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December 3, 2020

IMPORTANT INFORMATION

Re: Influsplit Tetra German-Labelled Influenza Vaccine in Pre-Filled Syringes (NH 2020-2021 Influenza Season) for Canadian Market

Key Messages

Due to an increased demand for influenza vaccine in Canada as a result of concerns over the co-circulation of influenza and SARS-CoV-2, GSK has been asked to supply doses of an alternate GSK influenza quadrivalent vaccine in response to the Urgent Public Health Need (UPHN) identified by the Chief Public Health Officer of Canada.

Health Canada has facilitated the temporary importation from Belgium of Influsplit Tetra influenza vaccine in Pre-Filled Syringes format (PFS) from **Lots AFLBA528AC, AFLBA529AA, AFLBA529BA, AFLBA531AC and AFLBA530AA, Expiry 31Aug2021** with German packaging, approved for use in Germany.

Influsplit Tetra authorized in Germany is currently identified on Health Canada's List of Drugs for an Urgent Public Health Need (**German license number PEI.H.11629.01.1**).

While Influsplit Tetra is not approved in Canada, product quality is acceptable for use in Canada and differences of composition between FluLaval Tetra and Influsplit Tetra can be found in Table 1. In addition, Influsplit Tetra vaccine has been used in International markets since 14 December 2012 and the benefit risk profile has remained favorable.

Healthcare professionals should note, however, some differences in the product labelling between FluLaval Tetra and Influsplit Tetra (see Tables 3 and 4 below) and can refer to the FluLaval Tetra Product Monograph available in English at <https://ca.gsk.com/en-ca/products/flulaval-tetra/> and French at <https://ca.gsk.com/fr-ca/produits/flulaval-tetra/> for additional information. Of particular note is that the PFS format is not the standard presentation for GSK's influenza vaccine in Canada. Both FluLaval Tetra (Canadian Labelled MDV) and Influsplit Tetra (German Labelled PFS) are indicated for active immunization in persons 6 months of age and older for the prevention of disease caused by influenza virus types A and B contained in the vaccine, and are administered by intramuscular (IM) injection. FluLaval Tetra and Influsplit Tetra contain the same strains for the 2020-2021 influenza season.

Influsplit Tetra is manufactured with a different process at a different facility than FluLaval Tetra. The medicinal ingredients are the same and both vaccines are prepared in eggs. Influsplit Tetra and FluLaval Tetra contain some of the same clinically relevant nonmedicinal ingredients, except for the **additional component of octoxynol-10 (TRITON X-100), as well as gentamicin sulfate and magnesium chloride hexahydrate in Influsplit Tetra**. A list of components can be found

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below in Table 1. Also, Influsplit Tetra (German Labelled PFS) does not contain preservative (thimerosal) as it is a PFS. Additionally, the tip cap and plunger stopper of the pre-filled syringe for Influsplit Tetra does not contain any latex from natural origin. Please refer to Table 2 below for contraindications and to the English translation of the German Package Insert of Influsplit Tetra and the Canadian Product Monograph of FluLaval Tetra for more information on warnings & precautions.

Table 1 Comparison of Composition for FluLaval Tetra and Influsplit Tetra Drug Product

Ingredients	FluLaval Tetra	Influsplit Tetra
Active Substances		
Monovalent Split-virion Drug Substance, A/H1N1	✓	✓
Monovalent Split-virion Drug Substance, A/H3N2	✓	✓
Monovalent Split-virion Drug Substance, B (Victoria lineage)	✓	✓
Monovalent Split-virion Drug Substance, B (Yamagata lineage)	✓	✓
Excipients		
Phosphate Buffered Saline, composed of:		
Sodium Chloride	✓	✓
Potassium Chloride	✓	✓
Disodium Hydrogen Phosphate Heptahydrate	✓	N/Ap
Disodium Phosphate Dodecahydrate	N/Ap	✓
Potassium Dihydrogen Phosphate	✓	✓
Magnesium chloride hexahydrate	N/Ap	✓
Water for Injection	✓	✓
Polysorbate-80 (Tween-80)	✓	✓
α-tocopheryl hydrogen succinate (Vitamin E Succinate)	✓	✓
Octoxinol 10 (Triton® X-100)	N/Ap	✓
Thimerosal	✓	N/Ap
Residuals		
Formaldehyde	✓	✓
Sodium deoxycholate	✓	✓
Ovalbumin	✓	✓
Gentamicin sulphate	N/Ap	✓

N/Ap: Not Applicable

Both vaccines may also contain the following further residuals from the manufacturing process: ethanol and sucrose.

