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Public Assessment Report

Scientific discussion

Mebeverine SanoSwiss 135 mg film-coated tablets (Mebeverine hydrochloride)

LT/H/0225/001/DC

Date: 2026-05-06

This module reflects the scientific discussion for the approval of Mebeverine SanoSwiss 135 mg film-coated tablets. The procedure was finalised at 2026-02-11. 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 *Mebeverine SanoSwiss 135 mg film-coated tablets* (UAB SanoSwiss, Lithaunia),
The product is indicated:
For the symptomatic treatment of irritable bowel syndrome, particularly gastrointestinal spasm, colicky abdominal pain and cramps, associated with defecation disorders and meteorism.
A comprehensive description of the indications and posology is given in the SmPC.

This decentralised procedure concerns a generic application claiming essential similarity with the innovator product *Duspatal 135 mg coated tablets* by Viatris Healthcare GmbH, Germany, registered since 30 December 1981. Reference medicinal product used in the bioequivalence studies is *Colofac Tablets 135 mg* of Mylan Products Limited, UK, registered since 14 March 1978. Viatris was formed in November 2020, through the combination of Mylan and Upjohn.

The concerned member state (CMS) involved in this procedure were Latvia and Estonia

The marketing authorisation has been granted pursuant to Article 10(1) of Directive 2001/83/EC."

II. QUALITY ASPECTS

II.1 Introduction

135 mg film-coated tablets
White colored, circular biconvex shaped, film-coated tablets, plain on both the sides.
Diameter of the film-coated tablet: 10.10 ± 0.20 mm. Thickness of the film-coated tablet 4.40 ± 0.30 mm.

Excipients are: lactose monohydrate, microcrystalline cellulose, sodium strach glycolate (Type A), povidone K-30, talc, magnesium stearate, hypromellose, macrogols, titanium dioxide.

Drug product is packed in Alu/PVC or Alu/PVC/PVdC blister packs

II.2 Drug Substance

The active substance is Mebeverine hydrochloride, which is included in the Ph. Eur.
The Certificate of Suitability (CEP) procedure is used for the active substance.

Manufacturing process
A reference to the CEPs is provided from the active substance manufacturers.

Quality control of drug substance
A drug substance specification of the drug product manufacturer is according to ICH requirements. Batch analytical data demonstrating compliance with this specification have been provided.

Stability of drug substance
The retest period of the Mebeverine hydrochloride is covered by the CEP.

II.3 Medicinal Product

Pharmaceutical development
The medicinal product is established pharmaceutical form and the development is adequately described in accordance with the relevant European guidelines. The choice of excipients is justified, and their functions explained. The main development studies performed were dissolution testing. The critical

quality attributes (CQAs) of the formulation of drug product were identified.

Comparative *in vitro* dissolution testing at three pH's has been successfully studied in support of the bioequivalence study. The pharmaceutical development of the product has been adequately performed.

Manufacturing process
A flow chart of the manufacturing process and accompanying descriptive narrative are provided.
The manufacturing process is relatively straightforward and uses standard processes. Manufacturing equipment is indicated. The level of detail provided in the manufacturing process is deemed adequate. The process validation scheme and protocols were provided.

Control of excipients
The excipients present in the drug product are indicated to be Ph. Eur. grade and therefore specifications have not been provided. This is accepted. Similarly, analytical procedures, method validation and justification of specifications are not required for Ph. Eur. excipients.
There are no novel excipients used in the finished product formulation.

Quality control of drug product
The finished product specification is adequate to control the relevant parameters for the dosage form. A release and shelf-life specifications are provided and include requested tests. Limits in the specification have been justified and are considered appropriate for adequate quality control of the product. Satisfactory validation data for the analytical methods have been provided. Batch analytical data from the proposed production site have been provided, demonstrating compliance with the specification.

Stability of drug product
Stability studies are carried out under ICH conditions. The tested batches were stored in the intended packaging. The tested parameters are considered to indicate stability sufficiently. Data is available at long term (25°C/60%RH) and accelerated (40°C/75%RH) conditions. It is evident that the drug product in its commercial presentations is a stable product with no OOS results/obvious trends observed. All results met the proposed specifications. The provided stability data support the claimed shelf life of 36 months.
According to photostability studies, medicinal product is photostable.

II.4 Discussion on chemical, pharmaceutical and biological aspects

Based on the submitted dossier, the member states consider that Mebeverine SanoSwiss 135 mg film-coated tablets have a proven chemical-pharmaceutical quality. Sufficient controls have been laid down for the active substance and finished product.

No post-approval commitments were made.

