17 November 2011
EMA/11666/2012
Committee for medicinal products for human use (CHMP)

Assessment report

Desloratadine Actavis

International nonproprietary name: Desloratadine

Procedure No. EMEA/H/C/002435

Assessment Report as adopted by the CHMP with all information of a commercially confidential nature deleted

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List of abbreviations

CHMP	Committee for Medicinal Products for Human Use
EMA	European Medicines Agency
ERA	Environmental Risk Assessment
MA	Marketing Authorisation
MAH	Marketing Authorisation Holder
PL	Package Leaflet
PSUR	Periodic Safety Update Report
RMP	Risk Management Plan

1. Background information on the procedure

1.1. Submission of the dossier

The applicant Actavis Group PTC ehf, submitted on 31 January 2011 an application for Marketing Authorisation to the European Medicines Agency (EMA) for Desloratadine Actavis, through the centralised procedure under Article 3 (3) of Regulation (EC) No. 726/2004– 'Generic of a Centrally authorised product'. The eligibility to the centralised procedure was agreed upon by the EMA/CHMP on 21 October 2010.

The application concerns a generic medicinal product as defined in Article 10(2)(b) of Directive 2001/83/EC and refers to a reference product for which a Marketing Authorisation is or has been granted in the Union on the basis of a complete dossier in accordance with Article 8(3) of Directive 2001/83/EC.

The applicant applied for the following indication: relief of symptoms associated with allergic rhinitis and urticaria.

The legal basis for this application refers to:

Article 10(1) of Directive 2001/83/EC.

The application submitted is composed of administrative information, complete quality data and a bioequivalence study with the reference medicinal product Aerius instead of non-clinical and clinical unless justified otherwise.

Information on Paediatric requirements

Not applicable.

Information relating to Orphan Market Exclusivity

Not applicable.

Market Exclusivity

Not applicable.

The chosen reference product is:

■ Medicinal product which is or has been authorised in accordance with Community provisions in accordance with Community provisions in force for not less than 6/10 years in the EEA:

- Product name, strength, pharmaceutical form: Aerius 5mg film-coated tablets
- Marketing authorisation holder: Schering-Plough Europe
- Date of authorisation: 15-01-2001
- Marketing authorisation granted by: Community
  - Community Marketing authorisation number: EU/1/00/160/001-013

■ Medicinal product authorised in the Community/Members State where the application is made or European reference medicinal product:

- Product name, strength, pharmaceutical form: Aerius 5mg film-coated tablets
- Marketing authorisation holder: Schering-Plough Europe
- Date of authorisation: 15-01-2001

- Marketing authorisation granted by: Community
  - Community Marketing authorisation number: : EU/1/00/160/001-013

■ Medicinal product which is or has been authorised in accordance with Community provisions in force and to which bioequivalence has been demonstrated by appropriate bioavailability studies:

- Product name, strength, pharmaceutical form: Aerius 5 mg Film-Coated Tablets
- Marketing authorisation holder: Schering-Plough Europe
- Date of authorisation: 15-01-2001
- Marketing authorisation granted by: Community
  - Community Marketing authorisation number(s): EU/1/00/160/001-013
- Bioavailability study number(s): 2007/10

Scientific Advice

The applicant did not seek scientific advice at the CHMP.

Licensing status

The product was not licensed in any country at the time of submission of the application.

1.2. Steps taken for the assessment of the product

The Rapporteur appointed by the CHMP was: János Borvendég

- The application was received by the EMA on 31 January 2011.
- The procedure started on 23 February 2011.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 13 May 2011.
- During the meeting on 20-23 June 2011 the CHMP agreed on the consolidated List of Questions to be sent to the applicant. The final consolidated List of Questions was sent to the applicant on 23 June 2011.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 10 August 2011.
- The Rapporteur circulated the Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 29 September 2011.
- During the meeting on 17-20 October 2011 the CHMP agreed on a List of Outstanding Issues to be addressed in writing by the applicant.
- The applicant submitted the responses to the CHMP consolidated List of Outstanding Issues on 26 October 2011.
- The Rapporteur circulated the Assessment Report on the applicant's responses to the List of Outstanding Issues to all CHMP members on 4 November 2011.
- During the meeting on 14-17 November 2011, the CHMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion for granting a Marketing Authorisation to Desloratadine Actavis on 17 November 2011.