Table 2 Comparison of Contraindications for FluLaval Tetra and Influsplit Tetra

FluLaval Tetra	Influsplit Tetra
<ul style="list-style-type: none"> FluLaval Tetra should not be administered to subjects with known hypersensitivity to egg proteins or after previous administration of any influenza vaccine produced in eggs or to any component of the vaccine. 	<ul style="list-style-type: none"> Hypersensitivity to the active substances, to any of the excipients or to other excipients in trace levels from egg (ovalbumin, chicken protein), formaldehyde, gentamicin sulfate, and sodium deoxycholate. In case of febrile diseases and acute infections, the vaccination should be postponed until a later date.

Recommendations for influenza vaccination can be found in the Canadian Immunization Guide Chapter on Influenza and Statement on Seasonal Influenza Vaccine for 2020–2021 from the National Advisory Committee on Immunization.

(<https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/canadian-immunization-guide-statement-seasonal-influenza-vaccine-2020-2021.html>)

Audience

The information in this letter is being provided to healthcare professionals who will be receiving supplies of German labelled Influsplit Tetra influenza vaccine for the Canadian market.

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Table 3 Differences in Product Labelling: Container Label

Container Label			
Section of the Label	FluLaval Tetra MDV Canadian Label	Influsplit Tetra PFS German Label	Influsplit Tetra PFS German Label - Translation
Name of the Product	FluLaval Tetra	Influsplit Tetra	
Product Code	DIN 02420783	Not provided	
Manufacturer/Distributor	GlaxoSmithKline	Not provided	
Composition	15 mcg HA/ Strain (2020-2021)	Saison 2020/2021	<i>Season 2020/2021</i>
Dose	5 mL (10 doses) 0.5 ml dose	0.5mL	
Route of Administration	Intramuscular (IM)	i.m.	
Storage	Store between 2°C and 8°C	Im Kühlschrank lagern!	<i>Store in the refrigerator!</i>
Language	Bilingual (English, French)	German	
Lot and Expiry	Printed on the label	Printed on the label	
Other	Shake well. Discard the vial 28 days following first use. Prepared in eggs.	Wirtssystem: embryonierte Hühnereier	<i>Host system: embryonic chicken eggs</i>

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Table 4 Differences in Product Labelling: Carton Label

Carton			
Section of the Label	FluLaval Tetra Canadian Carton	Influsplit Tetra PFS German Carton	Influsplit Tetra PFS German Carton - Translation
Name of the Product	FluLaval Tetra (2020-2021) Influenza vaccine quadrivalent Inactivated, split-virion	Influsplit Tetra Saison 2020/2021 Influenza-Spaltimpfstoff (inaktiviert)	<i>Influsplit Tetra Saison 2020/2021 Split Influenza vaccine (inactivated)</i>
Indication	Not provided	Suspension zur Injektion (intramuskulär) bei Kindern ab 6 Monaten und Erwachsenen Fertigspritze (ohne Kanüle)	<i>Suspension for injection (intramuscular) in children from 6 months and adult pre-filled syringe (without needle)</i>
Manufacturer	ID Biomedical Corporation of Quebec	GlaxoSmithKline GmbH & Co. KG 80700 München	
Distributor	GlaxoSmithKline Inc.	Not provided	
Product Code	DIN 02420783	PEI.H.11629.01.1	
Dose	Single dose: 0.5 mL	0,5 ml	
Format	5 mL vial (10 doses)	10 x 1 Impfdosis (je 0,5 ml)	<i>10 x 1 dose (of 0,5 ml)</i>
Description and Instructions	Each 0.5 mL dose contains 15 mcg HA from each of the following influenza strains: A/Guangdong-Maonan/SWL1536/2019 (H1N1) pdm09-like virus, A/Hong Kong/2671/2019 (H3N2)-like virus, B/Washington/02/2019-like virus, B/Phuket/3073/2013-like virus and 50 mcg thimerosal as a preservative. Shake well. Discard the vial 28 days following first use. Directions for use: See packaged insert.	Zusammensetzung: 1 Impfdosis (0,5 ml) enthält: Influenza Virus (inaktiviert, Spaltantigene) der folgenden Stämme*: A/Guangdong-Maonan/SWL1536/2019 (H1N1)pdm09 – ähnlicher Stamm 15 µg HA** A/Hong Kong/2671/2019 (H3N2) – ähnlicher Stamm 15 µg HA** B/Washington/02/2019 – ähnlicher Stamm 15 µg HA** B/Phuket/3073/2013 – ähnlicher Stamm 15 µg HA** Natriumchlorid, Natriummonohydrogenophosphat x 12H ₂ O, Polysorbat 80 (Tween 80), Octoxinol 10 (Triton X-100), Kaliumdihydrogenphosphat, RRR-α-Tocopherolhydrogensuccinat, Kaliumchlorid, Magnesiumchlorid x 6H ₂ O, Wasser für Injektionszwecke *Wirtssystem: embryonierte Hühnereier **Hämagglutinin Packungsbeilage beachten! Verschreibungspflichtig! Vor Gebrauch schütteln!	Composition: 1 dose (0,5 ml) contains: Influenza Virus (inactivated, split antigen) of the following strains: A/Guangdong-Maonan/SWL1536/2019 (H1N1)pdm09 – like strain 15 µg HA** A/Hong Kong/2671/2019 (H3N2) – like strain 15 µg HA** B/Washington/02/2019 – like strain 15 µg HA** B/Phuket/3073/2013 – like strain 15 µg HA** Sodium chloride, Sodium monohydrogen phosphate dodecahydrate, Polysorbate-80 (Tween-80), Octoxinol 10 (Triton X-100), Potassium Dihydrogen Phosphate, α-tocopheryl hydrogen succinate, Potassium Chloride, Magnesium chloride hexahydrate, Water for Injection * Host system: embryonic chicken eggs **Haemagglutinin <i>Observe the package leaflet! Prescription! Shake before use!</i>
Storage	Store between 2°C and 8°C. Do not freeze.	Arzneimittel für Kinder unzugänglich aufbewahren! Vor Licht und Einfrieren schützen! Im Kühlschrank lagern!	Store medicines inaccessible to children! Protect from light and freezing! Store in the refrigerator!
Language	Bilingual (English, French)	German	
Lot and Expiry	Printed on the carton	Printed on the carton	