III. NON-CLINICAL ASPECTS

III.1 Introduction

Pharmacodynamic, pharmacokinetic and toxicological properties of Mebeverine are well known. As Mebeverine 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.

III.2 Ecotoxicity/environmental risk assessment (ERA)

The octanol–water partition coefficient (log Kow = 3.82) indicates a moderate lipophilicity and does not trigger concern for bioaccumulation. The environmental risk assessment was conducted using the standard approach, where the risk quotient (RQ) was calculated as the ratio of the predicted environmental concentration in surface water (PECsw) to the predicted no-effect concentration (PNEC).

Based on the refined PECsw and PNEC values, the resulting RQ is below 1, indicating that Mebeverine hydrochloride is unlikely to pose a risk to the aquatic environment under the proposed conditions of use.

III.3 Discussion on the non-clinical aspects

The pharmacodynamic, pharmacokinetic and toxicological properties of mebeverine hydrochloride are well established. As Mebeverine SanoSwiss 135 mg film-coated tablets is a generic medicinal product containing a widely used and well-known active substance, the submission of additional non-clinical studies is not considered necessary. An overview of the non-clinical data based on published literature is therefore considered adequate and sufficient.

IV. CLINICAL ASPECTS

IV.1 Introduction

Mebeverine hydrochloride is a well-known active substance with established efficacy and tolerability. A clinical overview has been provided, which is based on scientific literature. The overview justifies why there is no need to generate additional clinical data. Therefore, the member states agreed that no further clinical studies are required.
For this generic application, the MAH has submitted one bioequivalence study, which is discussed below.

IV.2 Pharmacokinetics

The reference product used for the bioequivalence study is from the UK market (*Colofac Tablets 135 mg*).
The applicant has provided the protocol of the bioequivalence (BE) clinical study of *Mebeverine Hydrochloride 135 mg Tablets* marketing authorization holder: UAB SanoSwiss versus *Colofac® Tablets 135 mg Tablets*, marketing authorization holder: Abbott Healthcare Products Limited, as well as the approval of Ethics committee.

In case of Mebeverine, after single dose administration it undergoes rapid and complete metabolization and it does not enter systemic circulation, and detectable levels are not achieved. Since, measurable concentrations are not achieved after single dose administration, estimation of PK parameters and bioequivalence conclusion on parent compound i.e., on Mebeverine is not feasible. Mebeverine is rapidly metabolized into Veratric acid and Mebeverine alcohol firstly and subsequently Mebeverine alcohol oxidizes to form Mebeverine acid and Mebeverine alcohol, and Mebeverine acid are further metabolized into desmethyl Mebeverine alcohol and desmethyl-mebeverine acid.

Efficacy was assessed by the pharmacokinetic properties of the test and the reference formulations by measurement of Mebeverine Acid, Desmethyl Mebeverine Acid and Veratric Acid concentrations in plasma.

The results of the study are presented in the tables below:

Relative Bioavailability Results for Mebeverine Acid (N = 36).

Parameters	Geometric Least Squares Means			90% Confidence Interval	Intra Subject CV (%)	Power (%)
	Test Product-T	Reference Product-R	Ratio (T/R)%			
$\ln C_{max}$	359.440	368.890	97.4	88.54 - 107.23	24.4	98.4
$\ln AUC_{0-t}$	736.780	743.429	99.1	95.79 - 102.54	8.6	100.0

Relative Bioavailability Results for Desmethyl Mebeverine Acid (N=36).

Parameters	Geometric Least Squares Means			90% Confidence Interval	Intra Subject CV (%)	Power (%)
	Test Product-T	Reference Product-R	Ratio (T/R)%			
lnC_{max}	517.016	504.689	102.4	96.40 - 108.87	15.3	100.0
$lnAUC_{0-t}$	1107.650	1080.207	102.5	100.13 - 105.01	6.0	100.0

Relative Bioavailability Results Vertaric acid (N = 36)

Parameters	Geometric Least Squares Means			90% Confidence Interval	Intra Subject CV (%)	Power (%)
	Test Product-T	Reference Product-R	Ratio (T/R)%			
lnC_{max}	5012.091	4949.167	101.3	94.61 - 108.40	17.2	100.0
$lnAUC_{0-t}$	11892.131	11661.636	102.0	99.77 – 104.23	5.5	100.0

Based on the submitted bioequivalence study *Mebeverine SanoSwiss 135 mg film-coated tablets* are considered bioequivalent with *Colofac® Tablets 135 mg Tablets.*

IV.3 Pharmacodynamics

No new data has been submitted. No data is required for this generic application.

