



## **Public Assessment Report**

**Name of the Product:**

**Ceftazidim AptaPharma  
1 g powder for solution for injection/infusion**

**(ceftazidime)**

**Procedure number: HU/H/0589/001/DC**

**Marketing authorisation holder: Apta Medica Internacional d.o.o.**

**Date: 8 July 2020**

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UPGRADE: STEPS TAKEN AFTER THE INITIAL PROCEDURE WITH AN INFLUENCE  
ON THE PUBLIC ASSESSMENT REPORT

## LAY SUMMARY

After careful assessment of its quality and therapeutic benefit/risk ratio, the member states have granted the marketing authorisation of the Ceftazidim AptaPharma 1 g powder for solution for injection/infusion. The holder of the marketing authorisation is Apta Medica Internacional d.o.o., Slovenia.

The active substance is 1 g of ceftazidime (present as ceftazidime pentahydrate).

The only other ingredient is sodium carbonate (anhydrous sterile).

Sterile white or pale yellow powder filled in glass 10 ml vial with a bromobutyl rubber closure and aluminium flip cap. Available in packs of 10 vials.

The doctor or pharmacist or nurse will make the injection or infusion up with Water for Injections or a suitable infusion fluid. When made up, the solution varies in colour from light yellow to amber. This is perfectly normal.

Ceftazidim AptaPharma 1 g powder for solution for injection/infusion (further on: Ceftazidim AptaPharma) is an antibiotic used in adults and children (including newborn babies). It works by killing bacteria that cause infections. It belongs to a group of medicines called cephalosporins.

Ceftazidim AptaPharma is used to treat severe bacterial infections of:

- the lungs or chest,
- the lungs and bronchi in patients suffering from cystic fibrosis,
- the brain (meningitis),
- the ear,
- the urinary tract,
- the skin and soft tissues,
- the abdomen and abdominal wall (peritonitis),
- the bones and joints.

Ceftazidim AptaPharma can also be used:

- to prevent infections during prostate surgery in men,
- to treat patients with low white blood cell counts (neutropenia) who have a fever due to a bacterial infection.

### **What patients need to know before they are given Ceftazidim AptaPharma**

*Patients who have the following conditions must not be given Ceftazidim AptaPharma:*

- are allergic to ceftazidime or any of the other ingredients of this medicine,
- have had a severe allergic reaction to any other antibiotic (penicillins, monobactams and

carbapenems) as they may also be allergic to Ceftazidim AptaPharma.

Those who think that this applies to them tell it their doctor before starting on Ceftazidim AptaPharma. They must not be given it.

*Taking special care with {(Invented) name}*

Patients must look out for certain symptoms such as allergic reactions, nervous system disorders and gastrointestinal disorders such as diarrhoea while they are being given Ceftazidim AptaPharma. This will reduce the risk of possible problems. Those who have had an allergic reaction to other antibiotics may also be allergic to Ceftazidim AptaPharma.

*If the patient needs a blood or urine test*

Ceftazidim AptaPharma can affect the results of urine tests for sugar and a blood test known as the Coombs test. Those who are having tests should tell the person taking the sample that they have been given Ceftazidim AptaPharma.

*Other medicines and Ceftazidim AptaPharma*

Patients should tell their doctor if they are taking, have recently taken or might take any other medicines. This includes medicines that can be obtained without a prescription.

Patients who are also taking the following medicines shouldn't be given Ceftazidim AptaPharma without talking to their doctor:

- an antibiotic called chloramphenicol.
- a type of antibiotic called aminoglycosides e.g. gentamicin, tobramycin,
- water tablets called furosemide.

*Pregnancy, breast-feeding and fertility*

Patients should ask their doctor for advice before they are given Ceftazidim AptaPharma:

- if they are pregnant, think they might be pregnant or are planning to become pregnant,
- if they are breast-feeding.

The doctor will consider the benefit of treating the patient with Ceftazidim AptaPharma against the risk to her baby.

*Driving and using machines*

Ceftazidim AptaPharma can cause side effects that affect the ability to drive, such as dizziness. Patients should not drive or use machines unless they are sure they are not affected.

