LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

FERANT
(palonosetron hydrochloride)

SE/H/1541/01/DC

This module reflects the scientific discussion for the approval of Ferant. The procedure was finalised on 2016-04-20. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

The application for Ferant, 50 mcg/ml, solution for injection, is a generic application made according to Article 10(1) of Directive 2001/83/EC. The applicant, Medochemie Ltd, apply through the Decentralised Procedure with Sweden acting as reference member state (RMS) and BG, CY, CZ, EE, EL, HR, LT, LV, MT, RO and SK as concerned member states (CMS).

The reference medicinal product chosen for the purposes of establishing the expiry of the data protection period is Aloxi, 250 mcg, solution for injection authorised in the union since 2005, with Helsinn Birex Pharmaceuticals Ltd as marketing authorisation holder.

For approved indications, see the Summary of Product Characteristics.

For recommendations to the marketing authorisation not falling under Article 21a/22 of Directive 2001/83 and conditions to the marketing authorisation pursuant to Article 21a or 22 of Directive 2001/83/EC to the marketing authorisation, please see section VI.

II. QUALITY ASPECTS

II.1 Drug Substance

The structure of the drug substance has been adequately proven and its physico-chemical properties are sufficiently described.

The manufacture of the drug substance has been adequately described and satisfactory specifications have been provided for starting materials, reagents and solvents.

The drug substance specification includes relevant tests and the limits for impurities and degradation products have been justified. The analytical methods applied are suitably described and validated.

Stability studies confirm the retest period.

II.2 Medicinal Product

The medicinal product is formulated using excipients listed in section 6.1 in the Summary of Product Characteristics.

The manufacturing process has been sufficiently described and critical steps identified.

The tests and limits in the specification are considered appropriate to control the quality of the finished product in relation to its intended purpose.

Stability studies have been performed and data presented support the shelf life and special precautions for storage claimed in the Summary of Product Characteristics, sections 6.3 and 6.4.

III. NON-CLINICAL ASPECTS

III.1 Discussion on the non-clinical aspects

Since this product has been shown to be essentially similar and refer to a product approved based on a full application with regard to preclinical data, no further such data have been submitted or are considered necessary.

IV. CLINICAL ASPECTS

IV.1 Pharmacokinetics

The product applied for is to be administered as an aqueous intravenous solution containing the same active substances in the same concentrations as the currently authorised product. The applied product also contains the same excipients in similar amounts as the reference product. No bioequivalence studies are required for this type of product according to the Guideline on the Investigation of Bioequivalence (CPMP/EWP/QWP/1401/98 Rev 1) and the applicant has submitted none.

IV.2 Discussion on the clinical aspects

Since this product has been shown to be essentially similar and refer to a product approved based on a full application with regard to clinical efficacy/safety data, no further such data have been submitted or are considered necessary.

IV.3 Risk Management Plan

The MAH 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 Ferant, 50 mcg/ml, solution for injection.

The applicant was requested to update the Summary of Safety Concern to be in line with most recent version of the originator's RMP (Aloxi RMP version 6, 24 July 2013). The applicant has updated the RMP accordingly and the RMP can thereby be accepted, see below.

Summary of Safety Concerns. RMP version 2, dated October 2015.

Important identified risks	Severe constipation Severe hypersensitivity reactions
Important potential risks	QT/QTc prolongation Convulsive events Serotonin syndrome

Missing information	Effect in pregnancy Effect in lactating women Effects on fertility Effect in children aged less than 1 month (potential off-label use for CINV prevention) Effects in patients with end stage renal disease undergoing haemodialysis

Pharmacovigilance Plan

Routine pharmacovigilance is suggested and no additional pharmacovigilance activities are proposed by the applicant, which is endorsed.

Risk minimisation measures

Routine risk minimisation is suggested and no additional risk minimisation activities are proposed by the applicant, which is endorsed.

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

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

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

The RMP is approved.

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 Alox, assessed and accepted in EMEA/H/C/00563/A/46/0016.
The bridging report submitted by the applicant has been found acceptable.

VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The quality of the generic product, Ferant, is found adequate. There are no objections to approval of Ferant, from a non-clinical and clinical point of view. The product information is acceptable.
The application is therefore recommended for approval.

List of recommendations not falling under Article 21a/22 of Directive 2001/83 in case of a positive benefit risk assessment

N/A

List of conditions pursuant to Article 21a or 22 of Directive 2001/83/EC

N/A

VII. APPROVAL

The Decentralised procedure for Ferant, 50 mcg/ml, solution for injection, was positively finalised on 2016-04-20.

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Public Assessment Report – Update

Procedure number*	Scope	Product Information affected	Date of end of procedure	Approval/ non approval	Summary/ Justification for refuse

*Only procedure qualifier, chronological number and grouping qualifier (when applicable)

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