IV.4 Clinical efficacy

To support the application, the applicant has submitted as report bioequivalence study. Provided that bioequivalence with the originator product is demonstrated, additional data is not necessary.

IV.5 Clinical safety

To support the application, the applicant has submitted as report bioequivalence study:
Both (test and reference) treatments were well tolerated.

IV.6 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, characterize, prevent or minimize risks relating to *Mebeverine SanoSwiss 135 mg film-coated tablets.*

Summary table of safety concerns as approved in RMP

Summary of safety concerns	
Important Identified Risks	• None
Important Potential Risks	• None
Missing Information	• None

IV.7 Discussion on the clinical aspects

The application contains an adequate review of published clinical data, and the bioequivalence has been shown between *Mebeverine SanoSwiss 135 mg film-coated tablets* and *Colofac® Tablets 135 mg Tablets*. No new clinical studies were conducted. Risk management is adequately addressed. This generic medicinal product can be used instead of the reference product.

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 Lithuanian.
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

Mebeverine SanoSwiss 135 mg film-coated tablets have a proven chemical-pharmaceutical quality and are generic form of the innovator product which is well-known medicinal product with established favourable efficacy and safety profile.

Bioequivalence has been shown to be in compliance with the requirements of European guidance documents.

The decentralised procedure was finalized with a positive outcome on 2026-02-11.

Summary Public Assessment Report

Generics

Mebeverine SanoSwiss 135 mg film-coated tablets (Mebeverine hydrochloride)

LT/H/0225/001/DC

Date: 2026-05-06

Summary Public Assessment Report

Generics

Mebeverine SanoSwiss 135 mg film-coated tablets
Active substance: Mebeverine hydrochloride

This is a summary of the public assessment report (PAR) for Mebeverine SanoSwiss. It explains how Mebeverine SanoSwiss was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Mebeverine SanoSwiss.

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

What is Mebeverine SanoSwiss and what is it used for?

Mebeverine SanoSwiss is a 'generic medicine'. This means that Mebeverine SanoSwiss is similar to a 'reference medicine' already authorised in the European Union (EU) called Duspatal.

Mebeverine SanoSwiss is used to treat symptoms of irritable bowel syndrome (IBS) in adult patients.

How does Mebeverine SanoSwiss work?

Mebeverine SanoSwiss contains the active substance mebeverine hydrochloride. This belongs to a group of medicines called antispasmodics.Mebeverine is a musculotropic antispasmodic with a direct action on the smooth muscle of the gastrointestinal tract, without affecting normal gut motility.

How is Mebeverine SanoSwiss used?

The pharmaceutical form of Mebeverine SanoSwiss is film-coated tablets, and the route of administration is oral.
Use in adults
The recommended dose is one tablet three times a day.

Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription.

What benefits of Mebeverine SanoSwiss have been shown in studies?

Because Mebeverine SanoSwiss is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Duspatal. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects of Mebeverine SanoSwiss?

Because Mebeverine SanoSwiss is a generic medicine and is bioequivalent to the reference medicine, its benefits and possible side effects are taken as being the same as the reference medicine.
For the full list of all side effects reported with Mebeverine SanoSwiss, see section 4 of the package leaflet.
For the full list of restrictions, see the package leaflet.

Why is Mebeverine SanoSwiss approved?

It was concluded that, in accordance with EU requirements, Mebeverine SanoSwiss has been shown to have comparable quality and to be bioequivalent/be comparable to reference medicine. Therefore, the State Medicines Control Agency of Lithuania decided that, as for reference medicine called Duspatal, the benefits are greater than its risk and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Mebeverine SanoSwiss?

A risk management plan has been developed to ensure that Mebeverine SanoSwiss is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Mebeverine SanoSwiss, 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 as well.

Other information about Mebeverine SanoSwiss

The marketing authorisation for Mebeverine SanoSwiss was granted on 2026-03-18.

The full PAR for Mebeverine SanoSwiss can be found on the website . For more information about treatment with Mebeverine SanoSwiss, read the package leaflet (*link*) or contact your doctor or pharmacist.

This summary was last updated in May 2026.

Viešojo vertinimo protokolo apžvalga

Mebeverine SanoSwiss 135 mg plėvele dengtos tabletės
mebeverino hidrochloridas

Trumpa kokybinės dalies apžvalga

Vaistinio preparato veiklioji medžiaga – mebeverino hidrochloridas. Mebeverino hidrochlorido gamintojai pateikė atitikties Europos farmakopėjai sertifikatus (CEP).
Gatavo produkto gamintojo veikliosios medžiagos mebeverino hidrochlorido specifikacija yra tinkamos kokybės ir atitinka ES gairių reikalavimus. Pateikti serijų analizės sertifikatai atitinka patvirtintos specifikacijos reikalavimus.