2. Scientific discussion

2.1. Introduction

The Marketing Authorization Application of Desloratadine Actavis 5 mg film-coated tablet was submitted to the centralised procedure according to regulation (EC) No 726/2004, Article 3(3). The application has been made under Article 10(1) of Directive 2001/83/EC. The drug product is a generic of the centrally authorised medicinal product Aerius 5 mg film-coated tablets. The reference medicinal products Aerius 5 mg tablets (MA holder Schering-Plough Europe) was centrally authorised on 15 January 2001.

The reference medicinal product is indicated for the relief of symptoms associated with allergic rhinitis and urticaria. The recommended daily dose is 5 mg in adults and adolescents.

The active substance of the medicinal product is desloratadine. Desloratadine is a non-sedating, long-acting histamine antagonist with selective peripheral H1-receptor antagonist activity. After oral administration, desloratadine selectively blocks peripheral histamine H1-receptors. The selectivity is achieved because the substance is excluded from the entry into the central nervous system.

This application is a generic application, therefore, demonstration of therapeutic equivalence is shown by means of bioequivalence. No new clinical studies are either required or submitted with this application. The Applicant provided a comprehensive overview of clinical data on desloratadine in clinical use based upon the conclusions of the relevant clinical studies published in the literature.

The relative oral bioavailability of Desloratadine Actavis 5 mg film-coated tablets and the European brand product Aerius 5mg film-coated tablets (manufactured by SP Europe, Belgium) was established by comparing the single dose pharmacokinetics of desloratadine from the two formulations, under fasting conditions, in a randomised crossover study.

2.2 Quality aspects

2.2.1 Introduction

Desloratadine is available as 5 mg film-coated tablets for oral administration containing desloratadine as the active ingredient. The full list of ingredients is defined in section 6.1 of the SPC. The tablets are stored in polyamide/aluminium/polyvinyl chloride/aluminium foil blisters.

2.2.2 Active Substance

At the time of the CHMP opinion, the active substance desloratadine is not described in the European Pharmacopoeia. The Active substance Master File (ASMF) procedure is applied.

The active substance is sourced from one manufacturer.

Desloratadine is slightly soluble in water, sparingly soluble in methanol, ethanol, propylene glycol, acetonitrile and toluene. In acidic environments the solubility increases. Desloratadine exists in two different polymorphic forms: Form I and Form II. The manufacturing process produces consistently the same crystalline form or ratio of crystalline forms of desloratadine. Both crystalline forms have similar

solubility and therefore no difference in the bioavailability and performance of the product are expected.

Manufacture

During evaluation of this dossier, the starting materials have been re-defined to an earlier point of the synthesis and consequently additional information has been included in the Restricted and Applicant's parts of the ASMF. The sources of the starting material have been provided. In the detailed description of the manufacturing process of desloratadine reaction conditions, equipments and quantities of the used materials are appropriately described. Organic and inorganic impurities as well as residual solvents of desloratadine drug substance are well discussed. Adequate in process controls are in place and appropriate specifications have been adopted for the starting materials, solvents and reagents.

The validation procedures are in compliance with ICH Q2 requirements, so the methods are considered adequate for the control of the active substance on a routine basis.

Specification

The set specifications are appropriate in view of the Ph Eur Monograph 'Substances for Pharmaceutical use', the Q6A Guideline on Setting Specifications and the impurity discussion. The specification includes tests for appearance, identification (IR), loss on drying, melting range, sulphated ash, heavy metals, related substances (HPLC), residual solvents, polymorphism (XRD) and particle size.

Limits of specified and unspecified related substances are set in line with ICH Q3A guidelines.

Analytical tests are correctly drawn up and validated according ICH. Batch results confirm batch to batch consistency and uniformity of the quality of the substance and indicate that the process is under control.

Stability

The stability results of accelerated and long-term studies carried out under ICH conditions demonstrate the stability of the drug substance. The results of the long-term and accelerated studies on samples of 6 representative batches stored for up to 48 months fulfil the proposed specification and justify the proposed retest period. The active substance is packed in primary clear PE bags and secondary black PE bags placed into fibre board drums.

2.2.3 Finished Medicinal Product

Pharmaceutical Development

The aim of the product development was to formulate Desloratadine 5 mg tablets essentially similar, robust, stable and bioequivalent to the reference product. Desloratadine Actavis has the same qualitative composition and the same pharmaceutical form (film coated tablet) as the reference medicinal product Aerius.

