RISK MANAGEMENT PLAN
For
Teduglutide
Version 0.3

RMP Version to be Assessed as Part of this Application:

RMP Version Number	0.3
Data Lock Point for this RMP	04-Sep-2024
Date of Final Sign Off	14-Aug-2025
Rationale for Submitting an Updated RMP	Not applicable
Summary of Significant Changes in this RMP	Not applicable

Details of the Current RMP:

Version Number	Not applicable
Approved with Procedure	Not applicable
Date of Approval (Opinion Date)	Not applicable

QPPV: Dr Eiko Soehlke, MD MPH, EEA QPPV

QPPV oversight declaration: The content of this RMP has been reviewed and approved by the marketing authorisation applicant´s QPPV. The electronic signature is available on file.

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LIST OF ABBREVIATIONS

Abbreviation	Definition
ADR	Adverse Drug Reaction
ATC	Anatomical Therapeutic Chemical Classification System
CHMP	Committee for Medicinal Products for Human Use
CNS	Central Nervous System
CMDh	Coordination Group for Mutual Recognition and Decentralised Procedures – Human
CRP	C-Reactive Protein
DCP	Decentralised Procedure
DDD	Daily Defined Dose
DHPC	Direct Healthcare Professional Communication
DPP-IV	Dipeptidyl Peptidase-IV
EEA	European Economic Area
EPAR	European Public Assessment Report
EU	European Union
EURD	European Union Reference Date
GI	Gastrointestinal
GLP-2	Glucagon-like peptide-2
HCP	Healthcare Professional
ICSR	Individual Case Safety Report
MAA	Marketing Authorization Applicant
MAH	Marketing Authorization Holder
MRP	Mutual Recognition Procedure
PAC	Patient Alert Card
PL	Package Leaflet
PPP	Pregnancy Prevention Programme
PRAC	Pharmacovigilance Risk Assessment Committee
PSUR	Periodic Safety Update Report
PTC	Patient Treatment Course
PTD	Patient Treatment Days
PTM	Patient Treatment Months
PTY	Patient Treatment Years
PVA	Pharmacovigilance Agreement
QPPV	Qualified Person for Pharmacovigilance
MedDRA	Medical Dictionary for Regulatory Activities
DLP	Data Lock Point
SBS	Short Bowel Syndrome
SmPC	Summary of Product Characteristics
WHO	World Health Organization

PART I: PRODUCT(S) OVERVIEW

Table 1: Part 1.1-Product Overview

Active Substance(s) (INN or Common Name)	Teduglutide
Pharmacotherapeutic Group(s) (ATC Code)	Other alimentary tract and metabolism products, various alimentary tract and metabolism products, ATC code: A16AX08.
Marketing Authorisation Holder	Viatris Limited
Medicinal Products to Which this RMP Refers	1
Invented Name(s) in the European Economic Area (EEA)	Teduglutide Viatris 5 mg powder and solvent for solution for injection
Marketing Authorisation Procedure	Centralised (EMEA/H/C/006564)
Brief Description of the Product	Chemical class: Teduglutide is novel recombinant analogue of the human Glucagon-like peptide 2 (GLP-2), a peptide secreted by the lower gastrointestinal (GI) tract. Summary of mode of action: The naturally occurring human glucagon-like peptide-2 (GLP-2) is a peptide secreted by L cells of the intestine which is known to increase intestinal and portal blood flow, inhibit gastric acid secretion, and decrease intestinal motility. Teduglutide is an analogue of GLP 2. In several nonclinical studies, teduglutide has been shown to preserve mucosal integrity by promoting repair and normal growth of the intestine through an increase of villus height and crypt depth. Important information about its composition: Not applicable
Hyperlink to the Product Information:	PI available in section 1.3.1 of the dossier
Indication(s) in the EEA	Current: Teduglutide Viatris is indicated for the treatment of patients 4 months corrected gestational age and above with Short Bowel Syndrome (SBS). Patients should be stable following a period of intestinal adaptation after surgery. Proposed: Not applicable

Dosage in the EEA **Current**	Current: Adults: The recommended dose of Teduglutide Viatris is 0.05 mg/kg body weight once daily. The injection volume per body weight is provided in the SmPC. If a dose is missed, that dose should be injected as soon as possible on that day. Paediatrics (≥1 year): The recommended dose of Teduglutide Viatris in children and adolescents (aged 1 to 17 years) is the same as for adults (0.05 mg/kg body weight once daily). The injection volume per body weight when using the 5 mg strength vial is provided in the SmPC. If a dose is missed, that dose should be injected as soon as possible on that day. A treatment period of 6 months is recommended after which treatment effect should be evaluated. In children below the age of two years, treatment should be evaluated after 12 weeks. Paediatric population (aged 4 months to less than 12 months). For paediatric patients aged 4 months to less than 12 months, teduglutide 1.25 mg vials should be used. Other medicinal products with the active substance teduglutide are available for administration to paediatric patients aged 4 months to less than 12 months. Proposed: Not applicable
Pharmaceutical Form(s) and Strengths **Current**	Current: Powder and solvent for solution for injection. The powder is white and the solvent is clear and colourless. One vial of powder contains 5 mg of teduglutide. After reconstitution, each vial contains 5 mg teduglutide in 0.5 ml of solution, corresponding to a concentration of 10 mg/ml. Proposed: Not applicable
Is the Product Subject to Additional Monitoring in the EU?	No

PART II: SAFETY SPECIFICATION

Part II: Module SI - Epidemiology of the Indication(s) and Target Population(s)

Not applicable.

