Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

Public Assessment Report

Decentralised Procedure

SITAGLIPTIN 25, 50 and 100 mg film-coated tablets

(sitagliptin tartrate hemihydrate)

Procedure No: UK/H/6493/001-03/DC

UK Licence Number: PL 30652/0010-12

LABORATOIRES BIOGARAN

LAY SUMMARY

SITAGLIPTIN 25, 50 and 100 mg film-coated tablets (sitagliptin tartrate hemihydrate)

This is a summary of the Public Assessment Report (PAR) for SITAGLIPTIN 25, 50 and 100 mg film-coated tablets (PL 30652/0010-12; UK/H/6493/001-03/DC). It explains how SITAGLIPTIN 25, 50 and 100 mg film-coated 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 these products.

The products will be collectively referred to as SITAGLIPTIN Tablets throughout this Lay Summary.

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

What are SITAGLIPTIN Tablets and what are they used for?
SITAGLIPTIN Tablets are 'generic medicines'. This means that SITAGLIPTIN Tablets are similar to 'reference medicines' already authorised in the European Union (EU) called Januvia® 25, 50 and 100 mg film-coated tablets (Merck Sharp & Dohme Ltd).

SITAGLIPTIN Tablets are used to lower blood sugar levels in adult patients with type 2 diabetes mellitus. Insulin is a hormone that enables body tissues to take glucose from the blood and to use it for energy or for storage for future use. People with Type 2 diabetes do not make enough insulin in their pancreas or the insulin that the body produces does not work as well as it should. This causes a build-up of glucose in the blood which can lead to serious medical problems like heart disease, kidney disease, blindness, and amputation. This medicine can be used alone or in combination with certain other medicines (insulin, metformin, sulphonylureas, or glitazones) that lower blood sugar, which the patient may already be taking for diabetes together with a food and exercise plan.

How do SITAGLIPTIN Tablets work?
The active substance in SITAGLIPTIN Tablets, sitagliptin tartrate hemihydrate, is a member of a class of medicines called DPP-4 inhibitors (dipeptidyl peptidase-4 inhibitors). This medicine works by increasing the levels of insulin produced after a meal and decreases the amount of sugar made by the body.

How are SITAGLIPTIN Tablets used?
The pharmaceutical form of this medicine is a tablet and the route of administration is oral (by mouth). This medicine can be taken with or without food and drink.

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

The usual dose of SITAGLIPTIN Tablets is one 100 mg film-coated tablets once a day.

Patients with kidney problems may receive lower doses (such as 25 mg or 50 mg).

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

This medicine can only be obtained with a prescription.

What benefits of SITAGLIPTIN Tablets have been shown in studies?
Because SITAGLIPTIN Tablets are generic medicines, studies in patients have been limited to tests to determine that they are bioequivalent to the reference medicines, Januvia® 25, 50 and 100 mg film-coated tablets (Merck Sharp & Dohme Ltd). Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of SITAGLIPTIN Tablets?
Because SITAGLIPTIN Tablets are generic medicines and are bioequivalent to the reference medicines Januvia® 25, 50 and 100 mg film-coated tablets (Merck Sharp & Dohme Ltd), 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 SITAGLIPTIN Tablets, see section 4 of the package leaflet available on the MHRA website.

Why was SITAGLIPTIN Tablets approved?
It was concluded that, in accordance with EU requirements, SITAGLIPTIN Tablets has been shown to have comparable quality and to be bioequivalent to Januvia® 25, 50 and 100 mg film-coated tablets (Merck Sharp & Dohme Ltd). Therefore, the MHRA decided that, as for Januvia® 25, 50 and 100 mg film-coated tablets (Merck Sharp & Dohme Ltd); 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 SITAGLIPTIN Tablets?
A risk management plan (RMP) has been developed to ensure that SITAGLIPTIN Tablets are used as safely as possible. Based on this plan, safety information has been included in the Summaries of Product Characteristics (SmPC) and the package leaflets for SITAGLIPTIN 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 SITAGLIPTIN Tablets
Belgium, Czech Republic, Poland, Romania, Slovak Republic and the UK agreed to grant Marketing Authorisations for SITAGLIPTIN Tablets on 05 February 2018. Marketing Authorisations were granted in the UK on 07 March 2018.

The full PAR for SITAGLIPTIN Tablets follows this summary.

