Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Public Assessment Report

Decentralised Procedure

Diazepam 5 mg tablets
Diazepam 10 mg tablets

(Diazepam)

Procedure No: UK/H/5974/002-003/DC

UK Licence Number: PL 30139/0039-0040

Intas Pharmaceuticals Limited.

LAY SUMMARY

Diazepam 5 mg tablets
Diazepam 10 mg tablets

(diazepam, tablets, 5 mg and 10 mg)

This is a summary of the Public Assessment Report (PAR) for Diazepam 5 mg tablets (PL 30139/0039; UK/H/5974/002/DC) and Diazepam 10 mg tablets (PL 30139/0040; UK/H/5974/003/DC). It explains how Diazepam 5 mg and 10 mg tablets 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 Diazepam 5 mg and 10 mg tablets.

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

For practical information about using Diazepam tablets, patients should read the package leaflet or contact their doctor or pharmacist.

What are Diazepam tablets and what are they used for?
Diazepam tablets are 'generic medicines'. This means that Diazepam tablets are similar to 'reference medicines' already authorised in the European Union (EU) called Valium 5mg and 10mg tablets (Roche Products Limited, UK).

Diazepam tablets are used in adults for:
- short-term (2-4 weeks) symptomatic treatment of anxiety that is severe, disabling or subjecting the individual to extreme distress
- Symptomatic treatment of acute alcohol withdrawal.

How do Diazepam tablets work?
Diazepam tablets contain the active substance diazepam which belongs to a group of medicines called benzodiazepines. Diazepam has anxiolytic, sedative and muscle relaxant effect.

How are Diazepam tablets used?
The pharmaceutical form of this medicine is a tablet and the route of administration is oral (by mouth). The patient should swallow the tablets with a glass of water.

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

The patient's doctor will decide the appropriate dose and for how long they need to take the tablets. The usual duration of treatment is not longer than 4 weeks including tapering off process. If needed, the patient's doctor might increase the duration of treatment.

The usual doses:
Adults
For anxiety: 2 mg to 5 mg diazepam 2 to 3 times daily. In severe cases, the patient's doctor may decide to increase the dose depending on their condition up to a maximum of 30 mg daily in 2 to 4 divided doses.

For treatment of alcohol withdrawal symptoms: 5 mg to 20 mg diazepam which may be repeated once after 2 to 4 hours if necessary.

In order to obtain suitable doses of less than 5mg diazepam alternative products have to be used.

Elderly patients
If the patient is elderly or frail they are likely to be more sensitive to the effects of this medicine and their dose needs to be reduced. The patient's doctor will decide how much Diazepam tablets they should be given and how often. Usual starting dose is 2mg to 2.5 mg once or twice daily.

In order to obtain suitable doses of less than 5mg diazepam alternative products have to be used.

Impaired kidney function
Dose adjustment is usually not necessary.

Impaired liver function
If the patient suffers from cirrhosis or other liver problems their dose needs to be reduced.

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 Diazepam tablets 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 Diazepam tablets been shown in studies?
Diazepam tablets are generic medicines therefore studies in patients have been limited to tests to determine that they are bioequivalent to the reference medicines Valium 5mg and 10mg tablets (Roche Products Limited, UK). Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Diazepam tablets?
Diazepam tablets are generic medicines and are bioequivalent to the reference medicines Valium 5mg and 10mg tablets (Roche Products Limited, UK), therefore their benefits and possible side effects are taken as being the same as the reference medicines.

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

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

Why were Diazepam tablets approved?
It was concluded that, in accordance with EU requirements, Diazepam tablets has been shown to have comparable quality and to be bioequivalent to Valium 5mg and 10mg tablets (Roche Products Limited, UK). Therefore, the MHRA decided that, as for Valium 5mg and 10mg tablets (Roche Products 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 Diazepam tablets?
A risk management plan (RMP) has been developed to ensure that Diazepam tablets is 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 Diazepam tablets 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/reviewed continuously.