All excipients are described in the European Pharmacopoeia and its specifications and analytical procedures are also in accordance with the European Pharmacopoeia standards with the exception of

Opadry Blue which complies with an In-house monograph. Compliance with EU directive 2008/128/ EC has also been declared for Indigo Carmine Aluminium lake.

Microcrystalline cellulose and pregelatinised maize starch used intragranular, colloidal anhydrous silica and talc used extragranular are applied in the tablet core. Opadry II Blue is a hypromellose based film coating.

The active substance exists in different polymorphic forms. Both known polymorphic forms (I and II) have almost the same solubility characteristics, therefore the differences in the two drug substance sources are not relevant for the product performance.

Satisfactory comparative impurity profiles have been presented for the test and reference products.

Comparative in vitro dissolution profiles of the reference and test biobatches were performed using three dissolution medium and the results are comparable. Similar dissolution profiles were also observed at all three pH tested (pH 1.2, pH 4.8 and pH 6.8). The dissolution profiles at pH 1.2 and 6.8 proved to be similar without mathematical evaluation since more than 85% of desloratadine dissolved in 15 minutes.

OPA/ Aluminium/ PVC /Aluminum blisters were selected as the primary packaging. The suitability of this container closure system has been demonstrated by means of stability studies.

Adventitious agents

Not applicable

Manufacture of the product

The manufacturing process is a conventional direct compression technology where the main manufacturing steps are dry blending and compression followed by a coating step.

The manufacturing formula, flow chart and description of the manufacturing process are presented

The main process steps are supervised by suitable in-process controls and their acceptance criteria are specified.

Batch analysis data on three pilot batches were within the specification limits and confirm both the consistency of production and good performance of the analysis methods. Therefore, the analytical tests are considered suitable, manufacturing process and analysis are well controlled.

Product Specification

The specification of the finished medicinal product is acceptable and includes tests for description, identification (HPLC, HPLC-DAD), uniformity of dosage units, average tablet mass, assay (HPLC), dissolution, impurities/degradation products and microbiological quality.

The proposed test procedures and acceptance criteria comply with the requirements of the Ph.Eur. and ICH guidelines. All tests included in the specification have been satisfactorily described and validated.

Certificates of analysis and typical IR spectra are presented. The batch analysis results of pilot batches confirm that the finished product meets the proposed specification.

Stability of the product

Stability studies were carried out according to relevant CHMP/ICH stability guidelines. The control tests and specification of the drug product are adequately drawn up.

3 pilot scale batches were stored for up to 12 and 6 months at long term (30±2°C/75±5%RH) and accelerated (40±2°C/75±5%RH) ICH conditions respectively. In addition to this, one production batch was stored for photostability at ICH conditions and the results demonstrated that the product is not sensitive to light.

Based on these stability data, the proposed shelf life and storage conditions as stated in the SPC are acceptable. It is confirmed that the start of shelf-life complies with the CHMP guideline Start of shelf-life of the finished dosage form.

2.2.4 Discussion on chemical, and pharmaceutical aspects

Satisfactory information on development, manufacture and control of the drug substance and drug product has been presented. The results of tests carried out indicate consistency and uniformity of important product quality characteristics, and these in turn lead to the conclusion that the product should have a satisfactory and uniform performance.

2.2.5 Conclusions on the chemical, pharmaceutical and biological aspects

The quality of this product is considered to be acceptable when used in accordance with the conditions defined in the SPC. Physicochemical and biological aspects relevant to the uniform clinical performance of the product have been investigated and are satisfactorily controlled.

2.2.6 Recommendation(s) for future quality development

Not applicable.

2.3 Non- clinical aspects

2.3.1 Introduction

A non-clinical overview on the pharmacology, pharmacokinetics and toxicology has been provided, which is based on up-to-date and adequate scientific literature. The overview justifies why there is no need to generate additional non-clinical pharmacology, pharmacokinetics and toxicology data. The non-clinical aspects of the SmPC are in line with the SmPC of the reference product. The impurity profile has been discussed and was considered acceptable.

Therefore, the CHMP agreed that no further non-clinical studies are required.