Part II: Module SII - Non-clinical Part of the Safety Specification

Not applicable.

Part II: Module SIII - Clinical Trial Exposure

Not applicable.

Part II: Module SIV - Populations Not Studied in Clinical Trials

SIV.1 Exclusion Criteria in Pivotal Clinical Studies Within the Development Programme

Not applicable.

SIV.2 Limitations to Detect Adverse Reactions in Clinical Trial Development Programmes

Not applicable.

SIV.3 Limitations in Respect to Populations Typically Under-represented in Clinical Trial Development Programmes

Not applicable.

Part II: Module SV - Post-authorisation Experience

Not applicable.

Part II: Module SVI - Additional EU Requirements for the Safety Specification

Not applicable.

Part II: Module SVII - Identified and Potential Risks

SVII.1 Identification of Safety Concerns in the Initial RMP Submission

This is a MAA for a generic medicine in which the safety concerns available in the RMP in public domain have been adopted by the MAH (Takeda: EPAR Risk Management Plan for Revestive (teduglutide) published on 11-Feb-2020 and last updated on 06-Mar-2024 on the EMA website).

Table 2: SVII- Summary of safety concerns

Summary of Safety Concerns	
Important Identified Risks	- Biliary AEs

Summary of Safety Concerns	
	- Pancreatic AEs - Cardiovascular AEs associated with fluid overload. - GI stenosis and obstruction - GI stoma complications - Intestinal polyp - Benign neoplasia of the GI tract including the hepatobiliary system - Tumour promoting ability - Anxiety
Important Potential Risks	- AEs associated with increased absorption of oral concomitant medications. - Local skin reactions - Potential for off-label use in patients with active Crohn's diseases - Medication errors - Compromised nutritional status
Missing Information	- Lack of experience for administration of teduglutide in subjects with severe, clinically unstable concomitant diseases e.g., cardiovascular, respiratory, renal, infectious, endocrine, hepatic or Central Nervous System (CNS) or in patients with malignancies within the last 5 years - Lack of experience in pregnant or lactating women - Long-term safety in paediatric population - Limited long-term safety data over one year of exposure - Lack of data in patients with pre-existing severe haptic impairment.

SVII.1.1. Risks Not Considered Important for Inclusion in the List of Safety Concerns in the RMP

Not applicable as all risks from RMP in public domain have been considered in this RMP.

SVII.1.2. Risks Considered Important for Inclusion in the List of Safety Concerns in the RMP

Not applicable as all risks from RMP in public domain have been considered in this RMP.

SVII.2 New Safety Concerns and Reclassification with a Submission of an Updated RMP

Not applicable as this is the initial RMP for teduglutide.

SVII.3 Details of Important Identified Risks, Important Potential Risks, and Missing Information

SVII.3.1. Presentation of Important Identified Risks and Important Potential Risks

Not applicable as this RMP for teduglutide follows the same safety concerns as the safety concerns of the RMP published on the EMA website.

SVII.3.2. Presentation of the Missing Information

Not applicable as this RMP for teduglutide follows the same safety concerns as the safety concerns of the RMP published on the EMA website.

Part II: Module SVIII - Summary of the Safety Concerns

Table 3: SVIII- Summary of safety concerns

Important Identified Risks	- Biliary AEs - Pancreatic AEs - Cardiovascular AEs associated with fluid overload. - GI stenosis and obstruction - GI stoma complications - Intestinal polyp - Benign neoplasia of the GI tract including the hepatobiliary system - Tumour promoting ability - Anxiety
Important Potential Risks	- AEs associated with increased absorption of oral concomitant medications. - Local skin reactions - Potential for off-label use in patients with active Crohn's diseases - Medication errors - Compromised nutritional status
Missing Information	- Lack of experience for administration of teduglutide in subjects with severe, clinically unstable concomitant diseases e.g., cardiovascular, respiratory, renal, infectious, endocrine, hepatic or CNS, or in patients with malignancies within the last 5 years - Lack of experience in pregnant or lactating women - Long-term safety in paediatric population - Limited long-term safety data over one year exposure - Lack of data in patients with pre-existing severe haptic impairment.

PART III: PHARMACOVIGILANCE PLAN (INCLUDING POST-AUTHORISATION SAFETY STUDIES)

The Pharmacovigilance System Master File contains details of the system and processes that the MAH has in place to identify and characterize the risks recognised in the safety specification.

III.1 Routine Pharmacovigilance Activities

Routine pharmacovigilance activities beyond ADRs reporting and signal detection:

Specific adverse reaction follow-up questionnaires for the following risks:

Safety concern	Questionnaire
Biliary AEs such as cholecystitis and GI stenosis	Gallbladder disorder/cholecystitis questionnaire
Pancreatic AEs such as chronic and acute pancreatitis, pancreatic duct stenosis, pancreas infection and increased blood amylase and lipase	Pancreatitis questionnaire
Cardiovascular AEs associated with fluid overload	Fluid overload questionnaire
GI stenosis and obstruction	GI stenosis/intestinal obstruction questionnaire
Benign neoplasia of the GI tract including the hepatobiliary system.	Neoplasm questionnaire

The forms are provided in Annex 4 - Specific Adverse Drug Reaction Follow-up Forms of the RMP.

