limited, UK) versus the reference product Molipaxin 100mg Capsules / Trazodone Hydrochloride 100mg Capsules (Winthrop Pharmaceuticals UK Limited, UK) in healthy, adult, subjects under fed conditions.

Following an overnight fast of at least 10 hours, subjects were served a high-fat, high-calorie breakfast which they consumed completely within 30 minutes. Exactly after 30 minutes of the actual start time of the high-fat, high-calorie breakfast, subjects were administered a single dose (1 x 100 mg capsule) of the test or reference product with 240 mL of water.

Blood samples were collected for plasma levels before dosing and up to and including 60 hours after each administration. The washout period between the treatment phases was 8 days. The pharmacokinetic results are presented below:

Table: Geometric Least Squares Mean, ratios and 90% Confidence Interval for pharmacokinetic parameters (C_{max} and AUC_{0-t}) of trazodone

Pharmacokinetic Parameters (Units)	Ln- transformed Geometric Least Squares Mean			90% Confidence Interval (Parametric)	
	Test Product (T)	Reference Product (R)	T/R (%)	Lower	Upper
C_{max} (ng/mL)	1506.7920	1547.3492	97.38	91.79	103.30
AUC_{0-t} (ng.hr/mL)	17269.7678	17118.7985	100.88	96.82	105.11

AUC_{0-t} area under the plasma concentration-time curve from zero to t hours
C_{max} maximum plasma concentration

Study Conclusion
The 90% confidence intervals of the test/reference ratio for AUC and C_{max} values for trazodone lie within the acceptable limits of 80.00% to 125.00%, in line with the 'Guideline on the Investigation of Bioequivalence (CPMP/EWP/QWP/1401/98 Rev 1/Corr**). Thus, these data support the claim that the applicant's test product is bioequivalent to the reference product Molipaxin 100mg Capsules / Trazodone Hydrochloride 100mg Capsules (Winthrop Pharmaceuticals UK Limited, UK).

As the 50 mg and 100 mg strength test products meet the biowaiver criteria specified in the current bioequivalence guidance, the results and conclusions of the bioequivalence study with the 100 mg capsule strength can be extrapolated to the 50 mg strength capsule.

IV.3 Pharmacodynamics
No new pharmacodynamic data were submitted and none were required for applications of this type.

IV.4 Clinical efficacy
No new efficacy data were submitted and none were required for applications of this type.

IV.5 Clinical safety
No new safety concerns were identified in the clinical study. No other safety data were submitted.

IV.6 Risk Management Plan (RMP) and Pharmacovigilance System
The Applicant has submitted a risk management plan, in accordance with the requirements of Directive 2001/83/EC as amended.

There are no differences from the reference product in terms of proposed uses, maximum pack size / strength or pharmaceutical form/formulation that would have any implications for safety.

In line with the reference product, the applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns (labelling in the SmPC and the PIL). This is agreed.

The MAH shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the Marketing Authorisation and any agreed subsequent updates of the RMP.
An updated RMP should be submitted:

- At the request of the RMS;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

If the dates for submission of a PSUR and the update of a RMP coincide, they can be submitted at the same time, but via different procedures.

IV.7 Discussion on the clinical aspects

The grant of marketing authorisations is recommended for these applications from a clinical point of view.

V User consultation

The package leaflet has been evaluated via a user consultation study in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC. The language used for the purpose of user testing the PIL was English.

The results show that the package leaflet meets the criteria for readability as set out in the Guideline on the readability of the label and package leaflet of medicinal products for human use.

VI Overall conclusion, benefit/risk assessment and recommendation

The quality of the products is acceptable, and no new non-clinical or clinical safety concerns have been identified. Extensive clinical experience with trazodone hydrochloride is considered to have demonstrated the therapeutic value of the compound. The products are bioequivalent to the marketed reference products and their risk-benefit balance is considered similar and positive.

Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and Labels

In accordance with Directive 2010/84/EU the Summaries of Product Characteristics (SmPCs) and Patient Information Leaflets (PILs) for products granted Marketing Authorisations at a national level are available on the MHRA website.

The following text is the approved label text for this medicine, no label mock-ups have been provided. In accordance with medicines legislation, the product shall not be marketed in the UK until approval of the label mock-ups has been obtained:

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

Trazodone Hydrochloride 50 mg Hard Capsules

Trazodone hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each capsule contains 50 mg Trazodone hydrochloride.

3. LIST OF EXCIPIENTS

Also contains lactose monohydrate.
See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Capsule, hard

28 hard capsules
56 hard capsules
84 hard capsules
100 hard capsules

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in the original package, in order to protect from moisture

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

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11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Eywa Pharma Limited
Suite # G19
The Business & Technology Centre (btc),
Bessemer Drive,
Stevenage,
SG1 2DX, UK

12. MARKETING AUTHORISATION NUMBER(S)

PL 48278/0010

13. BATCH NUMBER

BN

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Trazodone Hydrochloride 50 mg Hard Capsules

17. UNIQUE IDENTIFIER – 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

< PC: {number} [product code]
SN: {number} [serial number]
NN: {number} [national reimbursement number or other national number identifying the medicinal product]>

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

1. NAME OF THE MEDICINAL PRODUCT

Trazodone Hydrochloride 50 mg Hard Capsules

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Eywa Pharma Limited
Suite # G19
The Business & Technology Centre (btc),
Bessemer Drive,
Stevenage,
SG1 2DX, UK

3. EXPIRY DATE

EXP

4. BATCH NUMBER

BN

5. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON

1. NAME OF THE MEDICINAL PRODUCT

Trazodone Hydrochloride 100 mg Hard Capsules

Trazodone hydrochloride

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each capsule contains 100 mg Trazodone hydrochloride.

3. LIST OF EXCIPIENTS

Also contains lactose monohydrate.

See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Capsule, hard

28 hard capsules
56 hard capsules
84 hard capsules
100 hard capsules

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP

9. SPECIAL STORAGE CONDITIONS

Store in the original package, in order to protect from moisture

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

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BN

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Trazodone Hydrochloride 100 mg Hard Capsules

17. UNIQUE IDENTIFIER – 2D BARCODE

<2D barcode carrying the unique identifier included.>

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

< PC: {number} [product code]
SN: {number} [serial number]
NN: {number} [national reimbursement number or other national number identifying the medicinal product]>

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Trazodone Hydrochloride 100 mg Hard Capsules

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Suite # G19
The Business & Technology Centre (btc),
Bessemer Drive,
Stevenage,
SG1 2DX, UK

3. EXPIRY DATE

EXP

4. BATCH NUMBER

BN

5. OTHER

Annex 1

Table of content of the PAR update

Steps taken after the initial procedure with an influence on the Public Assessment Report (Type II variations, PSURs, commitments)

Scope	Procedure number	Product information affected	Date of start of the procedure	Date of end of procedure	Approval/ non approval	Assessment report attached Y/N (version)