2.3.2 Ecotoxicity/environmental risk assessment

No Environmental Risk Assessment (ERA) was submitted. This was justified by the applicant as the introduction of Desloratadine Actavis manufactured by Actavis Group PTC ehf is considered unlikely to result in any significant increase in the combined sales volumes for all desloratadine containing

products and the exposure of the environment to the active substance. Thus, the ERA is expected to be similar and not increased.

2.3.3 Discussion on non-clinical aspects

The CHMP agreed that no further non-clinical studies are required. The ERA is expected to be similar and not increased.

2.3.4 Conclusion on the non-clinical aspects

The CHMP agreed that no further non-clinical studies are required. The ERA is expected to be similar and not increased.

2.4 Clinical aspects

2.4.1 Introduction

This is an application for film-coated tablets containing desloratadine. To support the marketing authorisation application the applicant conducted one bioequivalence study with cross-over design under fasting conditions. This study was the pivotal study for the assessment.

No formal scientific advice by the CHMP was given for this medicinal product. For the clinical assessment the Guideline on the Investigation of Bioequivalence CPMP/EWP/QWP/1401/98 Rev.1) in its current version is of particular relevance.

GCP

The Clinical trials were performed in accordance with GCP as claimed by the applicant.

The applicant has provided a statement to the effect that clinical trials conducted outside the community were carried out in accordance with the ethical standards of Directive 2001/20/EC.

Clinical studies

To support the application, the applicant has submitted one bioequivalence study.

Table 2. Tabular overview of clinical study

Type of Study	BE
Study Identifier	2007/10
Objective(s) of the Study	To assess the bioequivalence of desloratadine 5 mg film-coated tablets of Actavis Group PTC ehf, Iceland and Aerius 5 mg film-coated tablets (Manufactured by Schering- Plough Europe, Belgium) in healthy adult subjects, under fasting conditions.
Study Design and Type of control	Single-dose, randomized, open-label, two treatment, two sequences, two period, cross-over study.
Test Product(s); Dosage Regimen; **Route of Administration**	Test: Desloratadine Actavis 5 mg film-coated tablets Reference: Aerius® 5 mg film-coated tablets Dose: 1 x 5 mg Mode of Administration: Oral under fasting conditions
Number of subjects	24 healthy adult male subjects were enrolled of which 21 were included in the statistical analysis.
Healthy Subjects or Diagnosis of Patients	Healthy male subjects; all non-smokers
Duration of Treatment	The study consisted of two study periods. All subjects were housed from at least 11 hours before dosing until after 72 hours post dose blood draw in both periods. Subjects were dosed with the test or the reference product in each period as determined by the randomization schedule. There was a washout period of 17 days between each drug administration.
Study status; Type of Report	Complete

2.4.2 Pharmacokinetics

Methods

Study design

Study 2007/10 was a single-dose, randomized, open-label, two-period, two-sequence, two-treatment, single-centre, cross-over, comparative bioavailability study of desloratadine 5 mg film-coated tablets of Actavis Group PTC ehf, Iceland and Aerius 5 mg film-coated tablets of SP Europe, Belgium, in healthy, adult subjects, under fasting conditions .

Subjects were randomly assigned to the test or reference product and administered with a single oral dose of 5mg. Treatments were separated by a washout period of 17 days.

Prior to dosing subjects fasted overnight for at least 10 hours. Both formulations were taken with 240 ml of water. Subjects were served meals/snacks 4 hours after dosing and at appropriate times thereafter. Water was not permitted 1 hour before dosing and until 1 hour after dosing, but was allowed at all other times.

Twenty-four (24) healthy adult male subjects were enrolled in the study. Twenty (20) subjects completed the study.

During each study period, blood samples were taken pre-dose and at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 8, 10, 12, 24, 36, 48 and 72 h post dose in both periods. Plasma was harvested from these samples and analysed for desloratadine using validated LC/MS/MS method.

The study was conducted at a single site at Lotus Labs Pvt. Ltd.; No. 02, M.M Towers; Jakkur Plantations; Yelahanka Hobli; Bangalore - 560 064, India.

Test and reference products

Desloratadine Actavis 5 mg film-coated tablets manufactured by Actavis Group PTC ehf, Iceland (batch no: F23183 (S47681, manufacturing date 13 March 2010; exp. date not communicated) has been compared to Aerius 5 mg film-coated tablets manufactured by SP Europe, Belgium (batch no: 9STBAB3B01, exp. Date August 2011).