Other forms of routine pharmacovigilance activities:

Obligatory expedited reporting independent of seriousness, implemented for the following safety concerns:
- Growth of pre-existing polyps of the colon
- Benign neoplasia of the gastrointestinal tract including the hepatobiliary system
- Tumour promoting ability.

III.2 Additional Pharmacovigilance Activities

As current routine pharmacovigilance activities are sufficient, no additional pharmacovigilance activities are recommended.

III.3 Summary Table of Additional Pharmacovigilance Activities

None.

PART IV: PLANS FOR POST-AUTHORISATION EFFICACY STUDIES

Not applicable.

PART V: RISK MINIMISATION MEASURES (INCLUDING EVALUATION OF THE EFFECTIVENESS OF RISK MINIMISATION ACTIVITIES)

Risk Minimisation Plan

The safety information in the proposed product information is aligned to the reference medicinal product (Revestive®, MAH: Takeda Pharmaceuticals International AG Ireland).

V.1 Routine Risk Minimisation Measures

Not applicable.

V.2 Additional Risk Minimisation Measures

Not applicable.

V.3 Summary of Risk minimisation measures

Not applicable.

PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of Risk Management Plan for Teduglutide Viatris 5 mg powder and solvent for solution for injection (Teduglutide)

This is a summary of the risk management plan (RMP) for Teduglutide Viatris 5 mg powder and solvent for solution for injection. The RMP details important risks of Teduglutide Viatris 5 mg powder and solvent for solution for injection, how these risks can be minimised, and how more information will be obtained about Teduglutide Viatris 5 mg powder and solvent for solution for injection's risks and uncertainties (missing information).

Teduglutide Viatris 5 mg powder and solvent for solution for injection's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how it should be used.

This summary of the RMP for Teduglutide Viatris 5 mg powder and solvent for solution for injection should be read in the context of all the information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

Important new concerns or changes to the current ones will be included in updates of Teduglutide Viatris 5 mg powder and solvent for solution for injection's RMP.

I. The Medicine and What it is Used For

Teduglutide Viatris is indicated for the treatment of patients 4 months corrected gestational age and above with Short Bowel Syndrome (SBS). Patients should be stable following a period of intestinal adaptation after surgery.

It contains teduglutide as the active substance and it is given by subcutaneous route.

Further information about the evaluation of Teduglutide Viatris 5 mg powder and solvent for solution for injection's benefits can be found in Teduglutide Viatris 5 mg powder and solvent for solution for injection's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage.

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

Important risks of Teduglutide Viatris 5 mg powder and solvent for solution for injection, together with measures to minimise such risks and the proposed studies for learning more about Teduglutide Viatris 5 mg powder and solvent for solution for injection's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific Information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the public (e.g. with or without prescription) can help to minimises its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse events is collected continuously and regularly analysed, so that immediate action can be taken as necessary. These measures constitute routine pharmacovigilance activities.

If important information that may affect the safe use of Teduglutide Viatris 5 mg powder and solvent for solution for injection is not yet available, it is listed under 'missing information' below.

II.A List of Important Risks and Missing Information

Important risks of Teduglutide Viatris 5 mg powder and solvent for solution for injection are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered to patients. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of Teduglutide Viatris 5 mg powder and solvent for solution for injection. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine/use in special patient populations etc.).

Table 4: Part VI.1- Summary of safety concerns

List of Important Risks and Missing Information	
Important Identified Risks	- Biliary AEs - Pancreatic AEs - Cardiovascular AEs associated with fluid overload. - GI stenosis and obstruction - GI stoma complications - Intestinal polyp - Benign neoplasia of the GI tract including the hepatobiliary system - Tumour promoting ability - Anxiety
Important Potential Risks	- AEs associated with increased absorption of oral concomitant medications - Local skin reactions - Potential for off-label use in patients with active Crohn's diseases - Medication errors - Compromised nutritional status
Missing Information	- Lack of experience for administration of teduglutide in patients with severe, clinically unstable concomitant diseases e.g., cardiovascular, respiratory, renal, infectious, endocrine, hepatic or CNS, or in patients with malignancies within the last 5 years - Lack of experience in pregnant or lactating women - Long-term safety in paediatric population - Limited long-term safety data over one year exposure - Lack of data in patients with pre-existing severe haptic impairment.

II.B Summary of Important Risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Post-Authorisation Development Plan

II.C.1 Studies Which are Conditions of the Marketing Authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Teduglutide Viatris 5 mg powder and solvent for solution for injection.

II.C.2 Other Studies in Post-Authorisation Development Plan

There are no studies required for Teduglutide Viatris 5 mg powder and solvent for solution for injection.

