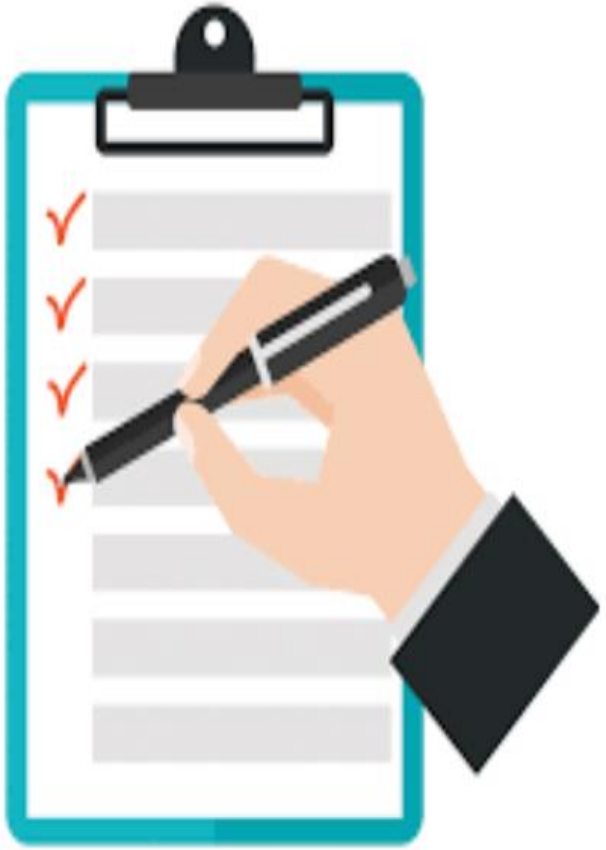
LTC/RH CoP (Huddle)
March 19, 2024

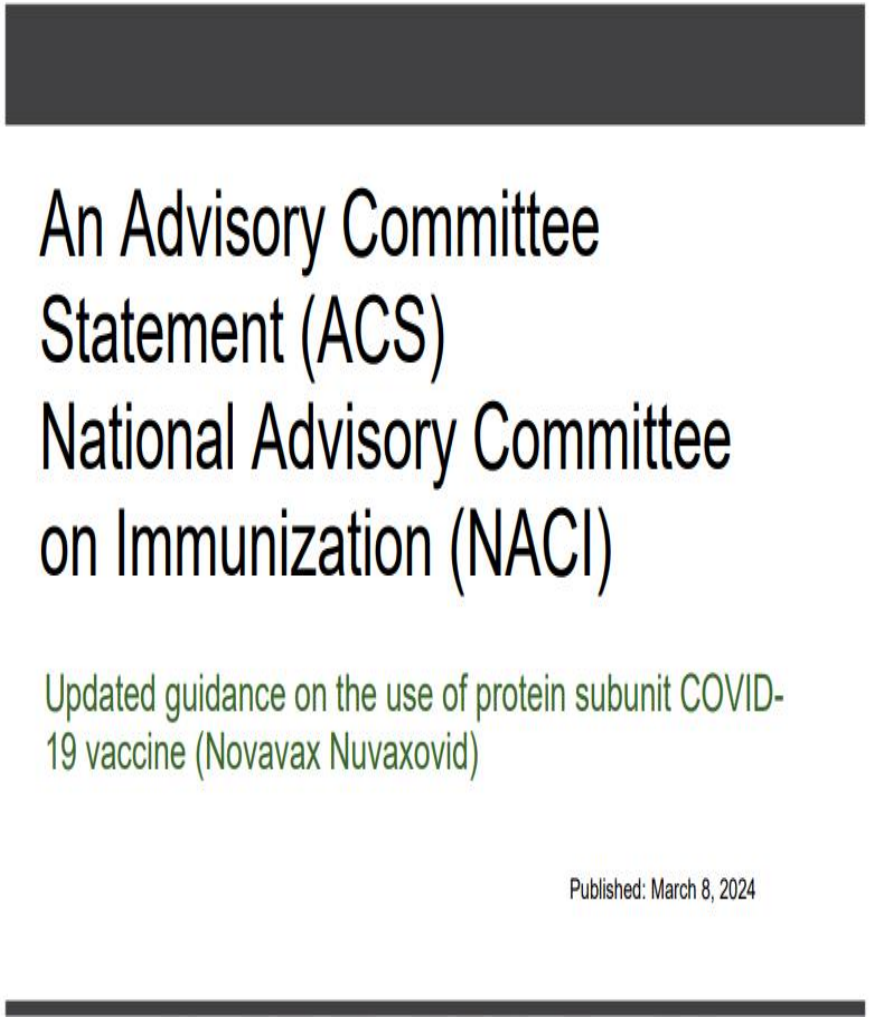
Agenda

1. NACI: Updated guidance on the use of protein subunit COVID-19 vaccine (Novavax Nuvaxovid



Background

- On March 8, 2024, NACI published an updated guidance on the protein subunit COVID-19 vaccine, Novavax Nuvaxovid.
- Health Canada granted authorization for the use of the Novavax Nuvaxovid XBB.1.5 vaccine on December 5, 2023.
- This authorization extends to individuals aged 12 years and older.
- For those previously vaccinated against COVID-19, a single dose is recommended, while individuals who have not been vaccinated against COVID-19 should receive a 2-dose series of the vaccine.



Background

Preference for Most Recent Vaccine