Population(s) studied

Twenty-four (24) healthy male subjects were enrolled of which 20 completed the study. Three subjects voluntarily dropped-out while not completing the period II of treatment and one dropped out for personal reasons and his 72 hour sample was not collected. Twenty-one subjects were included in the pharmacokinetic and statistical analysis.

The study population was defined as healthy male volunteers, aged between 18-55 years, having a body mass index between 18.5-30kg/m^2, non-smokers, South-Asian race.

There was no protocol violation reported including no substantial difference between the planned and actual sampling times.

Analytical methods

An LC/MS/MS assay for the determination of desloratadine in human plasma was developed and validated. The analytical method was calibrated between 21.3 to 4917 pg/mL Precision and accuracy criteria were met.

Planned stability study was mentioned in the bioanalytical report.

Pharmacokinetic variables

The primary pharmacokinetic parameters were AUC_{0-72h} and C_{max}. Other pharmacokinetic parameters, such as K_{el}, $T_{1/2}$ and T_{max} .

Statistical methods

ANOVA including sequence, subjects nested within sequence, period and treatment was to be performed on the ln-transformed data for AUC_{72} and C_{max} and on the raw data for AUC_{72}, C_{max}. Tmax were to be analyzed using an additional non-parametric test (Wilcoxon test).

The 90% confidence intervals (CI) of the Test/Reference ratios of geometric means for AUC_{72} and C_{max} were to be calculated based on the least square means. The predefined acceptance range for the conclusion on bioequivalence based on AUC_{0-72h} and C_{max} was 80-125 %.

The contract research organisation that performed the study used the standard statistical model with industry standard statistical software (SAS).

Results

The summary of the pharmacokinetic results and statistical analysis are illustrated in the tables below.

Table 3 Pharmacokinetic parameters for desloratadine

Results

Table 1 - Summary of Pharmacokinetic Data for Desloratadine

Aerius® (Reference Product)

Pharmacokinetic parameter	Geometric mean	Arithmetic mean	Standard deviation
AUC_{0-72} (pg.h/mL)	47975.865	50258.511	15865.541
C_{max} (pg/mL)	2769.960	2872.482	779.478

Desloratadine (Test Product)

Pharmacokinetic parameter	Geometric mean	Arithmetic mean	Standard deviation
AUC_{0-72} (pg.h/mL)	45608.511	47538.768	14268.367
C_{max} (pg/mL)	2678.004	2748.613	628.696

Table 2 - Ratio and 90% Confidence Intervals of Test Product versus Reference Product

Pharmacokinetic parameter	Ratio (%)	90% Confidence Intervals	
		Lower 90% CI	Upper 90% CI
AUC_{0-72}	95.18	89.19	101.57
C_{max}	96.16	89.04	103.85

The geometric 90% confidence intervals for the ratios of AUC_{0-72} and C_{max} for the test reference products versus the reference product fall within the pre-specified acceptance range for bioequivalence of 80-125%.

The results show that the test product is bioequivalent to the reference product.

Safety data

There was one adverse event during the conduct of the study. The laboratory abnormality (documented as adverse event) detected during the end of the study safety analysis was raised liver enzymes (serum glutamic oxaloacetic transaminase and serum glutamic pyruvic transaminase). This adverse event was detected during the end of study safety analysis and hence could not be attributed

to either the test or the reference product. No serious adverse events were reported during the conduct of this study.

Conclusions

Based on the presented bioequivalence study desloratadine Actavis 5 mg film-coated tablets is considered bioequivalent with Aerius 5 mg film-coated tablets.

2.4.3 Pharmacodynamics

No new pharmacodynamic studies were presented and no such studies are required for this application.

2.4.4 Post marketing experience

No post-marketing data are available. The medicinal product has not been marketed in any country.

2.4.5 Discussion on clinical aspects

A single bioequivalence study was performed to support this generic application. The study has been conducted according to GCP.

The study was a cross-over, two-period, two-sequence, open-label study. It was conducted in fasting state and the parent compound desloratadine was the analyte for the pharmacokinetic assessment including the conclusions on bioequivalence. Overall, the study design is in line with the regulatory requirements, in particular with the applicable Guideline on the Investigation of Bioequivalence (CPMP/EWP/QWP/1401/98 Rev.1).