PART VII: ANNEXES

Annex 4 - Specific Adverse Drug Reaction Follow-up Forms

Special questionnaires for follow-up for the following safety concerns:

- Biliary AEs such as cholecystitis and GI stenosis
- Pancreatic AEs such as chronic and acute pancreatitis, pancreatic duct stenosis, pancreas infection and increased blood amylase and lipase
- Cardiovascular AEs associated with fluid overload
- GI stenosis and obstruction
- Benign neoplasia of the GI tract including the hepatobiliary system

TARGETED FOLLOW UP FORM	Template v3.0, Effective date: 23-Dec-2024
Viatris Case No.:	

You have reported an adverse reaction(s) of gallbladder disorder/cholecystitis questionnaire for teduglutide. This questionnaire is being sent to you for obtaining valuable additional information about the reported case to thoroughly evaluate the relation to teduglutide exposure. The Questionnaire is already prefilled with all the available information collected at the time of the initial report, only additional information should be filled in. By providing as detailed information as possible, you can make a useful contribution to the safety of teduglutide.

1. Patients Details:

Patient's Initials	
Age/Date of birth	years/months (DD-MMM-YYYY)
Gender	☐ Male ☐ Female
Weight	lbs/kg
Height	ins/cms

2. Drug information at the time of event:

Product(s) suspected to have caused the Adverse Event (Check box to indicate confirmed Viatris products)	**Batch No. / Expiry Date**	**Route**	**Daily Dose**		**Treatment Dates**		**Indication** (what drug is being taken for)
			Dose/ Unit	**Frequency**	**Start Date**	**Stop Date**	
☐							
☐							
☐							
☐							
☐							

TARGETED FOLLOW UP FORM	Template v3.0, Effective date: 23-Dec-2024
Viatris Case No.:	

☐							

3. Medical history and Adverse Event details:

	Question	Response
1.	Reported medical history: What is the patients OTHER medical history and concurrent illnesses including history of cholecystitis and/or cholelithiasis (include dates and treatment)? What is the onset date and reason for short bowel syndrome (SBS)?	
2.	What symptoms of the adverse event(s) did the patient have and what date did they first appear?	
3.	Was the patient hospitalised? If yes, date of hospitalisation: Date of discharge: What was the final hospital diagnosis?	☐ Yes ☐ No ☐ Unknown
4.	If no, did the patient seek treatment at an emergency room or medical office? Please specify (include dates)	☐ Yes ☐ No ☐ Unknown
5.	What treatment did the patient receive (i.e., surgery, medication for pain), if any?	
6.	Was a new diet prescribed? If yes what is the new diet?	☐ Yes ☐ No ☐ Unknown
7.	Does the patient have a family history of cholecystitis and/or cholelithiasis?	☐ Yes ☐ No ☐ Unknown

8.	If yes, who in the patients family and what was the disorder?	
9.	Is the patient overweight and/or has his/her weight fluctuated?	☐ Yes ☐ No ☐ Unknown
10	If yes, describe the weigh issue (i.e., degree of obesity, duration, BMI) or/or fluctuation observed:	
11	How long has the patient been parenteral nutrition (PN) dependant?	
12	Has the patients PN been adjusted in response to the adverse event(s)? If yes, describe the adjustment:	☐ Yes ☐ No ☐ Unknown
13	Provide the dates the patient used teduglutide and the most recent dose used:	
14	Was teduglutide discontinued or was the dose adjusted in response to the adverse event(s) (if yes, please answer a-f)	☐ Yes ☐ No ☐ Unknown
a.	Provide date it was discontinued (even if temporarily) OR Date dose adjusted and the dose it was adjusted to:	
b.	Did the adverse event(s) recover or improve after teduglutide was discontinued/adjusted?	☐ Yes ☐ No ☐ Unknown
c.	If teduglutide was discontinued, has the patient restarted use of teduglutide?	☐ Yes ☐ No ☐ Unknown
d.	If yes, please provide date of resumption of teduglutide	
e.	Was teduglutide dose adjusted when it was resumed?	☐ Yes ☐ No ☐ Unknown
f.	If teduglutide was resumed, did the adverse event(s) reappear?	☐ Yes ☐ No ☐ Unknown
15. Reported concomitant medications:		

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What OTHER medications did the patient take at the time of or within 30 days prior to the adverse event?

Medication Name	Strength/ Volume	Frequency	Indication

16. What diagnostic test (i.e. USG, ERCP, Blood work, etc) did the patient have, if any and what were the results?

Test(s)	**Date(s)**	**Result(s)**

4. <u>Additional/supporting information:</u>

(Please give additional details on the adverse events, sequence of events, including hospitalisation details, treatment, and/or laboratory tests. This includes start and stop dates. This box can also be used to add extra information if you have run out of space in the other fields)

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Viatris Case No.:	

5. Outcome of event:

☐ Recovered/resolved ☐ Not recovered/ Not resolved

☐ Resolved with sequelae ☐ Fatal

☐ Unknown ☐ Other

If 'Other', please specify:

_____

_____

6. Reporter's Details:

I certify that this Questionnaire is accurate and truthful to the best of my knowledge and does not contain any false, fictitious, or fraudulent statements.

Name/Initials:

Occupation:

☐ Physician ☐ Pharmacist ☐ Nurse ☐ Other Healthcare Professional

☐ Patient/Consumer

Signature and Date:

Please be aware that information provided to Viatris relating to you, may be used to comply with applicable laws and regulations. Viatris processes your personal or sensitive data in accordance with applicable data protection laws and the Viatris Privacy Statement, available to you either on https://www.viatris.com/en/viatris-privacy-notice or upon request.