*Ceftazidim AptaPharma contains sodium*

This medicine contains approximately 2.28 mmol (approximately 52.44 mg) of sodium (main component of cooking/table salt) in each 1.0 g. This is equivalent to 2.62 % of the recommended

maximum daily dietary intake of sodium for an adult per 1.0 g dose which should be taken into consideration by patients on a controlled sodium diet.

### **How Ceftazidim AptaPharma is given**

Ceftazidim AptaPharma is usually given by a doctor or nurse. It can be given as a drip (intravenous infusion) or as an injection directly into a vein or into a muscle.

Ceftazidim AptaPharma is made up by the doctor, pharmacist or nurse using water for injections or a suitable infusion fluid.

#### *The recommended dose*

The correct dose of Ceftazidim AptaPharma for a given patient will be decided by the doctor and depends on: the severity and type of infection; whether the patient is on any other antibiotics; his/her weight and age; how well the kidneys are working.

#### *Newborn babies (0-2 months)*

For every 1 kg the baby weighs, they will be given 25 to 60 mg Ceftazidim AptaPharma per day divided in two doses.

#### *Babies (over 2 months) and children who weigh less than 40 kg*

For every 1 kg the baby or child weighs, they will be given 100 to 150 mg of Ceftazidim AptaPharma per day divided in three doses. Maximum 6 g per day.

#### *Adults and adolescents who weigh 40 kg or more*

1 to 2 g of Ceftazidim AptaPharma three times daily. Maximum of 9 g per day.

#### *Patients over 65*

The daily dose should not normally exceed 3 g per day, especially if the patient is over 80 years of age.

#### *Patients with kidney problems*

They may be given a different dose to the usual dose. The doctor or nurse will decide how much Ceftazidim AptaPharma the patient will need, depending on the severity of the kidney disease.

The doctor will check the patient closely and he/she may have more regular kidney function tests.

*What to do if more Ceftazidim AptaPharma has been given than it should have been?*

If accidentally more has been used than the prescribed dose, the doctor or the nearest hospital must be contacted straight away.

*What to do if using Ceftazidim AptaPharma has been forgotten?*

If an injection has been missed, it must be administered as soon as possible. However, no double dose (two injections at the same time) must be given to make up for a missed dose.

*May patients stop using Ceftazidim AptaPharma?*

Patients should not stop using Ceftazidim AptaPharma unless their doctor tells them to.

### **Possible side effects**

Like all medicines, Ceftazidim AptaPharma can cause side effects, although not everybody experiences them.

*Conditions patients need to look out for*

The following serious side effects have occurred in a small number of people but their exact frequency is unknown:

- severe allergic reaction. Signs include raised and itchy rash, swelling, sometimes of the face or mouth causing difficulty in breathing;
- skin rash, which may blister, and looks like small targets (central dark spot surrounded by a paler area, with a dark ring around the edge);
- a widespread rash with blisters and peeling skin. (These may be signs of Stevens-Johnson syndrome or toxic epidermal necrolysis),
- nervous system disorders: tremors, fits and, in some cases coma. These have occurred in people when the dose they are given is too high, particularly in people with kidney disease,
- there have been rare reports of severe hypersensitivity reactions with severe rash, which may be accompanied by fever, fatigue, swelling of the face or lymph glands, increase of eosinophils (type of white blood cells), effects on liver, kidney or lung (a reaction called DRESS).

Patients who get any of these symptoms must contact a doctor or nurse immediately!

Common side effects (these may affect up to 1 in 10 people):

- diarrhoea,
- swelling and redness along a vein,
- red raised skin rash which may be itchy,
- pain, burning, swelling or inflammation at the injection site.

Patients should contact your doctor if any of these are troubling them.

Common side effects that may show up in blood tests:

- an increase in a type of white blood cell (eosinophilia),

- an increase in the number of cells that help the blood to clot,
- an increase in liver enzymes.

Uncommon side effects (these may affect up to 1 in 100 people):

- inflammation of the gut which can cause pain, or diarrhoea which may contain blood,
- thrush (fungal infections in the mouth or vagina),
- headache,
- dizziness,
- stomach ache,
- feeling sick or being sick,
- fever and chills.