Other information about Diazepam tablets

For Diazepam 5 mg tablets (PL 30139/0039; UK/H/5974/002/DC):

Austria, Bulgaria, Cyprus, Germany, Denmark, Estonia, Finland, France, Ireland, Malta, Norway, Poland, Sweden, the Slovak Republic and the UK agreed to grant a Marketing Authorisation for Diazepam 5 mg tablets on 22 November 2017. A Marketing Authorisation was granted in the UK on 19 December 2017.

For Diazepam 10 mg tablets (PL 30139/0040; UK/H/5974/003/DC):

Austria, Bulgaria, Cyprus, Germany, Finland, France, Ireland, Malta, Sweden, the Slovak Republic and the UK agreed to grant Marketing Authorisations for Diazepam 10 mg tablets on 22 November 2017. A Marketing Authorisation was granted in the UK on 19 December 2017.

The full PAR for Diazepam Tablets follows this summary.

For more information about treatment with Diazepam tablets, read the package leaflet, or contact your doctor or pharmacist.

This summary was last updated in January 2018.

TABLE OF CONTENTS

I INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) granted Intas Pharmaceuticals Limited, marketing authorisations for the medicinal products Diazepam tablets (PL 30139/0039-0040; UK/H/5974/002-003/DC). The products are prescription-only medicines (POM) indicated in adults for the short-term (2-4 weeks) symptomatic treatment of anxiety that is severe, disabling or subjecting the individual to extreme distress. These products are also used for the symptomatic treatment of acute alcohol withdrawal.

The applications were submitted using the Decentralised Procedure (DCP), with the UK as Reference Member State (RMS), and

For Diazepam 5 mg tablets (PL 30139/0039; UK/H/5974/002/DC):

- Austria, Bulgaria, Cyprus, Germany, Denmark, Estonia, Finland, France, Ireland, Malta, Norway, Poland, Sweden, the Slovak Republic

For Diazepam 10 mg tablets (PL 30139/0040; UK/H/5974/003/DC):

- Austria, Bulgaria, Cyprus, Germany, Finland, France, Ireland, Malta, Sweden,

as Concerned Member States (CMS). The applications were submitted under Article 10(1) of Directive 2001/83/EC, as amended, as generic applications cross-referring to the reference products Valium 5mg and 10mg tablets which were first authorised to Roche Products Limited, UK on 07 July 1983 (PL 00031/5122-5123R). The applicant has cited the French reference product, Valium Roche comprime secable (Roche, France), first authorised on 22 October 1986, with respect to data exclusivity. The medicinal product to which bioequivalence has been demonstrated is Valium 10mg tabletten (Roche Pharma AG, Germany) taken from the German market. This is acceptable.

Diazepam is an agonist that binds specifically to benzodiazepine receptors in the brain, thus enhancing the normal transmission of the signal substance GABA. GABA inhibits the transmission of important signal substances, by which means a neuronal inhibition is achieved. The muscle-relaxant effect is mediated via spinal synaptic reflexes.

Diazepam is an anxiolytic that acts by subduing the anxiety symptoms of agitation, restlessness and tension. Diazepam also has a sedative and muscle-relaxant effect with amnesic properties.

One bioequivalence study (single-dose study conducted under fasting conditions) was submitted to support these applications. The applicant has stated that the bioequivalence study was conducted in accordance with Good Clinical Practice (GCP) guidelines.

With the exception of the bioequivalence study, no new non-clinical or clinical data were submitted, which is acceptable given that these applications were based on being 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 for this product type 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 manufacturer authorisations issued by inspection services of the competent authorities as certification that acceptable standards of GMP are in place at those sites.

The RMS and CMS considered that the applications could be approved at the end of procedure on 22 November 2017. After a subsequent national phase, licences were granted in the UK on 19 December 2017.

II QUALITY ASPECTS

II.1 Introduction

Each tablet contains 5 mg or 10 mg diazepam as the active ingredient. Other ingredients consist of the pharmaceutical excipients lactose monohydrate, maize starch, sodium starch glycolate (Type A), talc and magnesium stearate.