TARGETED FOLLOW UP FORM	Template v3.0, Effective date: 23-Dec-2024
Viatris Case No.:	

You have reported an adverse reaction(s) of pancreatitis questionnaire for teduglutide. This questionnaire is being sent to you for obtaining valuable additional information about the reported case to thoroughly evaluate the relation to teduglutide exposure. The Questionnaire is already prefilled with all the available information collected at the time of the initial report, only additional information should be filled in. By providing as detailed information as possible, you can make a useful contribution to the safety of teduglutide.

1. Patients Details:

Patient's Initials	
Age/Date of birth	years/months (DD-MMM-YYYY)
Gender	☐ Male ☐ Female
Weight	lbs/kg
Height	ins/cms

2. Drug information at the time of event:

Product(s) suspected to have caused the Adverse Event (Check box to indicate confirmed Viatris products)	**Batch No. / Expiry Date**	**Route**	**Daily Dose**		**Treatment Dates**		**Indication** (what drug is being taken for)
			Dose/ Unit	**Frequency**	**Start Date**	**Stop Date**	
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TARGETED FOLLOW UP FORM	Template v3.0, Effective date: 23-Dec-2024
Viatris Case No.:	

☐							

3. Medical history and Adverse Event details:

	Question	Response
1.	Reported medical history: What is the patient's OTHER medical history and concurrent illnesses including underlying condition precipitating Short Bowel Syndrome (SBS) and history of pancreatic disease (include dates and treatment) What is the onset date for the patients SBS?	
2.	If patient has a history of pancreatitis, is this episode a relapse?	☐ Yes ☐ No ☐ Unknown
3.	Is the diagnosis acute or chronic pancreatitis?	
4.	Was the pancreatitis attributed to a procedure (i.e., post ERCP pancreatitis) Please specify (include dates)	☐ Yes ☐ No ☐ Unknown
5.	What symptoms of this episode of pancreatitis did the patient have and what date did they first appear?	
6.	Since initially reported, have the adverse events(s) resolved? If yes, what were the dates of recovery for each?	☐ Yes ☐ No ☐ Unknown
7.	Was the patient hospitalised for this episode of pancreatitis? If yes, dates of hospitalisation?	☐ Yes ☐ No ☐ Unknown
8.	If no, did the patient seek treatment at an emergency room or medical office? Please specify (include dates)	☐ Yes ☐ No ☐ Unknown
9.	What treatment did the patient receive, if any?	☐ Yes ☐ No ☐ Unknown

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Viatris Case No.:	

10	Does the patient use alcohol? If yes, what kind?	☐ Yes	☐ No	☐ Unknown
11	How many drinks per week?			
12	Is the patient prone to binge drinking? If yes, when was the most recent episode?	☐ Yes	☐ No	☐ Unknown
13	Was the patient advised to discontinue use of alcohol?	☐ Yes	☐ No	☐ Unknown
14	Was the episode associated with alcohol consumption?	☐ Yes	☐ No	☐ Unknown
15	Does the patient have a history of cigarette smoking? If yes, how many packs/day and for how long?	☐ Yes	☐ No	☐ Unknown
16	Has the patient been treated for, or do they have gallstones?	☐ Yes	☐ No	☐ Unknown
17	If yes, were gallstones removed?	☐ Yes	☐ No	☐ Unknown
18	If gallstones were not removed, when was the most recent follow-up?			
19	Does the patient have elevated triglycerides?	☐ Yes	☐ No	☐ Unknown
20	If yes, is this a new condition?	☐ Yes	☐ No	☐ Unknown
21	If it is not a new elevation in triglycerides, describe the elevation, duration and treatment for the condition:			
22	Is there a family history of pancreatitis? If yes, does the patient have hereditary pancreatitis?	☐ Yes	☐ No	☐ Unknown
23	How long has the patient been Parenteral nutrition (PN) dependant?			
24	Has the patients PN been adjusted in response to the adverse event(s)? If yes, describe the adjustment	☐ Yes	☐ No	☐ Unknown

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25	Provide the dates the patient used teduglutide and the most recent dose used			
26	Was teduglutide discontinued or was the dose adjusted in response to the adverse event(s) If yes, please answer a-f	☐ Yes	☐ No	☐ Unknown
a.	Provide date teduglutide was discontinued (even if temporarily) OR Date dose was adjusted and the dose it was adjusted to:			
b.	Did the adverse event recover or improve after teduglutide was discontinued/adjusted?	☐ Yes	☐ No	☐ Unknown
c.	If teduglutide was discontinued, has the patient restarted use of teduglutide?	☐ Yes	☐ No	☐ Unknown
d.	If yes, please provide date of resumption of teduglutide			
e.	Was teduglutide dose adjusted when it was resumed?	☐ Yes	☐ No	☐ Unknown
f.	If teduglutide was resumed, did the adverse event reappear?	☐ Yes	☐ No	☐ Unknown

27. Reported concomitant medications:

What OTHER medications did the patient take at the time of or within 30 days prior to the adverse event?

