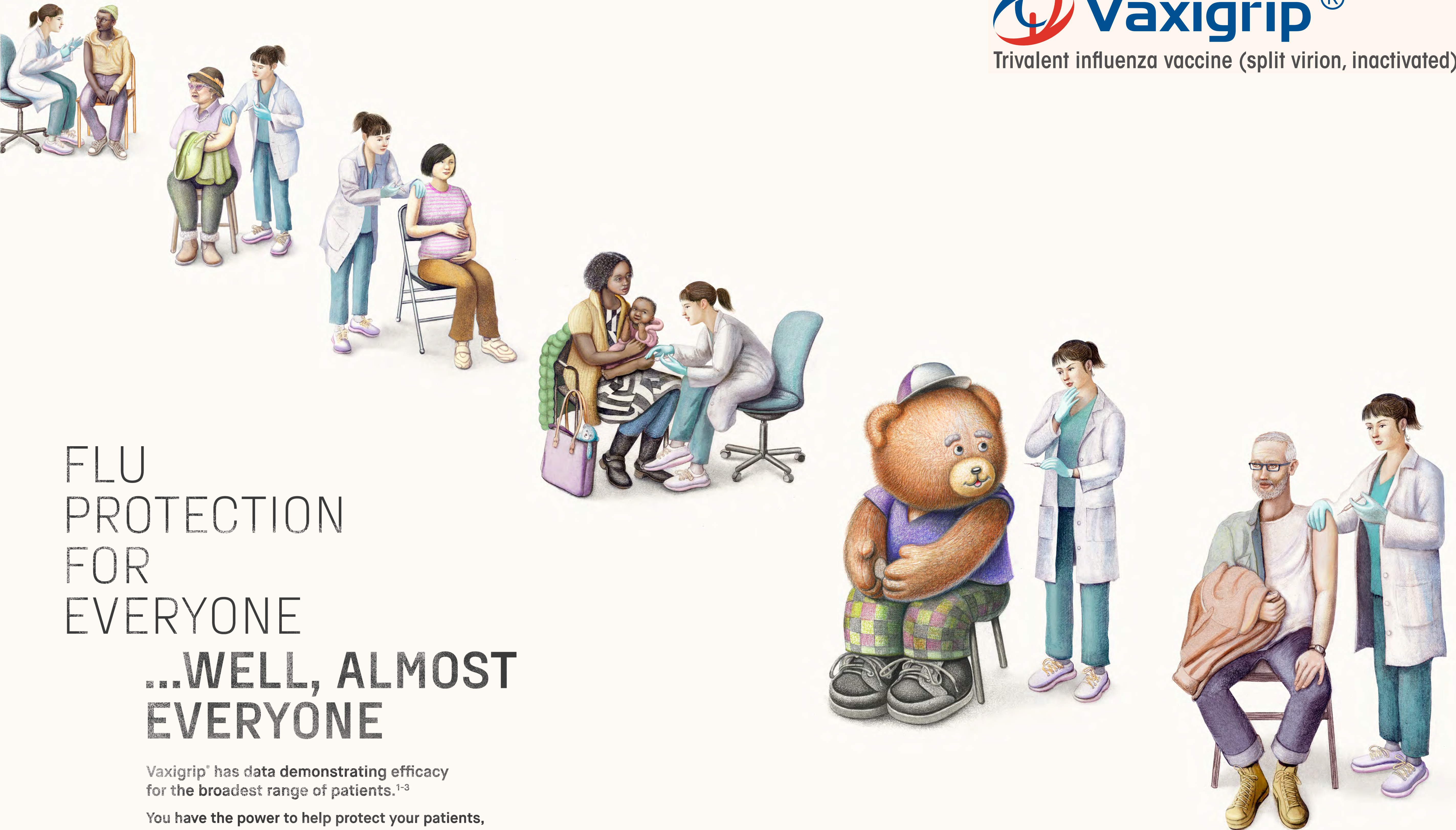




FLU
PROTECTION
FOR
EVERYONE
...WELL, ALMOST
EVERYONE

Vaxigrip® has data demonstrating efficacy
for the broadest range of patients.¹⁻³

You have the power to help protect your patients,
aged 6 months and up, against flu with Vaxigrip®.¹

View References

Before administration, please see full SmPC for Vaxigrip® at [here](#).

sanofi



References

1. Vaxigrip® Summary of Product Characteristics 2025.
2. Fröbert O, Götberg M, Erlinge D, et al. Influenza vaccination after myocardial infarction: a randomized, double-blind, placebo-controlled, multicenter trial. *Circulation*. 2021;144(18):1476-1484. doi:10.1161/CIRCULATIONAHA.121.057042
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FLU
PRO
FOR
EVE