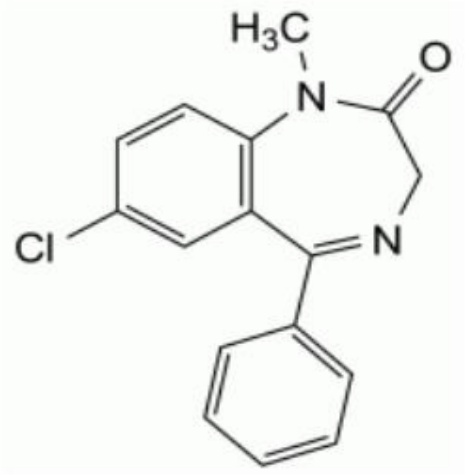
Diazepam 5 mg and 10 mg tablets are packaged in:

- Polyvinyl chloride (PVC)/ polyvinylidene chloride (PVdC) aluminium blisters and are available in pack sizes of 10, 20, 25, 28, 30, 40, 50, 60, 90 or 100 tablets in a carton.
- High-density polyethylene (HDPE) containers in a pack size of 30 tablets.

Not all pack sizes may be marketed. Satisfactory specifications and Certificates of Analysis have been provided for all packaging components.

II.2 Drug Substance

INN: Diazepam
Chemical name: 7-Chloro-1-methyl-5-phenyl-1,3-dihydro-2*H*-1,4-benzodiazepin-2-one.
Structure:



Molecular formula: $C_{16}H_{13}ClN_2O$
Molecular weight: 284.7
Description: White or almost white, crystalline powder.
Solubility Very slightly soluble in water, soluble in ethanol (96 per cent).

Diazepam is the subject of a European Pharmacopoeia monograph,

All aspects of the manufacture and control of the active substance are covered by the European Directorate for the Quality of Medicines and Healthcare (EDQM) Certificate of Suitability.

II.3. Medicinal Product

Pharmaceutical Development

The objective of the development programme was to formulate safe, efficacious tablets containing 5 mg or 10 mg diazepam per tablet that are generic versions of the reference products Valium 5mg and 10mg tablets (Roche Products Limited, UK). A satisfactory account of the pharmaceutical development has been provided.

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

All excipients comply with their respective European Pharmacopoeia. 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 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.

This product does not contain or consist of genetically modified organisms (GMO).

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

Finished Product Specification
The finished product specifications proposed are acceptable. Test methods have been described that have been adequately validated. Batch data have been provided that 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 for both presentation types (blisters and containers). This medicinal product does not require any special storage conditions.

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 diazepam 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.

Impurities

Drug substance

Impurity limits in the drug substance specification were set in accordance with current ICH guidelines for impurities in new drug substances (ICHQ3A(R2)) and/or the current version of the European Monograph. There are no issues from a toxicological perspective.

Drug product

Based on the a maximum daily dose of 30 mg per day; the proposed limits are all in compliance with the requirements of ICHQ3B(R2) - *Impurities in New Drug Products* and / or the limits set in the Ph Eur monograph. There are no toxicology issues with these specification limits.

III.5 Ecotoxicity/environmental risk assessment (ERA)

Since Diazepam tablets are intended for generic substitution, this will not lead to an increased exposure to the environment. 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 diazepam is well-known. With the exception of data from the bioequivalence study detailed below, no new pharmacodynamics or pharmacokinetic data are provided or are required for these applications.

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 diazepam.

Based on the data provided, Diazepam tablets can be considered bioequivalent to Valium 10mg tabletten (Roche Pharma AG, Germany).

IV.2 Pharmacokinetics

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

STUDY

An open label, balanced, randomised, two-treatment, two-period, two-sequence, crossover, single oral dose, bioequivalence study of the applicant's test product Diazepam 10 mg tablets (Intas Pharmaceuticals Limited, UK) versus the reference product is Valium 10mg tabletten (Roche Pharma AG, Germany) in healthy, adult, human subjects under fasting conditions.

