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Public Assessment Report

Scientific discussion

Vocasept s pomarančovou príchuťou bez cukru 8,75 mg tvrdé pastilky (flurbiprofen)

SK/H/0323/001/DC

Date: March 2026

This module reflects the scientific discussion for the approval of Vocasept s pomarančovou príchuťou bez cukru 8,75 mg tvrdé pastilky. The procedure was finalised 12 August 2025 (D210). For information on changes after this date please refer to the module 'Update'.

I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, the Member States have granted a marketing authorisation for Vocasept s pomarančovou príchuťou bez cukru 8,75 mg tvrdé pastilky, from MAPAEX CONSUMER HEALTHCARE (IRELAND) PRIVATE LIMITED.

The product is indicated for the local short-term symptomatic relief of sore throat in adults and adolescents over the age of 12 years.

A comprehensive description of the indications and posology is given in the SmPC.

The marketing authorisation has been granted pursuant to Article 10(3) of Directive 2001/83/EC.

II. QUALITY ASPECTS

II.1 Introduction

The medicinal product is a white to pale yellow coloured, round, flat bevelled lozenges with orange flavor. The active substance flurbiprofen is present in the medicinal product with a strength of 8,75 mg. Excipients used in the medicinal product (isomalt, maltitol liquid, acesulfame potassium, macrogol 400, levomenthol, orange juice flavor) are well known and widely used as pharmaceutical excipients. Medicinal product is available in PVC-PVDC Aluminum blisters in a printed cardboard box with 8, 16 or 24 lozenges.
The chemical-pharmaceutical documentation and Quality Overall Summary in relation to Vocasept s pomarančovou príchuťou bez cukru 8,75 mg lozenges are of sufficient quality in view of the present European regulatory requirements.

II.2 2.2Drug Substance

INN: flurbiprofen

Chemical name: (2*RS*)-2-(2-Fluoro[1,1′-biphenyl]-4-yl)propanoic acid

Appearance: white or almost white, crystalline powder

Solubility: practically insoluble in water, freely soluble in ethanol (96 per cent) and in methylene chloride. It dissolves in dilute solutions of alkali hydroxides and carbonates.

Chirality: stereo enantiomer is possible - flurbiprofen molecule contain one asymmetric carbon atom. The Ph. Eur. mentions racemic form (2RS)-2- (2-fluorobiphenyl-4-yl) propanoic acid (most stable form)

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

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

Specifications:
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:
Stability studies confirm the retest period.

II.3 Medicinal Product

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

Manufacture of the product
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 of the product
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.

II.4 Discussion on chemical, pharmaceutical and biological aspects

From the quality point of view the application was approvable. In general, the relevant information was presented in dossier.

III. NON-CLINICAL ASPECTS

III.1 Introduction

Pharmacodynamic, pharmacokinetic and toxicological properties of flurbiprofen are well known. As flurbiprofen is a widely used, well-known active substance, the applicant has not provided additional studies and further studies are not required. Overview based on literature review is, thus, appropriate.

The non-clinical overview on the pre-clinical pharmacology, pharmacokinetics and toxicology is adequate.

III.2 Ecotoxicity/environmental risk assessment (ERA)

The applicant provided logKow values found in literature which were below the threshold 4.5 and PECsurfacewater calculation which was above the threshold.

The Applicant also provided consumption data over the years 2018-2021 from Czech Republic, Hungary, Poland, Romania, Slovakia, Bulgaria, Estonia, Latvia and Lithuania which showed that in these countries, consumption is either stable or decreasing. Therefore, the environmental exposure is not expected to increase and no further ERA assessment is needed.

The assessor has access to a relevant ERA of flurbiprofen conducted in accordance with the current ERA guideline. The risk assessment demonstrates an acceptable risk to the environment and therefore specific labelling to limit environmental impact is not required.

III.3 Discussion on the non-clinical aspects

From the non-clinical perspective, the application was approvable.

IV. CLINICAL ASPECTS

IV.1 Introduction

To support the application, the applicant has submitted as report two studies:
- An open label, balanced, randomized, two-treatment, two-period, twosequence, single dose, crossover, oral comparative bioavailability pivotal study of flurbiprofen 8.75 mg sugar free lozenges orange (study number 003/22)
- An open label, balanced, randomized, two-treatment, two-period, two-sequence, single dose, crossover, oral local availability study of flurbiprofen 8.75 mg sugar free lozenges orange (study number 041/20)

The applicant submitted one bioequivalence study and one local availability study with 8.75 mg lozenge to support the authorisation of the same strength. The first (bioequivalence) study is expected to provide evidence that systemic exposure is comparable to the reference product and so that safety profile can be extrapolated from the reference product. The second local bioavailability study is expected to show that dissolution in mouth is comparable which should support extrapolation of efficacy. This approach is supported.