- NACI recommends that individuals eligible for COVID-19 vaccination should receive the most recently updated vaccine.

- As of now, this is the XBB.1.5 COVID-19 vaccine.

Options for Vaccine Type

- Individuals without contraindications to the vaccine can receive either:
- An mRNA vaccine:
  - Moderna Spikevax XBB.1.5
  - Pfizer-BioNTech Comirnaty XBB.1.5 OR

- A protein subunit vaccine:
  - Novavax Nuvaxovid XBB.1.5

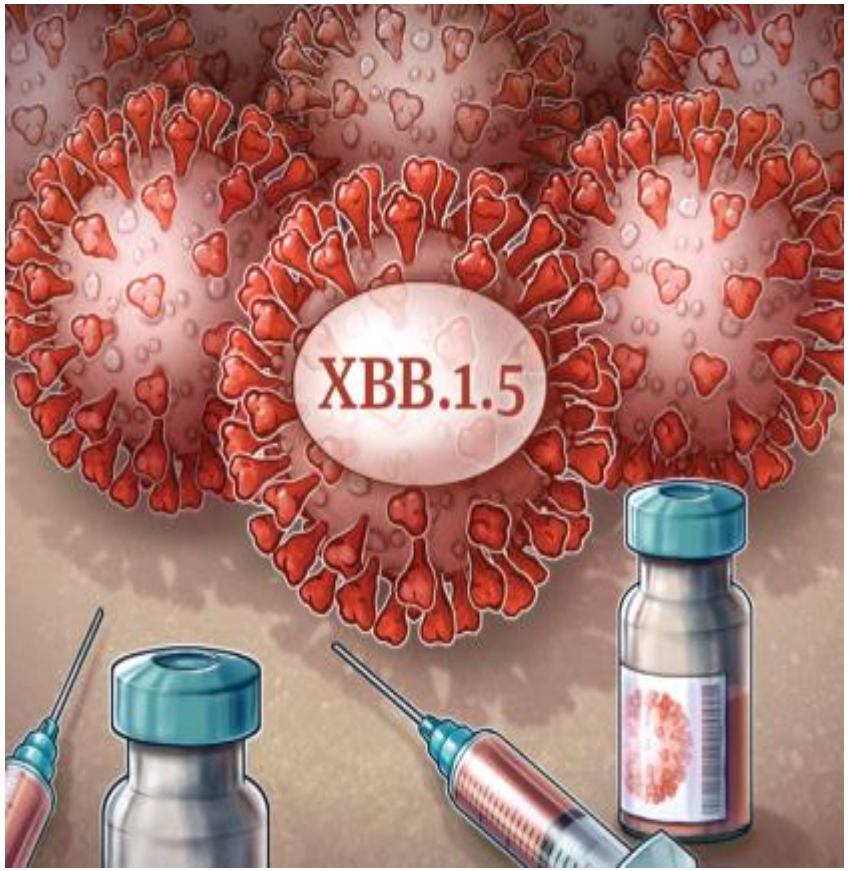
Regardless of their vaccination status

Overview of Evidence

- Omicron sublineages of COVID-19 continue to circulate globally and in Canada.

- There is high infection-acquired seroprevalence in the Canadian population, with older individuals having higher levels of immunity derived from vaccination alone.