Patients who get any of these should inform their doctor.

Uncommon side effects that may show up in blood tests:

- a decrease in the number of white blood cells,
- a decrease in the number of blood platelets (cells that help the blood to clot),
- an increase in the level of urea, urea nitrogen or serum creatinine in the blood.

Very rare side effect (that may affect up to 1 in 10,000 people): inflammation or failure of the kidneys.

Other side effects have occurred in a small number of people but their exact frequency is unknown:

- pins and needles,
- unpleasant taste in the mouth,
- yellowing of the whites of the eyes or skin.

Other side effects that may show up in blood tests:

- red blood cells destroyed too quickly,
- an increase in a certain type of white blood cells,
- severe decrease in the number of white blood cells.

### **How to store Ceftazidim AptaPharma**

This medicinal product does not require any special temperature storage conditions. It should be stored in the original package in order to protect from light and kept out of the sight and reach of children.

Reconstituted and diluted solution: the doctor, pharmacist or nurse will make up the medicine in Water for Injections or compatible fluids. Once made up, this medicine should be used within 24 hours if stored in refrigerator (2 to 8 °C) or should be used immediately, depending on the route of administration.

# **Scientific discussion**

## **during the initial phase**

**This module reflects the scientific discussion for the approval of Ceftazidim AptaPharma 1 g powder for solution for injection/infusion. The procedure was finalised at 31 October 2019. For information on changes after this date please refer to the module 'Update'.**

## I. INTRODUCTION

In accordance to the Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 *on the Community code relating to medicinal products for human use*, an application has been submitted to the reference and competent authorities of the Member State concerned.

This Decentralised Procedure application (Reference member state, RMS: Hungary, concerned member states, CMS: Austria, Bulgaria, Croatia, the Czech Republic, Poland, Romania and Slovenia) concerned the generic version of ceftazidime 1 g powder for solution for injection/infusion.

The application has been filed pursuant to Article 10(1) of Directive 2001/83/EC and therefore contained no new clinical or preclinical data, other than supporting literature.

The applicant has adequately stated bioequivalence between the product and reference products. The reference product was Fortum 1 g powder for solution for injection or infusion (GlaxoSmithKline) approved for more than 10 years within the European Economic Area.

Based on the review of the quality, safety and efficacy data, the Member States have granted marketing authorisation for Ceftazidim AptaPharma 1 g powder for solution for injection/infusion from Apta Medica Internacional d.o.o., Slovenia.

The product is indicated for the treatment of the infections listed below in adults and children including neonates (from birth):

- nosocomial pneumonia,
- broncho-pulmonary infections in cystic fibrosis,
- bacterial meningitis,
- chronic suppurative otitis media,
- malignant otitis externa,
- complicated urinary tract infections,
- complicated skin and soft tissue infections,
- complicated intra-abdominal infections,
- bone and joint infections,
- peritonitis associated with dialysis in patient on CAPD.

Treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above.

Ceftazidime may be used in the management of neutropenic patients with fever that is suspected to be due to a bacterial infection.

Prevention: ceftazidime may be used in the peri-operative prophylaxis of urinary tract infections for patients undergoing transurethral resection of the prostate (TURP).

A comprehensive description of the indications and posology is given in the Summary of Product Characteristics.

## II. QUALITY ASPECTS

### II.1 Introduction

This chemical-pharmaceutical assessment report concerns the application for Marketing Authorisation *via* the Decentralised Procedure for product Ceftazidim AptaPharma 1g powder for solution for injection/infusion according to Article 10(1) of consolidated Directive 2001/83/EC (i.e. a generic application).

The reference medicinal product is Fortum 1 g powder for solution for injection by GSK marketed in France.

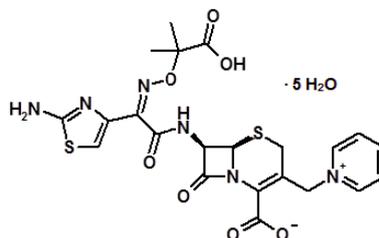
The finished dosage form is a powder for solution for injection/infusion. The sterile mixture of ceftazidime pentahydrate and sodium carbonate is filled in the packaging to use it as drug product. The product contains 1 g of the active substance ceftazidime in the form of pentahydrate. The drug product is packed in colourless glass vials, stoppered by a bromobutyl rubber closure, capped with an aluminium cap and a plastic flip-off disc.