Images of FluLaval Tetra Canadian and Influsplit Tetra German container labels are provided below.

Figure 1 FluLaval Tetra Canadian Vial Label

5 mL (10 doses)

DIN 02420783
GSK

FluLaval TETRA (2020-2021)

Influenza vaccine quadrivalent

Vaccin antigrippal quadrivalent

Composition / 0.5 mL Dose: 15 mcg HA / Strain (Souche)

I.M. Single Dose: 0.5 mL. Store between 2°C and 8°C. **Shake well.**

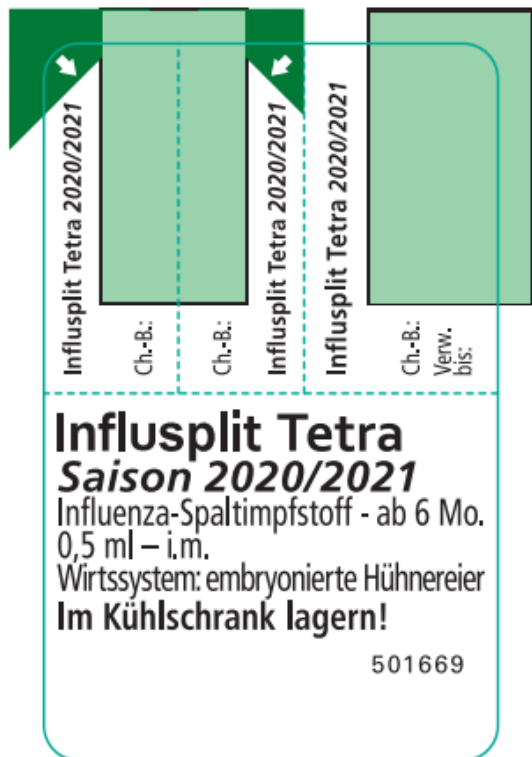
Discard the vial 28 days following first use. Prepared in eggs.

I.M. Dose unique : 0,5 mL. Conserver entre 2°C et 8°C. **Bien agiter.**

Jeter le flacon 28 jours après le premier usage. Préparé dans des œufs.

LOT/EXP:

Figure 2 Influsplit Tetra Pre-Filled Syringe Label



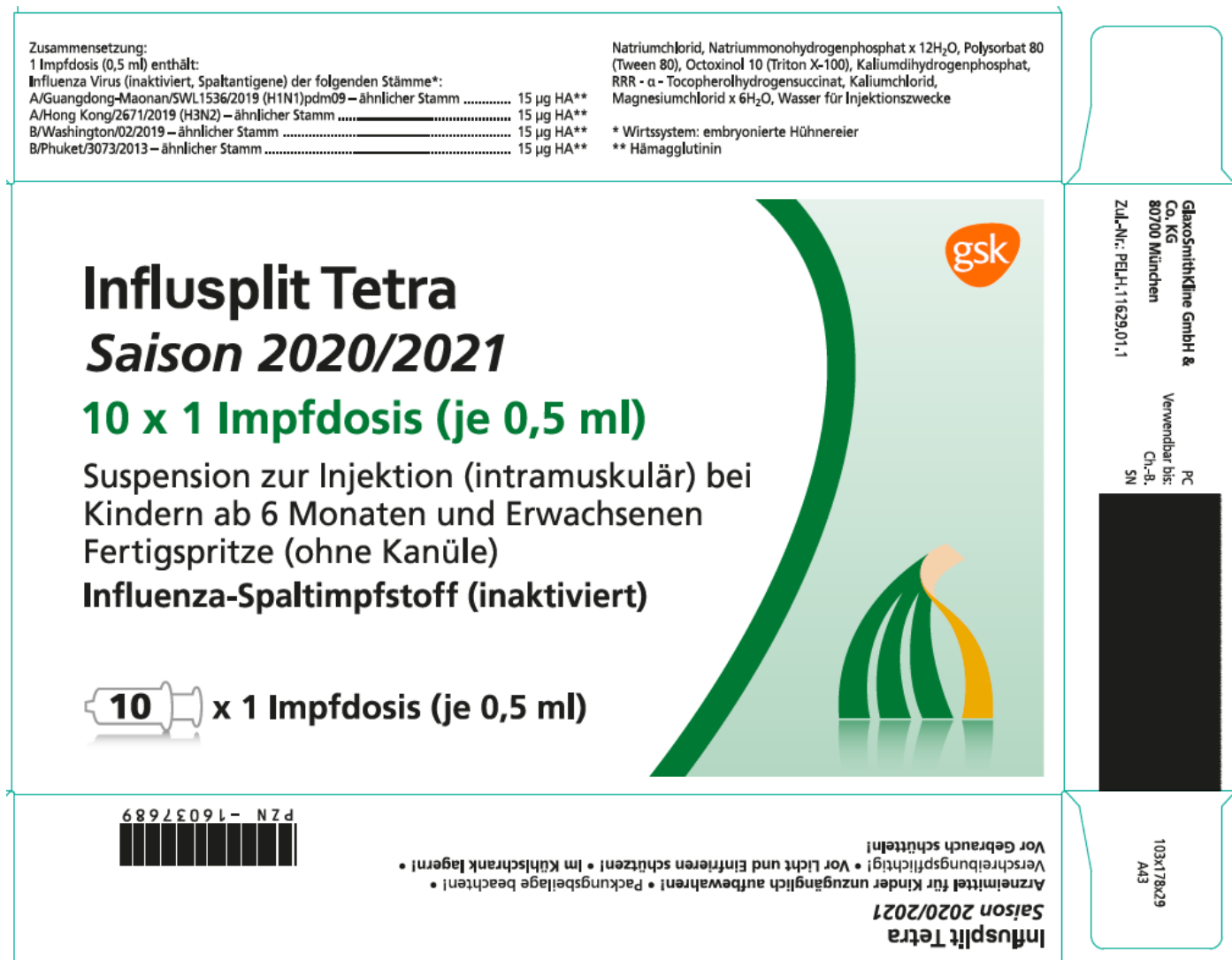
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Images of FluLaval Tetra MDV Canadian and Influsplit Tetra PFS German cartons are provided below.

Figure 3 FluLaval Tetra MDV Canadian Carton: Front and Back Panels



Figure 4 Influsplit Tetra PFS Carton



Report health or safety concerns

Managing marketed health product-related side effects depends on healthcare professionals and consumers reporting them. Adverse events following immunization in patients receiving FluLaval Tetra and Influsplit **Tetra** should be reported as per below. General questions can be directed to GSK and to your local Public Health unit in your province or territory.

GlaxoSmithKline Inc.

7333 Mississauga Road
Mississauga, Ontario
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Tel: 1-800-387-7374

For health care professionals:

If a patient experiences a side effect following immunization, please complete the Adverse Events Following Immunization (AEFI) Form appropriate for your province/territory (<https://www.canada.ca/en/public-health/services/immunization/federal-provincial-territorial-contact-information-ae-fi-related-questions.html>) and send it to your local Health Unit.

For the General Public:

Should you experience an adverse event following immunization, please report it to your doctor, nurse, or pharmacist.

Should you require information related to the management of the adverse event, please contact your healthcare provider. The Public Health Agency of Canada, Health Canada and GlaxoSmithKline Inc. cannot provide medical advice.

Please feel free to contact GSK Customer Service Centre at 1-800-387-7374 or cacsu@gsk.com if you have any questions or concerns.

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