- The original Novavax Nuvaxovid vaccine has been shown to work well with a good safety profile since its authorization in Canada in March 2022.



Overview of Evidence

- At the time of authorization of the mRNA XBB.1.5 vaccines, no clinical data were available for Novavax Nuvaxovid XBB.1.5.

- While mRNA COVID-19 vaccines have been more widely used, the existing clinical evidence on Novavax Nuvaxovid has shown a good safety profile and efficacy against COVID-19.

Overview of Evidence

- Individuals vaccinated with updated XBB.1.5-containing COVID-19 vaccines are expected to have a better immune response against currently circulating strains compared to earlier formulations, based on clinical data.

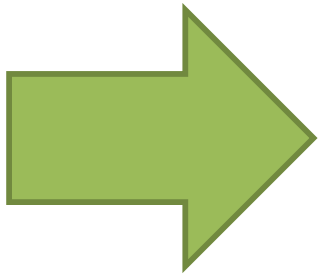
- With Novavax Nuvaxovid targeting XBB.1.5, both mRNA and protein subunit COVID-19 vaccines now target the same strain, reducing the need for product preference for mRNA vaccines.

NACI Recommendations

NACI recommends the following for the use of COVID-19 vaccines:

1. Individuals in the authorized age group for COVID-19 vaccination **receive the most recently updated COVID-19 vaccine.**

- STRONG NACI RECOMMENDATION



- Either mRNA or protein subunit COVID-19 vaccines can be used in unvaccinated or previously vaccinated individuals without contraindications.
- **mRNA** COVID-19 XBB.1.5 vaccines are authorized for individuals aged **6 months and older.**
- **Novavax Nuvaxovid** XBB.1.5 is authorized for those aged **12 years and older.**

NACI Recommendations

For unvaccinated individuals 12 years of age and over receiving Novavax Nuvaxovid XBB.1.5, NACI provides the following schedule advice:

1. Although the authorized schedule entails two doses, NACI suggests that **unvaccinated individuals** who are **not immunocompromised** and opt for Novavax Nuvaxovid XBB.1.5 may consider following **a 1-dose schedule.**

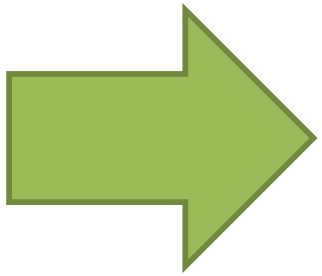
- DISCRETIONARY NACI RECOMMENDATION

NACI Recommendations

NACI recommends the following for the use of COVID-19 vaccines:

2. Unvaccinated individuals who are **moderately to severely immunocompromised** and receiving Novavax Nuvaxovid XBB.1.5 should receive a minimum of **2 doses.**

- STRONG NACI RECOMMENDATION



- Individuals with immunocompromising conditions face elevated risks of **prolonged infection and severe complications from COVID-19.**

- Additional doses in the primary series are recommended for this population to **increase immune response and vaccine effectiveness.**

Considerations on the use of Novavax Nuvaxovid XBB.1.5

Expanded Vaccine Options

- The use of either an mRNA or protein subunit COVID-19 vaccine is a change from the previous guidance, for Novavax Nuvaxovid to be for individuals unable or unwilling to receive an mRNA vaccine.
- This update broadens vaccine choices for individuals aged 12 and above, whether previously vaccinated or unvaccinated.

Dosing Interval Recommendations

- Receiving a two-dose series of Novavax Nuvaxovid XBB.1.5, NACI suggests an interval of 8 weeks for those not moderately to severely immunocompromised.
- For moderately to severely immunocompromised individuals, an interval of 4 to 8 weeks between doses in any primary series.

Considerations on the use of Novavax Nuvaxovid XBB.1.5

Single-Dose Consideration

- Although authorized as a two-dose regimen, NACI recommends considering Novavax Nuvaxovid XBB.1.5 as a single dose for individuals not moderately to severely immunocompromised.
- This aligns with European authorization and is consistent with authorized schedules and recommendations for mRNA vaccines in Canada.

Consistency with mRNA Vaccines

- Similar to mRNA COVID-19 XBB.1.5 vaccines, a single dose of Novavax Nuvaxovid XBB.1.5 is recommended for individuals with a prior vaccination series.