This summary was last updated in May 2018.
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I INTRODUCTION

Based on the review of the data on quality, safety and efficacy the Member States considered that the applications for SITAGLIPTIN 25, 50 and 100 mg film-coated tablets (PL 30652/0010-12; UK/H/6493/001-03/DC), are approvable. The products are prescription-only medicines (POM), indicated for adult patients with type 2 diabetes mellitus to improve glycaemic control:

as monotherapy

- in patients inadequately controlled by diet and exercise alone and for whom metformin is inappropriate due to contraindications or intolerance.

as dual oral therapy in combination with

- metformin when diet and exercise plus metformin alone do not provide adequate glycaemic control.
- a sulphonylurea when diet and exercise plus maximal tolerated dose of a sulphonylurea alone do not provide adequate glycaemic control and when metformin is inappropriate due to contraindications or intolerance.
- a peroxisome proliferator-activated receptor gamma (PPARγ) agonist (i.e. a thiazolidinedione) when use of a PPARγ agonist is appropriate and when diet and exercise plus the PPARγ agonist alone do not provide adequate glycaemic control.

as triple oral therapy in combination with

- a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control.
- a PPARγ agonist and metformin when use of a PPARγ agonist is appropriate and when diet and exercise plus dual therapy with these medicinal products do not provide adequate glycaemic control.

SITAGLIPTIN tablets are also indicated as add-on to insulin (with or without metformin) when diet and exercise plus stable dose of insulin do not provide adequate glycaemic control.

The applications were submitted using the Decentralised Procedure (DCP), with the UK as Reference Member State (RMS), and Belgium, Czech Republic, Poland, Romania and Slovak Republic as Concerned Member States (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 Januvia® 25, 50 and 100 mg film-coated tablets, which were originally authorised to Merck Sharp & Dohme Ltd (EU/1/07/383/001-006, 019-020) on 21 March 2007.

SITAGLIPTIN is a member of a class of oral anti-hyperglycaemic agents called dipeptidyl peptidase 4 (DPP-4) inhibitors. The improvement in glycaemic control observed with this medicinal product may be mediated by enhancing the levels of active incretin hormones. Incretin hormones, including glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP), are released by the intestine throughout the day, and levels are increased in response to a meal. The incretins are part of an endogenous system involved in the physiologic regulation of glucose homeostasis. When blood glucose concentrations are normal or elevated, GLP-1 and GIP increase insulin synthesis and release from pancreatic beta cells by intracellular signaling pathways involving cyclic AMP. Treatment with GLP-1 or with DPP-4 inhibitors in animal models of type 2 diabetes has been demonstrated to improve beta cell responsiveness to glucose and stimulate insulin biosynthesis and release. With higher insulin levels, tissue glucose uptake is enhanced. In addition, GLP-1 lowers glucagon secretion from pancreatic alpha cells.

One bioequivalence study (conducted under fasting conditions) was submitted to support these applications. The bioequivalence study is stated to have been 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 these applications were based on being generic medicinal products of originator products that have 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 member states considered that the applications could be approved at the end of procedure on 05 February 2018. After a subsequent national phase, licences (PL 30652/0010-12) were granted in the UK 07 March 2018.

II QUALITY ASPECTS

II.1 Introduction

Each tablet contains 34.76, 69.52 and 139.04 mg sitagliptin tartrate hemihydrate equivalent to 25, 50 and 100 mg sitagliptin, as the active ingredient. Other ingredients consist of the pharmaceutical excipients cellulose microcrystalline, calcium hydrogen phosphate dihydrate, croscarmellose sodium, magnesium stearate and sodium stearyl fumarate making up the tablet core. The film-coat is composed of Opadry II 85F230079 Orange (polyvinyl alcohol-part hydrolysed, titanium dioxide (E171), macrogol 3350, talc, yellow iron oxide (E172) and red iron oxide (E172)).

All excipients comply with their respective European Pharmacopoeia monographs with the exception of Opadry II 85F230079 Orange which complies with an in-house specification and yellow iron oxide (E172) and red iron oxide (E172) which are controlled by a national formulary (NF). Satisfactory Certificates of Analysis have been provided for all excipients. Suitable batch analysis data have been provided for each excipient.

None of the excipients used contain material of animal or human origin. Confirmation has been given that the magnesium stearate used in the tablets is of vegetable origin.

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

The finished product is packaged in polyvinylchloride (PVC), polyvinylidenechloride (PVdC) and aluminium blisters containing pack sizes of 28, 56 or 98 film-coated tablets.

Not all pack sizes may be marketed.

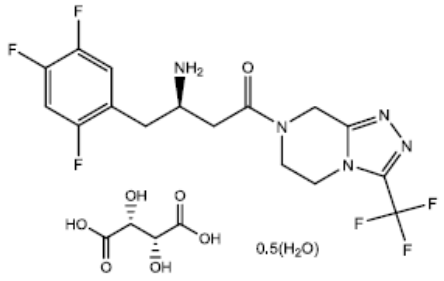
Satisfactory specifications and Certificates of Analysis have been provided for all packaging components.