Following an overnight fast of at least 10 hours, subjects were administered a single oral dose (1 x 10 mg tablet) of the test or reference product with 240 mL of drinking water.

Blood samples were collected for plasma levels before dosing and up to and including 72 hours after each administration. The washout period between treatment phases was 26 days. The pharmacokinetic results are presented below:

Table 1. Pharmacokinetic parameters (non-transformed values; arithmetic mean ± SD, t_{max} median, range)

Treatment	AUC_{0-72} ng/ml/h	C_{max} ng/ml	t_{max} h
Test	7968.024 ± 2508.2200	432.871 ± 112.5574	0.500 (0.333 - 3.000)
Reference	7795.839 ± 2685.2554	429.950 ± 111.6829	0.667 (0.333-3.000)
***Ratio (90% CI)**	103.2 (99.70 - 106.77)	100.5 (92.81 - 108.87)	

AUC_{0-t} AUC_{0-72h} can be reported instead of AUC_{0-t}, in studies with sampling period of 72 h, and where the concentration at 72 h is quantifiable. Only for immediate release products
C_{max} Maximum plasma concentration
t_{max} Time until Cmax is reached. Tmax is represented as *median (min-max)* value.

**ln-transformed values*

Table 2. ANOVA p-values, Intra and Inter-Subject CV for Diazepam

Parameters	ANOVA (p-value)				Intra Subject CV (%)	Inter Subject CV (%)
	Formulation	Sequence	Period	Subject (Seq)		
lnC_{max}	0.9127	0.1210	0.0848	0.0006	18.9	20.7
$lnAUC_{0-72}$	0.1323	0.0067	0.6023	<0.0001	8.1	33.5

Conclusion
The 90% confidence intervals of the test/reference ratio for AUC and C_{max} values for diazepam administered under fasting conditions for the 10 mg test product strength 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, the data support the claim that the applicant's test product is bioequivalent to the reference product Valium 10mg tabletten (Roche Pharma AG, Germany).

As the 5 mg and 10 mg strength test products meet the biowaiver criteria specified in the current bioequivalence guidance, the results and conclusions of the bioequivalence study with the 10 mg tablet strength can be extrapolated to the 5 mg strength tablets.

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 data were submitted and none are required.

IV.6 Risk Management Plan (RMP) and Pharmacovigilance System
Summary Pharmacovigilance system
The Applicant has submitted a signed Summary of the Applicant's Pharmacovigilance System. Provided that the Pharmacovigilance System Master File fully complies with the new legal requirements as set out in the Commission Implementing Regulation and as detailed in the GVP module, the RMS considers the Summary acceptable.

Risk Management Plan
The RMP submitted is approvable.

Periodic Safety Update Report (PSUR)

With regard to PSUR submission, the MAH should take the following into account:

- PSURs shall be submitted in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and published on the European medicines web-portal. Marketing authorisation holders shall continuously check the European medicines web-portal for the DLP and frequency of submission of the next PSUR.

- For medicinal products authorized under the legal basis of Article 10(1) or Article 10a of Directive 2001/83/EC, no routine PSURs need to be submitted, unless otherwise specified in the EURD list.
- For medicinal products that do not fall within the categories waived of the obligation to submit routine PSURs by the revised pharmacovigilance legislation, the MAH should follow the DLP according to the EURD list.

IV.7 Discussion on the clinical aspects

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

Conditions for the marketing authorisation

Proposed list of conditions pursuant to Article 21a or specific obligations pursuant to article 22 of Directive 2001/83/EC:

- The Applicant has committed to submit a variation within 6 months of the procedures closure to include the colouring agents in the formulations and that the products will not be commercialised until approval of such variation.

V User consultation

A user consultation with target patient groups on the package information leaflet (PIL) has been performed on the basis of a bridging report making reference to Diazepam Actavis 2/5/10 mg Tablets (Actavis, UK) and Solifenacin succinate 5/10mg film-coated tablets (Accord Healthcare Ltd.). The bridging report submitted by the applicant is acceptable.