Compatibility with Other Vaccines

- Novavax Nuvaxovid may be administered concurrently with non-COVID-19 vaccines or at any time before or after them, including both live and non-live vaccines.

MOH: Co-Administration

- Individuals can receive a COVID-19 vaccine simultaneously with non-COVID-19 vaccines, or at any time before or after them.
- If vaccines are co-administered, it is advisable to immunize on separate limbs.
- Exceptions:
  - COVID-19 vaccines should not be co-administered with the Imvamune vaccine for Mpox and the Arexvy vaccine for Respiratory Syncytial Virus (RSV).
  - For Imvamune vaccine, a waiting period of at least 4 weeks is recommended before or after administration.
  - For Arexvy vaccine, a waiting period of at least 2 weeks is recommended before or after administration.

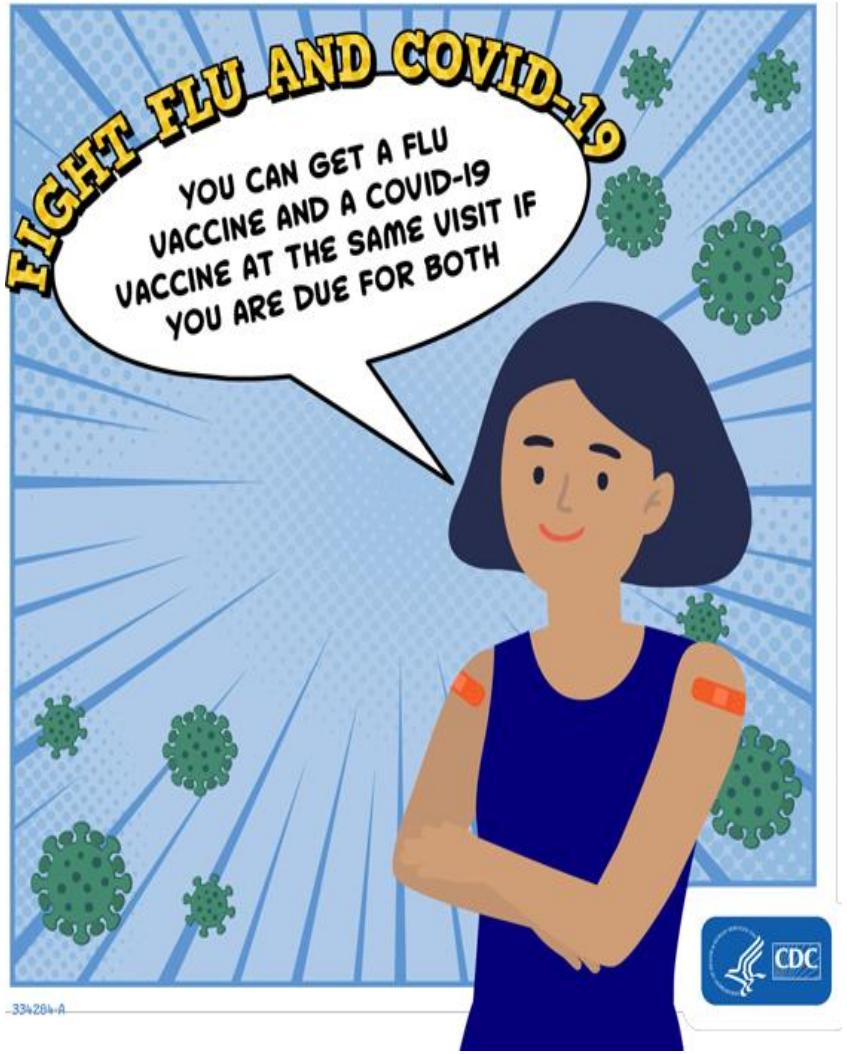


Table 1. Covid-19 Vaccine Platform Comparison

	Protein subunit COVID-19 vaccine	mRNA COVID-19 vaccines
XBB.1.5 vaccine product	Novavax Nuvaxovid XBB.1.5	• Moderna Spikevax XBB.1.5 • Pfizer-BioNTech Comirnaty Omicron XBB.1.5
Authorized age group	Authorized for those 12 years of age and over.	Authorized for those 6 months of age and over.
XBB.1.5 vaccine schedule for unvaccinated individuals	1 dose schedule[a] may be used for those who are not immunocompromised as per NACI recommendation. At least 2 doses are recommended for those who are moderately to severely immunocompromised[b].	1 dose schedule for those 5 years of age and over who are not immunocompromised[c]. At least 2 doses are recommended for those who are moderately to severely immunocompromised[b].
XBB.1.5 vaccine schedule for previously vaccinated individuals	1 dose[b]	1 dose[b,c]
Immunogenicity[d]	XBB.1.5 product induces a good immune booster response against XBB-related strains in mice and macaques, with a lower but still boosted response against	XBB.1.5 products induce a good immune booster response in humans against XBB-related strains, with a