The bioequivalence guideline sets the minimal sample size to 12 hence this requirement was met. Furthermore, the Applicant gave satisfactory explanations why data of three subjects (four for AUC) were not included into the final analysis.

Truncated AUC (AUC_{0-72h}) has been used as sampling period. This is in accordance with the bioequivalence guideline which considers a sampling period up to 72 hours is generally acceptable for oral immediate release formulations. The duration of the wash-out period was sufficiently long.

The 90% confidence intervals for the ratio (test/reference) of the geometric least squares means for the log-transformed parameters AUC_{0-72h} and C_{max} were within the range of 80.00% to 125.00%.

The bioanalytical method was adequately validated. Furthermore, the dissolution studies supported that the test and the reference product have similar dissolution profiles.

Bioequivalence between the test product desloratadine Actavis 5mg film-coated tablets with the reference product Aerius 5mg film-coated tablets is considered established.

2.4.6 Conclusions on clinical aspects

The bioequivalence of desloratadine Actavis 5 mg film-coated tablets to the reference medicinal product Aerius 5 mg film-coated tablets by SP Europe can be regarded as established.

2.5 Pharmacovigilance

Detailed description of the Pharmacovigilance system

The CHMP considered that the Pharmacovigilance system as described by the applicant fulfils the legislative requirements.

Risk Management Plan

The CHMP did not require the applicant to submit a risk management plan because the application concerns a medicinal product containing a known active substance for which no safety concern requiring additional risk minimisation activities has been identified.

PSUR submission

The PSUR submission schedule should follow the PSUR schedule for the reference product. The PSUR of the reference medicinal product is on a 2-yearly cycle. The last data lock point for the reference medicinal product was 15.07.2011

User consultation

The results of the user consultation with target patient groups on the package leaflet submitted by the applicant 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.*

3. Benefit-risk balance

This application concerns a generic version of desloratadine film-coated tablets. The reference product Aerius is indicated for relief of symptoms associated with allergic rhinitis and urticaria. No nonclinical studies have been provided for this application but an adequate summary of the available nonclinical information for the active substance was presented and considered sufficient. From a clinical perspective, this application does not contain new data on the pharmacokinetics and pharmacodynamics as well as the efficacy and safety of the active substance; the applicant's clinical overview on these clinical aspects based on information from published literature was considered sufficient.

The bioequivalence study forms the pivotal basis with a single-dose, randomized, open-label, two-period, two-sequence, two-treatment, single-centre, crossover study under fasting conditions. The study design was considered adequate to evaluate the bioequivalence of this formulation and was in line with the respective European requirements. Choice of dose, sampling points, overall sampling time as well as wash-out period were adequate. The analytical method was validated. Pharmacokinetic and statistical methods applied were adequate.

The test formulation of desloratadine Actavis 5 mg film-coated tablets met the protocol-defined criteria for bioequivalence when compared with the Aerius 5 mg film-coated tablets. The point estimates and their 90% confidence intervals for the parameters AUC_{0-72} and C_{max} were all contained within the protocol-defined acceptance range of 80.00 to 125.00%. Bioequivalence of the two formulations was demonstrated.

A benefit/risk ratio comparable to the reference product can therefore be concluded.

The CHMP, having considered the data submitted in the application and available on the chosen reference medicinal product, is of the opinion that no additional risk minimisation activities are required beyond those included in the product information.

4. Recommendation

Based on the CHMP review of data on quality, safety and efficacy, the CHMP considers by consensus that the benefit-risk balance of Desloratadine Teva in the treatment of relief of symptoms associated with allergic rhinitis and urticaria is favourable and therefore recommends the granting of the marketing authorisation.

Conditions or restrictions regarding supply and use

Medicinal product subject to medical prescription.

Conditions and requirements of the Marketing Authorisation

Pharmacovigilance System

The MAH must ensure that the system of pharmacovigilance, presented in Module 1.8.1 of the marketing authorisation, is in place and functioning before and whilst the product is on the market.

Risk Management System

Not applicable

PSUR cycle

The PSUR cycle for the product will follow PSURs submission schedule for the reference medicinal product.

Conditions or restrictions with regard to the safe and effective use of the medicinal product

Not applicable

Conditions or restrictions with regard to the safe and effective use of the medicinal product to be implemented by the Member States.

Not applicable.