Medication Name	Strength/ Volume	Frequency	Indication

28. What diagnostic test (i.e. USG, ERCP, Blood work, etc) did the patient have, if any and what were the results

Test(s)	Date(s)	Result(s)

4. Additional/supporting information:

(Please give additional details on the adverse events, sequence of events, including hospitalisation details, treatment, and/or laboratory tests. This includes start and stop dates. This box can also be used to add extra information if you have run out of space in the other fields)

5. Outcome of event:

☐ Recovered/resolved

☐ Not recovered/ Not resolved

☐ Resolved with sequelae

☐ Fatal

☐ Unknown

☐ Other

If 'Other', please specify:

_____

_____

6. Reporter's Details:

I certify that this Questionnaire is accurate and truthful to the best of my knowledge and does not contain any false, fictitious, or fraudulent statements.

Name/Initials:

TARGETED FOLLOW UP FORM	Template v3.0, Effective date: 23-Dec-2024
Viatris Case No.:	

Occupation:

☐ Physician ☐ Pharmacist ☐ Nurse ☐ Other Healthcare Professional

☐ Patient/Consumer

Signature and Date:

Please be aware that information provided to Viatris relating to you, may be used to comply with applicable laws and regulations. Viatris processes your personal or sensitive data in accordance with applicable data protection laws and the Viatris Privacy Statement, available to you either on https://www.viatris.com/en/viatris-privacy-notice or upon request.

TARGETED FOLLOW UP FORM	Template v3.0, Effective date: 23-Dec-2024
Viatris Case No.:	

You have reported an adverse reaction(s) of fluid overload questionnaire for teduglutide. This questionnaire is being sent to you for obtaining valuable additional information about the reported case to thoroughly evaluate the relation to teduglutide exposure. The Questionnaire is already prefilled with all the available information collected at the time of the initial report, only additional information should be filled in. By providing as detailed information as possible, you can make a useful contribution to the safety of teduglutide.

1. Patients Details:

Patient's Initials	
Age/Date of birth	years/months (DD-MMM-YYYY)
Gender	☐ Male ☐ Female
Weight	lbs/kg
Height	ins/cms

2. Drug information at the time of event:

Product(s) suspected to have caused the Adverse Event (Check box to indicate confirmed Viatris products)	**Batch No. / Expiry Date**	**Route**	**Daily Dose**		**Treatment Dates**		**Indication** (what drug is being taken for)
			Dose/ Unit	**Frequency**	**Start Date**	**Stop Date**	
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3. Medical history and Adverse Event details:

	Question	Response
1.	Reported medical history: What is the patients OTHER medical history and concurrent illnesses (including cardiovascular disease and type) and concurrent illnesses? What is the onset date and reason for Short Bowel Syndrome (SBS)?	
2.	Since initially reported, have the adverse event(s) resolved? If yes, what were the dates of recovery for each?	
3.	Was the patient hospitalised for the adverse event(s)? If yes, dates of hospitalisation: Date of discharge: What was the final hospital diagnosis?	☐ Yes ☐ No ☐ Unknown
4.	If no, did the patient seek treatment at an emergency room or medical office? Please specify	☐ Yes ☐ No ☐ Unknown
5.	What treatment did the patient receive, if any?	
6.	How long has the patient been Parenteral Nutrition (PN) dependant?	
7.	Has the patients PN been adjusted in response to the adverse event(s)? If yes, describe the adjustment:	☐ Yes ☐ No ☐ Unknown

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8.	Provide the dates the patient used teduglutide and the most recent dose used:	☐ Yes	☐ No	☐ Unknown
9.	Was the teduglutide discontinued or was the dose adjusted in response to the adverse event(s)? (if yes, please answer a-f)	☐ Yes	☐ No	☐ Unknown
a)	Provide date it was discontinued (even if temporarily) OR Date dose adjusted and the dose it was adjusted to:			
b)	Did the adverse event(s) recover or improve after teduglutide was discontinued/adjusted?	☐ Yes	☐ No	☐ Unknown
c)	If teduglutide was discontinued, has the patient restarted use of teduglutide?	☐ Yes	☐ No	☐ Unknown
d)	If yes, provide date of resumption of teduglutide			
e)	Was teduglutide dose adjusted when it was resumed?	☐ Yes	☐ No	☐ Unknown
f)	If teduglutide was resumed, did the adverse event(s) reappear?	☐ Yes	☐ No	☐ Unknown

10. Reported concomitant medications:

What OTHER medications did the patient take at the time of or within 30 days prior to the adverse event?

Medication Name	Strength/ Volume	Frequency	Indication

11. What diagnostic test (i.e. USG, ERCP, Blood work, etc) did the patient have, if any and what were the results

Test(s)	Date(s)	Result(s)

4. <u>Additional/supporting information:</u>

(Please give additional details on the adverse events, sequence of events, including hospitalisation details, treatment, and/or laboratory tests. This includes start and stop dates. This box can also be used to add extra information if you have run out of space in the other fields)

5. <u>Outcome of event:</u>

☐ Recovered/resolved
☐ Not recovered/ Not resolved
☐ Resolved with sequelae
☐ Fatal
☐ Unknown
☐ Other

If 'Other', please specify:

_____

6. Reporter's Details:

I certify that this Questionnaire is accurate and truthful to the best of my knowledge and does not contain any false, fictitious, or fraudulent statements.