	BA.2.86 in mice (no data were available for JN.1[e]) [7]. No data were available in humans for the XBB.1.5 product[e].	lower but still boosted response against JN.1 [11, 12].

Table 1. Covid-19 Vaccine Platform Comparison

Efficacy/effectiveness[d]	Good vaccine efficacy for original product. No efficacy or effectiveness data yet available for XBB.1.5 product.	Short-term vaccine effectiveness (VE) of XBB.1.5 vaccine approximately 50 to 60% against symptomatic disease and 60 to 70% against hospitalization [13-16].
Safety[d]	Novavax Nuvaxovid original has been shown to have a good safety profile, with over 1 million doses administered to date, globally [8-10]. Novavax Nuvaxovid original has been associated with rare cases of myocarditis and/or pericarditis based on the original vaccine. No data are currently available regarding the XBB.1.5 product.	mRNA COVID-19 vaccines have been shown to have a good safety profile, with over 100 million doses administered to date in Canada alone [17]. mRNA COVID-19 vaccines have been associated with rare cases of myocarditis and/or pericarditis, particularly in adolescents and young adult males, especially after the second dose in the primary series using the original vaccine and less so after a booster using the original vaccine or bivalent vaccine. No data are currently available regarding the XBB.1.5 product.
Use in specific populations (e.g., immunocompromised, pregnant people)	Less data available regarding use in these populations than with mRNA vaccines.	More data available regarding use in these populations than with protein subunit vaccines.

MOH: Table 1: Moderna or Pfizer XBB mRNA COVID-19 Vaccine Schedule Based on Immunization History and Immune Status

A. For those NOT moderately to severely immunocompromised

Age	Immunization History[1]	Recommended Number of XBB Doses and Interval[2] Between Doses	
		Moderna XBB Schedule[3]	Pfizer XBB Schedule[3]
6 months – 4 years	3 or more doses	N/A	**1 dose** • Recommended: ***168 days*** from last dose • Minimum: 84 days from last dose[4]
	2 doses	**1 dose** • Recommended: ***168 days*** from last dose • Minimum: 84 days from last dose[4]	**1 dose** • Recommended: ***56 days*** from last dose • Minimum: o 28 days from last dose (if 2nd dose was Moderna) o 56 days from last dose (if 2nd dose was Pfizer)
	1 dose	**1 dose** • Recommended: ***56 days*** from last dose • Minimum: 28 days from last dose	**2 doses** • Recommended: ***56 days*** from last dose and between doses • Minimum: o 28 days from last dose (if 1st dose was Moderna) and between doses o If 1st dose was Pfizer: ▪ 21 days between dose 1 & 2 ▪ 56 days between dose 2 & 3
	0 doses	**2 doses** • Recommended: ***56 days*** between doses • Minimum: 28 days between doses	**3 doses** • Recommended: ***56 days*** between doses • Minimum: o 21 days between dose 1 & 2 o 56 days between dose 2 & 3

MOH: Table 1: Moderna or Pfizer XBB mRNA COVID-19 Vaccine Schedule Based on Immunization History and Immune Status

Age	Immunization History[1]	Recommended Number of XBB Doses and Interval[2] Between Doses	
		Moderna XBB Schedule[3]	Pfizer XBB Schedule[3]
5 years +	2 or more doses	**1 dose** • Recommended: ***168 days*** from last dose • Minimum: 84 days from last dose[4]	
	1 dose	**1 dose** • Recommended: ***56 days*** from last dose • Minimum: o 28 days from last dose (if 1st dose was Moderna) o 21 days from last dose (if 1st dose was Pfizer)	
	0 doses	**1 dose**	

MOH: Table 1: Moderna or Pfizer XBB mRNA COVID-19 Vaccine Schedule Based on Immunization History and Immune Status