### II.2 Drug substance

Data on the quality and manufacture of the active substance were provided in the submission using the European Pharmacopoeia (Ph. Eur.) Certificate of Suitability (CEP) procedure in the marketing authorization dossier. The Quality Overall Summary is adequate.

I.N.N.: ceftazidime pentahydrate  
Chemical name: (6R,7R)-7-[[[(2Z)-2-(2-Aminothiazol-4-yl)-2-[(1-carboxy-1-methylethoxy)imino]acetyl]amino]-8-oxo-3-[(pyridin-1-ium-1-yl)methyl]-5-thia-1-azabicyclo[4.2.0]oct-2-ene-2-carboxylate pentahydrate

Structure:



The drug substance is an established active substance, the pentahydrate form is described in the Ph. Eur. It is slightly soluble in water and in methanol, practically insoluble in acetone and in ethanol (96 per cent). It dissolves in acid and alkali solutions.

All aspects of the manufacture and control of the active substance, ceftazidime pentahydrate, are covered by European Directorate for the Quality of Medicines and Healthcare (EDQM) CEP.

The drug substance has been specified according to the requirements of the current Ph. Eur. monograph on ceftazidime pentahydrate with additional requirements stated on the CEPs.

Analytical procedures are performed using methods in accordance with the Ph. Eur. monograph on ceftazidime pentahydrate, the CEP and in-house methods.

Batch analysis data justify the limits, indicate the good performance of testing methods and demonstrate the batch to batch consistency of the production.

Re-test period of the drug substance has been assigned in the CEP.

Good Manufacturing Practice (GMP) compliance of the drug substance manufacture is demonstrated by the applicant.

### **II.3 Medicinal product**

The pharmaceutical development aimed to manufacture a stable powder for solution for injection/infusion as a generic formulation of reference product Fortum 1 g powder for solution for injection/infusion. The same quantity of drug substance in one vial and the same route of administration is used.

The control of excipients is in line with pharmacopoeial requirements.

Compliance of the product with the general monograph of the Ph. Eur. on the *Products with the risk of TSE* has been demonstrated by the applicant.

A description and flow chart of the manufacturing method has been provided. Appropriate in-process controls are included in the manufacturing process. Satisfactory batch formulae were also presented. GMP compliance of the manufacturing site has been demonstrated.

The finished product specification is satisfactory. Acceptance criteria have been justified with respect to conventional pharmaceutical requirements as prescribed in the relevant dosage form monograph of the Ph. Eur. and the International Council of Harmonisation (ICH) Q6A guideline. Appropriate control strategy was selected. The test methods have been described and have been adequately validated, as appropriate. Batch data have been provided and complied with the specification. The testing results of the batches demonstrate that the drug product can be manufactured in a consistently good quality.

The provided data and documents of the container-closure system confirm the suitability of the immediate packaging materials.

Finished product stability studies have been conducted in accordance with the current guidelines. Based on the results, a shelf-life of 36 months is approved with the following storage

condition: ‘This medicinal product does not require any special temperature storage conditions. Keep the container in the outer carton in order to protect from light.’

The Summary of Product Characteristics, Package Leaflet and label texts are pharmaceutically acceptable.

#### **II.4 Discussion on chemical, pharmaceutical and biological aspects**

Ceftazidim AptaPharma 1g powder for solution for injection/infusion has been shown to meet the current regulatory requirements with regards to its quality and content of the active substance as well as dosage-form characteristics until the end of the approved shelf-life consistently. The manufacture and the quality standards applied adequately support the safe use and efficacy of the product.

From quality aspects the product is approvable.

### **III. NON-CLINICAL ASPECTS**

#### **III.1 Introduction**

Pharmacodynamic, pharmacokinetic and toxicological properties of ceftazidime are well known. As ceftazidime is a widely used, well-known active substance, no further studies are required and the applicant provided none. Overview based on literature review is, thus, appropriate. The submitted overview is adequate.