The design of the BE study is acceptable, wash-out period is long enough concerning the T1/2 of flurbiprofen (3-6 hrs), sampling period is adequate, sampling scheme is also adequate as Cmax of flurbiprofen is expected around 45 minutes after administration. As SmPC does not specify relation of administration to food, study design in fasted state is acceptable. The administration instructions (to move lozenge around in mouth) is in line with method of administration specified in the SmPC. To wet mouth with 20 ml of water before administration is acceptable and in line with recommendations for orodispersible formulations. To use placebo 12 hrs before period I to ensure more standardised administration in all subjects is acceptable. Test and reference products are adequate. The reference product is correct. The chosen population is adequate. Blood draw deviations were not of a nature that could significantly affect the results of bioequivalence assessment. The analytical method is acceptable and validated. The handling of samples was adequate. The reasons for sample reanalysis were acceptable and in line with the SOP. No protocol deviations were reported. The statement on GLP compliance is provided. Pharmacokinetic variables are adequate. The statistics is described adequately and methods are acceptable. Handling of dropouts and missing data was acceptable. Statistical significance of some factors mentioned above will not be questioned as conduct of BE study was appropriate. The bioequivalence is shown also in terms of specific enantiomers. No issues related to safety were observed. A slight difference (10 to 15 minutes) in Tmax is not considered to be clinically relevant as it is small and lozenge is expected to work locally.

The applicant carried out a dissolution study to assess similarity of the dissolution profile of the active substance flurbiprofen. Flurbiprofen 8.75 mg lozenges Orange flavour (biobatch) and Dobendan Direkt Flurbiprofen 8.75mg Honig & Zitrone-Geschmack (biobatch) were compared. The conditions of the study were appropriate – basket apparatus with rpm 100, volume 900 ml, temp 37°C and sampling time points, also biobatches used in the BE study were used. Besides standard pH range, the applicant even carried out a dissolution at pH 7.2 to mimic precisely pH of saliva in mouth which is welcome. At all pH tested, more than 85% of substance was dissolved within 15 minutes which confirms similarity of dissolution profiles between test and reference product.

The applicant carried out a local availability study to confirm comparable dissolution in mouth. Batches of products used in the BE study were used. Population of healthy adults according to standard BE criteria is acceptable. Fasted administration, cross-over design and wash-out is also acceptable. The study showed comparable dissolution according to f2 factor, however, it is questioned how precise this measurement is and how properly it mirrors real life use if subjects had to remove lozenge repeatedly from mouth and this was repeatedly weighed. Also, it is uncertain whether the result was not affected by saliva spit out together with lozenge. However, as the BE study and in vitro dissolution study showed comparability with reference product, result from this study is considered only as supportive. Considering that its result does not contradict results from other two studies, this is considered

acceptable and no further questions will be raised.

IV.2 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 Vocasept s pomarančovou príchuťou bez cukru 8,75 mg tvrdé pastilky.

Summary table of safety concerns as approved in RMP

Important identified risks	none
Important potential risks	none
Missing information	none

IV.3 Discussion on the clinical aspects

From the and clinical perspective, the application was approvable.

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 PIL 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

This was an application for a marketing authorisation of a medicinal product for human use as it is defined in Article 10(3) (hybrid application) of the European Directive 2001/83/EC as amended. Decentralised procedure according to Article 28(3) of Directive 2001/83/EC as amended with Slovak Republic acting as RMS. The Applicant Naiax Pharma S.L. has submitted this MAA under procedural number SK/H/0323/001/DC; CMSs are Czech Republic, Hungary, Poland, Romania, Estonia, Latvia, Lithuania and Bulgaria. This application was submitted as a duplicate of the procedure SK/H/0293/001/DC.

As a reference medicinal product for proving the proof of data exclusivity expiry Strepfen Citroen & Honing 8,75 mg, zuigtabletten (NL/H/4456) from Reckitt Benckiser Healthcare B.V. was chosen. For the reference medicinal product authorised in the RMS and CMSs products from Reckitt Benckiser under several brand names (Strepfen/Strepsils) were chosen.

Because of the fact that the efficacy of flurbiprofen lozenges is due to systemic but also local effects of the drug, not only a bioequivalence study (conform to CPMP/EWP/QWP/1401/98 Rev. 1/Corr**) but also a local availability study (conform to CPMP/EWP/239/95) has been conducted. Reference medicinal product used in the studies was Dobendan Direkt Flurbiprofen 8,75 mg Lutschtabletten from Reckitt Benckiser Deutschland GmbH.

Agreement between the member states was reached during a written procedure. Based on submitted data the member states have considered the application as approvable and have therefore granted marketing authorisation. The decentralised procedure was finalised with positive outcome on 12 August 2025.