II.2. Drug Substance

INN: Sitagliptin tartrate hemihydrate

Chemical names: R)-3-amino-1-(3-(trifluoromethyl)-5,6-dihydro-[1,2,4]triazolo[4,3a]pyrazin-7(8H)-yl)-4-(2,4,5-trifluorophenyl)butan-1-one (2R,3R)-2,3-dihydroxysuccinate hemihydrate

Structural formula:



Molecular formula: $C_{20}H_{21}F_6N_5O_7$,½H_2O

Molecular mass: 566.41 g/mol

Appearance: White to off-white, crystalline powder.

Solubility: Slightly hygroscopic powder.

Sitagliptin tartrate hemihydrate is the subject of an Active Substance Master File (ASMF).

Synthesis of the drug 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.

An appropriate specification is provided for the drug substance. Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications. Certificates of Analysis for all working standards have been provided.

Batch analysis data are provided and comply with the proposed specification.

Satisfactory specifications and Certificates of Analysis have been provided for all packaging used to store the drug substance. Confirmation has been provided that the primary packaging complies with current guidelines concerning materials in contact with food.

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

II.3. Medicinal Product

Pharmaceutical Development

The objective of the development programme was to formulate safe, efficacious tablets containing 25, 50 or 100 mg sitagliptin per tablet, that are generic versions of the reference products Januvia® 25, 50 and 100 mg film-coated tablets (Merck Sharp & Dohme Ltd). A satisfactory account of the pharmaceutical development has been provided.

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

Manufacture of the product

Satisfactory batch formulae have been provided for the manufacture of the products, together with an appropriate account of the manufacturing processes. The manufacturing processes have been validated at pilot scale batch size and has shown satisfactory results. The applicant has committed to perform process validation on three full scale commercial-scale batches.

Finished Product Specification

The finished product specifications proposed are acceptable. The 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 30 months with no 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 sitagliptin tartrate hemihydrate 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 these products are intended for generic substitution, their use 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

No new non-clinical studies were conducted, which is acceptable given that the applications were based on being generic medicinal products of originator products that have been licensed for over 10 years.

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 sitagliptin tartrate hemihydrate 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 these types of applications. A comprehensive review of the published literature has been provided by the applicant, citing the well-established clinical pharmacology, efficacy and safety of sitagliptin tartrate hemihydrate.

Based on the data provided, SITAGLIPTIN 25, 50 and 100 mg film-coated tablets can be considered bioequivalent to Januvia® 25, 50 and 100 mg film-coated tablet (Merck Sharp & Dohme Ltd (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 Sitagliptin 100 mg film-coated tablet versus the reference product, Januvia® 100 mg film-coated tablet (Merck Sharp & Dohme Ltd (UK), in healthy, adult, subjects under fasting conditions.

Blood samples were collected for plasma levels before dosing and up to and including 48 hours after each administration. The washout period between the treatment phases was 7 days. The pharmacokinetic results are presented below:

Table: Geometric Least Squares mean, Ratios and 90 % confidence interval for PK parameters of sitagliptin (n=24):

Parameter (n = 24)	p- values ANOVA	GMR (%), 90% CI, CVintra (%)	Bioequivalence in [80.00% – 125.00%]
C_{max}	• Treatment = 0.5124 • Sequence = 0.7792 • Period = 0.0968	97.77 [92.24 – 103.63] 11.78	Passed
AUC_{0-T}	• Treatment = 0.0364 • Sequence = 0.6981 • Period = 0.0936	97.46 [95.55 – 99.41] 4.00	Passed
AUC_{0-inf}	• Treatment = 0.0282 • Sequence = 0.6848 • Period = 0.1138	97.38 [95.52 – 99.29] 3.91	Passed

Conclusion
The 90% confidence intervals of the test/reference ratio for C_{max}, $AUC_{(0-T)}$ and AUC_{0-inf} values for Sitagliptin 100 mg film-coated tablet 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 Januvia® 100 mg film-coated tablet (Merck Sharp & Dohme Ltd. (UK)).

As the 25 mg and 50 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 tablet strength can be extrapolated to the 25 and 50 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
The marketing authorisation holder (MAH) has submitted a risk management plan (RMP), in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to SITAGLIPTIN 25, 50 and 100 mg film-coated tablets.