#### **III.2 Pharmacology**

Ceftazidime is a third-generation cephalosporin, a beta-lactam antibacterial agent.

Ceftazidime inhibits bacterial cell wall synthesis following attachment to penicillin binding proteins. This results in the interruption of cell wall (peptidoglycan) biosynthesis, which leads to bacterial cell lysis and death.

#### **III.3 Pharmacokinetics**

Absorption: after intramuscular administration of ceftazidime, peak plasma levels are achieved rapidly.

Distribution: the serum protein binding of ceftazidime is low. Concentrations in excess of the MIC for common pathogens can be achieved in tissues such as bone, heart, bile, sputum, aqueous humour, synovial, pleural and peritoneal fluids. Ceftazidime crosses the placenta readily, and is excreted in the breast milk. Penetration of the intact blood-brain barrier is poor.

Biotransformation: ceftazidime is not metabolised.

Elimination: ceftazidime is excreted unchanged mostly into the urine.

#### **III.4 Toxicology**

Non-clinical data reveal no special hazard for humans based on studies of safety pharmacology, repeat dose toxicity, genotoxicity, toxicity to reproduction. Carcinogenicity studies have not been performed with ceftazidime.

#### **III.5 Ecotoxicology/environmental risk assessment (ERA)**

Evaluation of the potential environmental risk posed by the medicinal product has not been

provided.

Since Ceftazidim AptaPharma 1 g powder for solution for injection/infusion is 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**

Abridged applications avoid the need for repetitive tests on animals. The submitted literature overview is adequate.

There are no objections to approval of Ceftazidim AptaPharma 1 g powder for solution for injection/infusion from a non-clinical point of view.

## IV. CLINICAL ASPECTS

### IV.1 Introduction

Ceftazidime has a well-established efficacy and safety profile and is generally well-tolerated. As ceftazidime is a widely used, well-known active substance, no further studies are required and the applicant provided none. Overview based on literature review is, thus, appropriate. The submitted overview is adequate.

### IV.2 Pharmacokinetics

No in vivo pharmacokinetic studies have been performed by the applicant. Bioequivalence to the marketed reference product, Fortum 1 g powder for solution for injection or infusion (GSK) was established, for the conditions in *Guideline on the Investigation of Bioequivalence CPMP/EWP/QWP/1401/98 Rev. 1/corr\**, namely aqueous solutions, the same qualitative and quantitative compositions, same excipient were fulfilled.

According to literature data, after intramuscular administration of 500 mg and 1 g of ceftazidime, peak plasma levels of 18 and 37 mg/l respectively are achieved rapidly. Five minutes after intravenous bolus injection of 500 mg, 1 g or 2 g, plasma levels are 46, 87 and 170 mg/l, respectively. The kinetics of ceftazidime are linear within the single dose range of 0.5 to 2 g following intravenous or intramuscular dosing.

The serum protein binding of ceftazidime is low at about 10%. Penetration of the intact blood-brain barrier is poor, resulting in low levels of ceftazidime in the CSF in the absence of inflammation. However, concentrations of 4 to 20 mg/l or more are achieved in the CSF when the meninges are inflamed.

Ceftazidime is not metabolised.

After parenteral administration plasma levels decrease with a half-life of about 2 h. Ceftazidime is excreted unchanged into the urine by glomerular filtration; approximately 80 to 90 % of the dose is recovered in the urine within 24 h. Less than 1 % is excreted via the bile.

### IV.3 Pharmacodynamics

No new data have been submitted. Pharmacodynamics of ceftazidime is well-known.

### IV.4 Clinical efficacy

No new data have been submitted. Efficacy was established through a review of key published information on the use of i.v. ceftazidime in the indications that are currently approved for the reference product.

## IV.5 Clinical safety

Specific clinical studies have not been conducted in support of the generic drug product. The safety statements proposed within the Summary of Product Characteristics (SmPC) are taken directly from the relevant sections of the SmPC for the reference product. Confirmation of the suitability of the proposed safety information has been obtained through a review of key published information and case reports available within the public domain. The aim of this review has been to compile, review and analyse, as far as was possible, the safety profile of ceftazidime, particularly when used for i.v. infusion.