Name/Initials:

Occupation:
☐ Physician ☐ Pharmacist ☐ Nurse ☐ Other Healthcare Professional
☐ Patient/Consumer

Signature and Date:

Please be aware that information provided to Viatris relating to you, may be used to comply with applicable laws and regulations. Viatris processes your personal or sensitive data in accordance with applicable data protection laws and the Viatris Privacy Statement, available to you either on https://www.viatris.com/en/viatris-privacy-notice or upon request.

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Viatris Case No.:	

You have reported an adverse reaction(s) of GI stenosis/intestinal obstruction questionnaire for teduglutide. This questionnaire is being sent to you for obtaining valuable additional information about the reported case to thoroughly evaluate the relation to teduglutide exposure. The Questionnaire is already prefilled with all the available information collected at the time of the initial report, only additional information should be filled in. By providing as detailed information as possible, you can make a useful contribution to the safety of teduglutide.

1. Patients Details:

Patient's Initials	
Age/Date of birth	years/months (DD-MMM-YYYY)
Gender	☐ Male ☐ Female
Weight	lbs/kg
Height	ins/cms

2. Drug information at the time of event:

Product(s) suspected to have caused the Adverse Event (Check box to indicate confirmed Viatris products)	**Batch No. / Expiry Date**	**Route** (oral, etc.)	**Daily Dose** (e.g. 20 mg tablet 3 times a day)		**Treatment Dates**		**Indication** (what drug is being taken for)
			Dose/ Unit	**Frequency**	**Start Date**	**Stop Date**	
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3. Medical history and Adverse Event details:

	Question	Response
1.	Reported medical history: What is the patients OTHER medical history and concurrent illnesses (including Crohn's disease and GI obstruction) and concurrent illnesses? What is the onset date and reason for Short Bowel Syndrome (SBS)?	
2.	In addition to the above, does the patient have a history of abdominal cancer treated with radiation?	
3.	How many abdominal surgeries has the patient had to date?	
4.	Does the patient have a stoma?	☐ Yes ☐ No ☐ Unknown
5.	What symptoms of the adverse event(s) did the patient have and when did they first appear?	
6.	Since initially reported, have the adverse event(s) resolved? If yes, what were the dates of recovery for each?	
7.	Was the patient hospitalised for the adverse event(s)? If yes, dates of hospitalisation: Date of discharge: What was the final hospital diagnosis?	☐ Yes ☐ No ☐ Unknown
8.	If no, did the patient seek treatment at an emergency room or medical office? Please specify, include dates:	☐ Yes ☐ No ☐ Unknown

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9.	What treatment did the patient receive, if any?			
10.	How long has the patient been Parenteral nutrition (PN) dependant?			
11.	Has the patients PN been adjusted in response to the adverse event(s)? if yes, describe the adjustment:	☐ Yes	☐ No	☐ Unknown
12.	Provide the dates the patient used teduglutide and the most recent dose used:			
13.	Was the teduglutide discontinued or was the dose adjusted in response to the adverse event(s): (If yes, please answer a-f)	☐ Yes	☐ No	☐ Unknown
a.	Provide date it was discontinued (even if temporarily) OR Fate dose adjusted and the dose it was adjusted to:			
b.	Did the adverse event(s) recover or improve after teduglutide was discontinued/adjusted?	☐ Yes	☐ No	☐ Unknown
c.	If teduglutide was discontinued, has the patient restarted use of teduglutide?	☐ Yes	☐ No	☐ Unknown
d.	If yes, provide date of resumption of teduglutide			
e.	Was teduglutide dose adjusted when it was resumed?	☐ Yes	☐ No	☐ Unknown
f.	If teduglutide was resumed, did the adverse event(s) reappear?	☐ Yes	☐ No	☐ Unknown

14. Reported concomitant medications:

What OTHER medications did the patient take at the time of or within 30 days prior to the adverse event?

Medication Name	Strength/ Volume	Frequency	Indication

15. What diagnostic test (i.e. USG, ERCP, Blood work, etc) did the patient have, if any and what were the results

Test(s)	Date(s)	Result(s)

4. <u>Additional/supporting information:</u>

(Please give additional details on the adverse events, sequence of events, including hospitalisation details, treatment, and/or laboratory tests. This includes start and stop dates. This box can also be used to add extra information if you have run out of space in the other fields)

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5. Outcome of event:

☐ Recovered/resolved ☐ Not recovered/ Not resolved

☐ Resolved with sequelae ☐ Fatal

☐ Unknown ☐ Other

If 'Other', please specify:

_____

_____

6. Reporter's Details:

I certify that this Questionnaire is accurate and truthful to the best of my knowledge and does not contain any false, fictitious, or fraudulent statements.

Name/Initials:

Occupation:

☐ Physician ☐ Pharmacist ☐ Nurse ☐ Other Healthcare Professional

☐ Patient/Consumer

Signature and Date:

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TARGETED FOLLOW UP FORM	Template v3.0, Effective date: 23-Dec-2024
Viatris Case No.:	

You have reported an adverse reaction(s) of neoplasm questionnaire for teduglutide. This questionnaire is being sent to you for obtaining valuable additional information about the reported case to thoroughly evaluate the relation to teduglutide exposure. The Questionnaire is already prefilled with all the available information collected at the time of the initial report, only additional information should be filled in. By providing as detailed information as possible, you can make a useful contribution to the safety of teduglutide.