A summary of safety concerns as approved in the RMP, is listed below:

Summary of safety concerns	
Important identified risks	• Hypersensitivity reactions, including anaphylactic reaction, angioedema, rash, urticaria, cutaneous vasculitis, skin exfoliation and Stevens-Johnson syndrome • Hypoglycaemia with concomitant sulfonylurea • Hypoglycaemia with concomitant insulin • Gastrointestinal disorders • Musculoskeletal disorders: osteoarthritis, pain in extremity, and related terms (e.g. arthralgia, myalgia, myopathy) • Pancreatitis • Bullous pemphigoid
Important potential risks	• Infections: Upper respiratory tract infection, nasopharyngitis • Neurotoxicity: tremor, ataxia, and balance disorders • Suicidal ideation, suicide and depression • Impaired renal function, including acute renal failure (sometimes requiring dialysis) • Pancreatic cancer • Rhabdomyolysis • Skin reactions: contact dermatitis.
Missing information	• Patients below18 years of age • Exposure during pregnancy and Lactation • Theoretic carcinogenic potential • Patients with severe hepatic impairment.

Routine pharmacovigilance and routine risk minimisation are proposed for all safety concerns.

IV.7 Discussion on the clinical aspects

With the exception of the bioequivalence study, no new clinical studies were conducted, which is acceptable given that the applications were based on being generic medicinal products of originator products that have been licensed for over 10 years.

Bioequivalence has been demonstrated between the applicant's test product Sitagliptin 100 mg film-coated tablet versus the reference product, Januvia® 100 mg film-coated tablet (Merck Sharp & Dohme Ltd. (UK)).

As the 25 mg and 50 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 tablet strength can be extrapolated to the 25 and 50 mg strength tablets.

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

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 package leaflet 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 concerns have been identified. Extensive clinical experience with sitagliptin tartrate hemihydrate is considered to have demonstrated the therapeutic value of the compound. The benefit-risk is, therefore, considered to be 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 approved text labelling for SITAGLIPTIN 25, 50 and 100 mg film-coated tablets is presented below:

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON FOR BOTTLE

1. NAME OF THE MEDICINAL PRODUCT

Sitagliptin 25 mg film coated tablets
Sitagliptin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 34.76 mg sitagliptin tartrate hemihydrate equivalent to 25 mg of sitagliptin.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

28 film coated tablets
56 film coated tablets
98 film coated 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

LABORATOIRES BIOGARAN

15, BOULEVARD CHARLES DE GAULLE
92700 COLOMBES
FRANCE

12. MARKETING AUTHORISATION NUMBER(S)

PL 30652/0010

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Sitagliptin /…/ 25 mg

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 OR STRIPS

BLISTERS

1. NAME OF THE MEDICINAL PRODUCT

Sitagliptin 25 mg film coated tablets
Sitagliptin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

BIOGARAN

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Batch

5. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON FOR BOTTLE

1. NAME OF THE MEDICINAL PRODUCT

Sitagliptin 50 mg film coated tablets
Sitagliptin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 69.52 mg sitagliptin tartrate hemihydrate equivalent to 50 mg of sitagliptin.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

28 film coated tablets
56 film coated tablets
98 film coated 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

LABORATOIRES BIOGARAN

15, BOULEVARD CHARLES DE GAULLE
92700 COLOMBES
FRANCE

12. MARKETING AUTHORISATION NUMBER(S)

PL 30652/0011

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Sitagliptin /…/ 50 mg

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 OR STRIPS

BLISTERS

1. NAME OF THE MEDICINAL PRODUCT

Sitagliptin 50 mg film coated tablets
Sitagliptin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

BIOGARAN

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Batch

5. OTHER

PARTICULARS TO APPEAR ON THE OUTER PACKAGING

CARTON FOR BOTTLE

1. NAME OF THE MEDICINAL PRODUCT

SITAGLIPTIN 100 mg film coated tablets
Sitagliptin

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each tablet contains 139.04 mg sitagliptin tartrate hemihydrate equivalent to 100 mg of sitagliptin.

3. LIST OF EXCIPIENTS

4. PHARMACEUTICAL FORM AND CONTENTS

28 film coated tablets
56 film coated tablets
98 film coated 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

LABORATOIRES BIOGARAN
15, BOULEVARD CHARLES DE GAULLE
92700 COLOMBES

FRANCE

12. MARKETING AUTHORISATION NUMBER(S)

PL 30652/0012

13. BATCH NUMBER

Batch

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription.

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Sitagliptin /…/ 100 mg

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 OR STRIPS

BLISTERS

1. NAME OF THE MEDICINAL PRODUCT

SITAGLIPTIN 100 mg film coated tablets
Sitagliptin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

BIOGARAN

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Batch

5. OTHER

Table of content of the PAR update for MRP and DCP

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)