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 diazepam is considered to have demonstrated the therapeutic value of the compound. These products are bioequivalent to the reference products and their benefit-risk balance is, therefore, considered to be 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 (SmPC) and Patient Information Leaflets (PIL) 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 FOR BLISTER}

1. NAME OF THE MEDICINAL PRODUCT

Diazepam 5 mg tablets
Diazepam 10 mg tablets
Diazepam

2. STATEMENT OF ACTIVE SUBSTANCE (S)

Each tablet contains 5 mg diazepam.
Each tablet contains 10 mg diazepam.

3. LIST OF EXCIPIENTS

Contains lactose monohydrate. See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Tablet.
10 tablets
20 tablets
25 tablets
28 tablets
30 tablets
40 tablets
50 tablets
60 tablets
90 tablets
100 tablets

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

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

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Intas Pharmaceuticals Limited
Sage House, 319, Pinner Road
North Harrow, Middlesex HA1 4HF
United Kingdom

12. MARKETING AUTHORISATION NUMBER (S)

PL 30139/0039 Diazepam 5 mg Tablets
PL 30139/0040 Diazepam 10 mg Tablets

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Diazepam #5 mg tablets
Diazepam #10 mg tablets

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC: {number}
SN: {number}
NN: {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

{LABEL FOR BLISTER}

1. NAME OF THE MEDICINAL PRODUCT

Diazepam 5 mg tablets
Diazepam 10 mg tablets
Diazepam

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Intas

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

PARTICULARS TO APPEAR ON THE OUTER AND IMMEDIATE PACKAGING

{CARTON AND LABEL FOR HDPE BOTTLE}

1. NAME OF THE MEDICINAL PRODUCT

Diazepam 5 mg tablets
Diazepam 10 mg tablets
Diazepam

2. STATEMENT OF ACTIVE SUBSTANCE (S)

Each tablet contains 5 mg diazepam.
Each tablet contains 10 mg diazepam.

3. LIST OF EXCIPIENTS

Contains lactose monohydrate. See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Tablet.
30 tablets

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

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

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PL 30139/0040 Diazepam 10 mg Tablets

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

(For carton only)
Diazepam #5 mg tablets
Diazepam #10 mg tablets

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC: {number}
SN: {number}
NN: {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

{CARTON FOR BLISTER}

1. NAME OF THE MEDICINAL PRODUCT

Diazepam 5 mg tablets
Diazepam 10 mg tablets
Diazepam

2. STATEMENT OF ACTIVE SUBSTANCE (S)

Each tablet contains 5 mg diazepam.
Each tablet contains 10 mg diazepam.

3. LIST OF EXCIPIENTS

Contains lactose monohydrate. See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Tablet.
10 tablets
20 tablets
25 tablets
28 tablets
30 tablets
40 tablets
50 tablets
60 tablets
90 tablets
100 tablets

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

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

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13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Diazepam #5 mg tablets
Diazepam #10 mg tablets

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC: {number}
SN: {number}
NN: {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS

{LABEL FOR BLISTER}

1. NAME OF THE MEDICINAL PRODUCT

Diazepam 5 mg tablets
Diazepam 10 mg tablets
Diazepam

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Intas

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. OTHER

PARTICULARS TO APPEAR ON THE OUTER AND IMMEDIATE PACKAGING

{CARTON AND LABEL FOR HDPE BOTTLE}

1. NAME OF THE MEDICINAL PRODUCT

Diazepam 5 mg tablets
Diazepam 10 mg tablets
Diazepam

2. STATEMENT OF ACTIVE SUBSTANCE (S)

Each tablet contains 5 mg diazepam.
Each tablet contains 10 mg diazepam.

3. LIST OF EXCIPIENTS

Contains lactose monohydrate. See leaflet for further information.

4. PHARMACEUTICAL FORM AND CONTENTS

Tablet.
30 tablets

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

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

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13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

POM

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

(For carton only)
Diazepam #5 mg tablets
Diazepam #10 mg tablets

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER – HUMAN READABLE DATA

PC: {number}
SN: {number}
NN: {number}

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)