1. Patients Details:

Patient's Initials	
Age/Date of birth	years/months (DD-MMM-YYYY)
Gender	☐ Male ☐ Female
Weight	lbs/kg
Height	ins/cms

2. Drug information at the time of event:

Product(s) suspected to have caused the Adverse Event (Check box to indicate confirmed Viatris products)	**Batch No. / Expiry Date**	**Route**	**Daily Dose**		**Treatment Dates**		**Indication** (what drug is being taken for)
			Dose/ Unit	**Frequency**	**Start Date**	**Stop Date**	
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3. Medical history and Adverse Event details:

	Question	Response
1.	Reported medical history: What is the patients OTHER medical history and concurrent illnesses (including history of neoplasm/cancer-include dates and treatment)? What is the onset date (dd/mmm/yyyy) and reason for Short Bowel Syndrome (SBS)?	
2.	If patient has a history of cancer, provide date(s), type of cancer, site, treatment and if it metastasized?	
3.	Does the patient have a family history of cancer?	☐ Yes ☐ No ☐ Unknown
4.	If yes, who in the family, what type of cancer, how it was treated and the outcome, if known?	
5.	If diagnosed with cancer, what other risk factors are present in the patient's profile that may have contributed to the development of thus type of cancer?	
	For gastrointestinal neoplasm: please answer a - j	
a.	Does the patient have a history of polyps?	☐ Yes ☐ No ☐ Unknown
b.	If yes, provide date(s), site and treatment (ddmmyyyy)	
c.	Prior to starting teduglutide, dud the patient have a colonoscopy?	☐ Yes ☐ No ☐ Unknown

d.	If yes, provide the date (ddmmyyyy) of the colonoscopy:			
e.	Was a complete colonoscopy performed?	☐ Yes	☐ No	☐ Unknown
f.	Was the prep for the colonoscopy done satisfactorily?	☐ Yes	☐ No	☐ Unknown
g.	Were any abnormalities noted such as polyps?	☐ Yes	☐ No	☐ Unknown
h.	Were the abnormalities addressed (e.g., the polyps were removed)?	☐ Yes	☐ No	☐ Unknown
i.	What was the pathology result, if applicable, including: - Size of polyps - Location of polyps			
j.	When is the patient to return for an additional colonoscopy			
6.	Since initially reported, have the adverse event(s) resolved? If yes, what were the dates of recovery for each?			
7.	Was the patient hospitalised for the adverse event(s)?	☐ Yes	☐ No	☐ Unknown
8.	If yes, dates (ddmmyyyy) of hospitalisation and final diagnosis of adverse event(s): Date of discharge:			
9.	If no, did the patient seek treatment at an emergency room or medical office? Please specify (include dates)	☐ Yes	☐ No	☐ Unknown
10.	What treatments did the patient receive if any?			
11.	How long has the patient been Parenteral nutrition (PN) dependant?			
12.	Has the patients PN been adjusted in response to the adverse event(s)?	☐ Yes	☐ No	☐ Unknown

	If yes, describe the adjustment	
13.	Provide the dates the patient used teduglutide and the most recent dose used:	
14.	Was teduglutide discontinued or was the dose adjusted in response to the adverse event(s) If yes, please answer k-p	☐ Yes ☐ No ☐ Unknown
k.	Provide date (ddmmyyyy)it was discontinued (even if temporarily) OR Date (ddmmyyyy) dose was adjusted and the dose it was adjusted to:	
l.	Did the adverse event(s) recover or improve after teduglutide was discontinued/adjusted?	☐ Yes ☐ No ☐ Unknown
m.	If teduglutide was discontinued, has the patient restarted use of teduglutide?	☐ Yes ☐ No ☐ Unknown
n.	If yes, provide date (ddmmyyyy) of resumption of teduglutide	
o.	Was teduglutide dose adjusted when it was resumed?	☐ Yes ☐ No ☐ Unknown
p.	If teduglutide was resumed, did the adverse event(s) reappear?	☐ Yes ☐ No ☐ Unknown

15. Reported concomitant medications:

What OTHER medications did the patient take at the time of or within 30 days prior to the adverse event?

Medication Name	Strength/ Volume	Frequency	Indication

16. What diagnostic test (i.e. USG, ERCP, Blood work, etc) did the patient have, if any and what were the results		
Test(s)	**Date(s)**	**Result(s)**

4. <u>Additional/supporting information:</u>

(Please give additional details on the adverse events, sequence of events, including hospitalisation details, treatment, and/or laboratory tests. This includes start and stop dates. This box can also be used to add extra information if you have run out of space in the other fields)

5. <u>Outcome of event:</u>

☐ Recovered/resolved ☐ Unknown

☐ Resolved with sequelae ☐ Not recovered/ Not resolved

☐ Fatal ☐ Other

If 'Other', please specify:

_____

_____

6. Reporter's Details:

I certify that this Questionnaire is accurate and truthful to the best of my knowledge and does not contain any false, fictitious, or fraudulent statements.

Name/Initials:

Occupation:

☐ Physician ☐ Pharmacist ☐ Nurse ☐ Other Healthcare Professional

☐ Patient/Consumer

Signature and Date:

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Annex 6 - Details of Proposed Additional Risk Minimisation Activities (If Applicable)

Not applicable.