B. For those moderately to severely immunocompromised

Age	Immunization History[5]	Recommended Number of XBB Doses and Interval[6] Between Doses	
		Moderna XBB[7]	Pfizer XBB[7]
6 months – 4 years	4 or more doses	N/A	**1 dose** • Recommended: ***168 days*** from last dose • Minimum: 84 days from last dose[8]
	3 doses	**1 dose** • Recommended: ***168 days*** from last dose • Minimum: 84 days from last dose[8]	**1 dose** • Recommended: ***56 days*** from last dose • Minimum: o 28 days from last dose (if 3rd dose was Moderna) o 56 days from last dose (if 3rd dose was Pfizer)
	2 doses	**1 dose** • Recommended: ***56 days*** from last dose • Minimum: 28 days from last dose *Moderna preferred*[9]	**2 doses** • Recommended: ***56 days*** from last dose and between doses • Minimum: o 28 days from last dose (if 2nd dose was Moderna) o If 2nd dose was Pfizer ▪ 56 days between dose 2 & 3 ▪ 56 days between dose 3 & 4
	1 dose	**2 doses** • Recommended: ***56 days*** from last dose and between doses • Minimum: 28 days from last dose and between doses *Moderna preferred*[9]	**3 doses** Recommended: ***56 days*** from last dose and between doses Minimum: o 28 days from last dose (if 1st dose was Moderna) o If 1st dose was Pfizer ▪ 21 days between dose 1 & 2 ▪ 56 days between dose 2 & 3 ▪ 56 days between dose 3 & 4

MOH: Table 1: Moderna or Pfizer XBB mRNA COVID-19 Vaccine Schedule Based on Immunization History and Immune Status

Age	Immunization History[5]	Recommended Number of XBB Doses and Interval[6] Between Doses	
		Moderna XBB[7]	Pfizer XBB[7]
6 months – 4 years	0 doses	**3 doses** • Recommended: ***56 days*** between doses • Minimum: 28 days between doses *Moderna preferred*[9]	**4 doses** • Recommended: ***56 days*** between doses • Minimum: o 21 days between dose 1 & 2 o 56 days between dose 2 & 3 o 56 days between dose 3 & 4
5 years +	3 or more doses	**1 dose** • Recommended: ***168 days*** from last dose • Minimum: 84 days from last dose[8]	
	2 doses	**1 dose** • Recommended: ***56 days*** from last dose • Minimum: o 28 days from last dose (if 2nd dose was Moderna) o 21 days from last dose (if 2nd dose was Pfizer)	
	1 dose	**2 doses** • Recommended: ***56 days*** from last dose and between doses • Minimum: o Moderna: 28 days from last dose (if 1st dose was Moderna) and between doses o Pfizer: 21 days from last dose (if 1st dose was Pfizer) and between doses	
	0 doses	**2 doses** Recommended: ***56 days*** between doses Minimum: o Moderna: 28 days between doses o Pfizer: 21 days between doses	

MOH: Table 2: Novavax XBB Vaccine Schedule Based on Immunization History and Immune Status

A. For those NOT moderately to severely immunocompromised

Age	Immunization History[10]	Recommended Number of XBB Doses and Interval Between Doses
12 yrs +	2 or more doses	**1 dose** • Recommended: ***168 days*** from last dose • Minimum: 84 days from last dose[11]
	1 dose	**1 dose** • Recommended: ***56 days*** from last dose • 21 days from last dose
	0 doses	**2 doses** • Recommended: ***56 days*** between doses • 21 days between doses

MOH: Table 2: Novavax XBB Vaccine Schedule Based on Immunization History and Immune Status

B. For those moderately to severely immunocompromised

Age	Immunization History[10]	Recommended Number of XBB Doses and Interval Between Doses
12 yrs +	3 or more doses	**1 dose** • Recommended: ***168 days*** from last dose • Minimum: 84 days from last dose[11]
	2 doses	**1 dose** • Recommended: ***56 days*** from last dose • 21 days from last dose
	1 dose	**2 doses** • Recommended: ***56 days*** from last dose and between doses • 21 days from last dose and between doses
	0 doses	**3 doses** • Recommended: ***56 days*** between doses • 21 days between doses

Q&A

Humber River Health
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1235 Wilson Avenue
Toronto, Ontario
M3M 0B2
416.242.1000

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