## IV.6 Pharmacovigilance

### *IV.6.1 Summary of the 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 legal requirements as set out in the Commission Implementing Regulation and as detailed in the Good Pharmacovigilance Practice module, the RMS considers the Summary acceptable.

### *IV.6.2 Risk Management Plan*

The applicant has submitted a risk management plan, 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 Ceftazidim AptaPharma 1 g powder for solution for injection/infusion

The applicant has identified the following safety concerns.

<i>Summary of safety concerns</i>	
Important identified risks	None.
Important potential risks	None.
Missing information	None.

*Pharmacovigilance Plan:* routine pharmacovigilance activities are considered sufficient to manage all of the safety concerns connected to to Ceftazidim AptaPharma 1 g powder for solution for injection/infusion. No additional activities are proposed.

*Risk Minimisation Measures:* routine measures (i.e. wording in the SmPC, Package Leaflet and classification as a prescription-only medicine) are considered sufficient to manage all of the safety concerns connected to to Ceftazidim AptaPharma 1 g powder

for solution for injection/infusion. No additional activities are proposed. For any further information on risk minimisation, please refer to the product information.

#### ***IV.6.3 Periodic Safety Update Reports***

With regard to Periodic Safety Update Reports (PSUR) submission, the marketing authorisation holder 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 Data Lock Point (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 marketing authorisation holder should follow the DLP according to the EURD list.

#### **IV.7 Discussion on the clinical aspects**

Abridged applications avoid the need for repetitive tests on animals and humans. For these application the bioequivalence described in section IV.2 is pivotal.

Since both Ceftazidim AptaPharma 1 g powder for solution for injection/infusion and the reference product Fortum 1 g powder for solution for injection or infusion are aqueous solutions with the same qualitative and quantitative composition, they can be taken bioequivalent without performing human comparative studies.

## V. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

### V.1 Summary

The present applications concern Ceftazidim AptaPharma 1 g powder for solution for injection/infusion, generic version of ceftazidime. The applicant and the future holder of authorisation is Apta Medica Internacional d.o.o., Slovenia.

The indications are as follows.

Treatment of the infections listed below in adults and children including neonates (from birth):

- nosocomial pneumonia,
- broncho-pulmonary infections in cystic fibrosis,
- bacterial meningitis,
- chronic suppurative otitis media,
- malignant otitis externa,
- complicated urinary tract infections,
- complicated skin and soft tissue infections,
- complicated intra-abdominal infections,
- bone and joint infections,
- peritonitis associated with dialysis in patient on CAPD.

Treatment of patients with bacteraemia that occurs in association with, or is suspected to be associated with, any of the infections listed above.

Ceftazidime may be used in the management of neutropenic patients with fever that is suspected to be due to a bacterial infection.

Prevention: ceftazidime may be used in the peri-operative prophylaxis of urinary tract infections for patients undergoing transurethral resection of the prostate (TURP).

The application was submitted according to Article 10(1) of Directive 2001/83/EC (generic application). The reference product was Fortum 1 g powder for solution for injection or infusion (GlaxoSmithKline). To support the application the applicant has adequately justified bioequivalence on the basis of rules concerning aqueous solutions of the same qualitative and quantitative composition.

The submitted documentation is administratively adequate and scientifically sound. The quality of the product is satisfactory. There were no non-clinical or clinical concerns raised.

The therapeutic benefit/risk assessment is, therefore, positive.

Based on the review of the quality, safety and efficacy data, the Member States have granted marketing authorisation for Ceftazidim AptaPharma 1 g powder for solution for injection/infusion.

## **V.2 Classification**

Prescription-only medicine.

## **V.3 Package Leaflet and 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 patient information 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. Upgrade: steps taken after the initial procedure with an influence on the Public Assessment Report**

**This module reflects the procedural steps and scientific information after the finalisation of the initial procedure.**

<b>Scope</b>	<b>Procedure number</b>	<b>Product information affected</b>	<b>Date of start of the procedure</b>	<b>Date of end of procedure</b>	<b>Approval or non approval</b>	<b>Assessment report attached</b>