Mebeverine SanoSwiss 135 mg plėvele dengtos tabletės
Baltos spalvos, apskritos, abipus išgaubtos plėvele dengtos tabletės, kurių abi pusės yra lygios. Plėvele dengtos tabletės skersmuo – 10,10 ± 0,20 mm. Plėvele dengtos tabletės storis – 4,40 ± 0,30 mm.
Gatavo produkto sudėtyje yra šių pagalbinių medžiagų: laktozės monohidrato, mikrokristalinės celiuliozės, karboksimetilkrakmolo A natrio druskos, povidono K-30, talko, magnio stearato, hipromeliozės, makrogolio, titano dioksido. Pagalbinių medžiagų pasirinkimas yra pagrįstas, jos yra plačiai naudojamos farmacinių preparatų gamyboje.
Bioekvivalentiškumo tyrimai atlikti su referenciniu vaistiniu preparatu Colofac 135 mg plėvele dengtos tabletės. Gamybos metodas standartinis. Gatavo produkto išleidimo ir tinkamumo laiko pabaigos specifikacijų kokybė atitinka ES gairių reikalavimus. Analizės procedūrų aprašymai pateikti, metodai yra validuoti. Serijų analizės sertifikatai atitinka specifikacijos reikalavimus. Gatavas produktas pakuojamas į aliuminio / PVC arba aliuminio / PVC/ PVdC lizdines plokšteles. Gatavo produkto stabilumo tyrimai atlikti pagal ES gairių reikalavimus. Remiantis stabilumo tyrimų duomenimis nustatytas 36 mėnesių tinkamumo laikas. Šiam vaistiniam preparatui specialių laikymo sąlygų nereikia.

Trumpa ikiklinikinės ir klinikinės dalies apžvalga

Mebeverine SanoSwiss 135 mg plėvele dengtos tabletės yra receptinis vaistinis preparatas, skirtas
simptominiam suaugusiųjų dirgliosios žarnos sindromo, ypatingai virškinimo trakto spazmų, pilvo dieglių ir skausmo, susijusio su tuštinimosi sutrikimais ir pilvo pūtimu, gydymui.

Paraiška registruoti vaistinį preparatą pateikta pagal direktyvos 2001/83/EB 10 str. 1d. („generinis“). Pareiškėjas įrodė, kad vaistinis preparatas *Mebeverine SanoSwiss 135 mg plėvele dengtos tabletės* (UAB SanoSwiss) yra iš esmės panašus į referencinį vaistinį preparatą *Duspatal 135 mg coated tablets* (Viatris Healthcare GmbH, Vokietija).

Mebeverine SanoSwiss sudėtyje esantis mebeverino hidrochloridas priklauso vaistų, vadinamų spazmolitikais, grupei. Mebeverinas yra raumenis veikianti, spazmus atpalaiduojanti medžiaga, pasižyminti tiesioginiu poveikiu lygiesiems virškinimo trakto raumenims ir nepaveikianti normalaus žarnyno judrumo.

Mebeverine SanoSwiss skirtas vartoti per burną, jo kiekybinė ir kokybinė sudėtis bei farmacinė forma tokios pat kaip referencinio vaistinio preparato *Duspatal*. Pateiktas klinikinis tyrimas, įrodantis šių vaistinių preparatų biologinį ekvivalentiškumą. Referencinė ir pripažįstančios valstybės narės sutarė, kad *Mebeverine SanoSwiss 135 mg plėvele dengtų tablečių* veiksmingumo ir saugumo duomenys yra panašūs į *Duspatal*.

Registruotojas turi veikiančią farmakologinio budrumo sistemą, kuri kartu su rizikos valdymo planu yra parengta kaip to reikalauja teisės aktai. Nepageidaujami reiškiniai yra nuolat analizuojami po vaistinio preparato registracijos.

Remiantis pateiktais kokybės, saugumo ir veiksmingumo duomenimis, decentralizuotoje procedūroje dalyvaujančios referencinė valstybė narė (Lietuva) ir pripažįstančiosios valstybės narės (Latvija ir Estija) nutarė, kad vaistinį preparatą *Mebeverine SanoSwiss 135 mg plėvele dengtos tabletės* registruoti galima ir europinė fazė buvo sėkmingai baigta (210 dieną) 2026-02-11.
Lietuvoje vaistinis preparatas užregistruotas 2026-03-18.