Flu can wreak havoc across major organ systems¹⁻⁴

INFLUENZA

Burden

Patients at Risk

Protection
Beyond Flu

VAXIGRIP®

Proven Efficacy

Immunogenicity

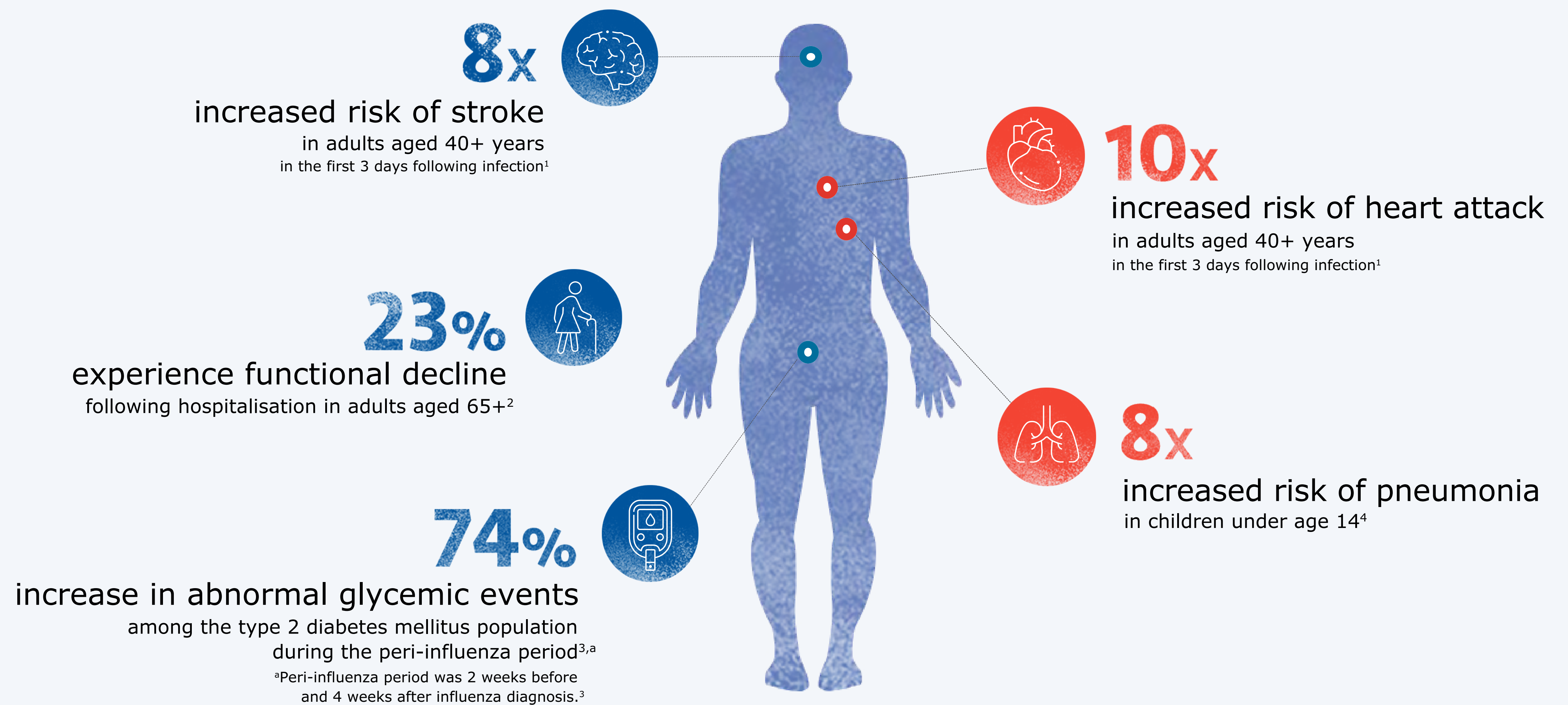
Safety Profile

Convenience

SUMMARY

SmPC >

Flu can have a devastating impact on the body, with complications including heart attack and pneumonia¹⁻⁴



You have the power to help protect your patients,
aged 6 months and up, against flu with Vaxigrip®⁵

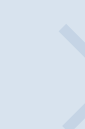


View References



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2. Andrew MK, MacDonald S, Godin J, et al. Persistent functional decline following hospitalization with influenza or acute respiratory illness. *J Am Geriatr Soc*. 2021;69:696-703.
3. Samson SI, Konty K, Lee W-N, et al. Quantifying the impact of influenza among persons with type 2 diabetes mellitus: a new approach to determine medical and physical activity impact. *J Diabetes Sci Technol*. 2021;15(1):44-52. doi:10.1177/1932296819883340
4. Kubale J, Kuan G, Gresh L, et al. Individual-level association of influenza infection with subsequent pneumonia: a case-control and prospective cohort study. *Clin Infect Dis*. 2021;73(11):e4288-e4295. doi:10.1093/cid/ciaa1053
5. Vaxigrip® Summary of Product Characteristics 2025.



Influenza can pose a real threat to patients you see daily

INFLUENZA

Burden

Patients at Risk

Protection
Beyond Flu

VAXIGRIP®

Proven Efficacy

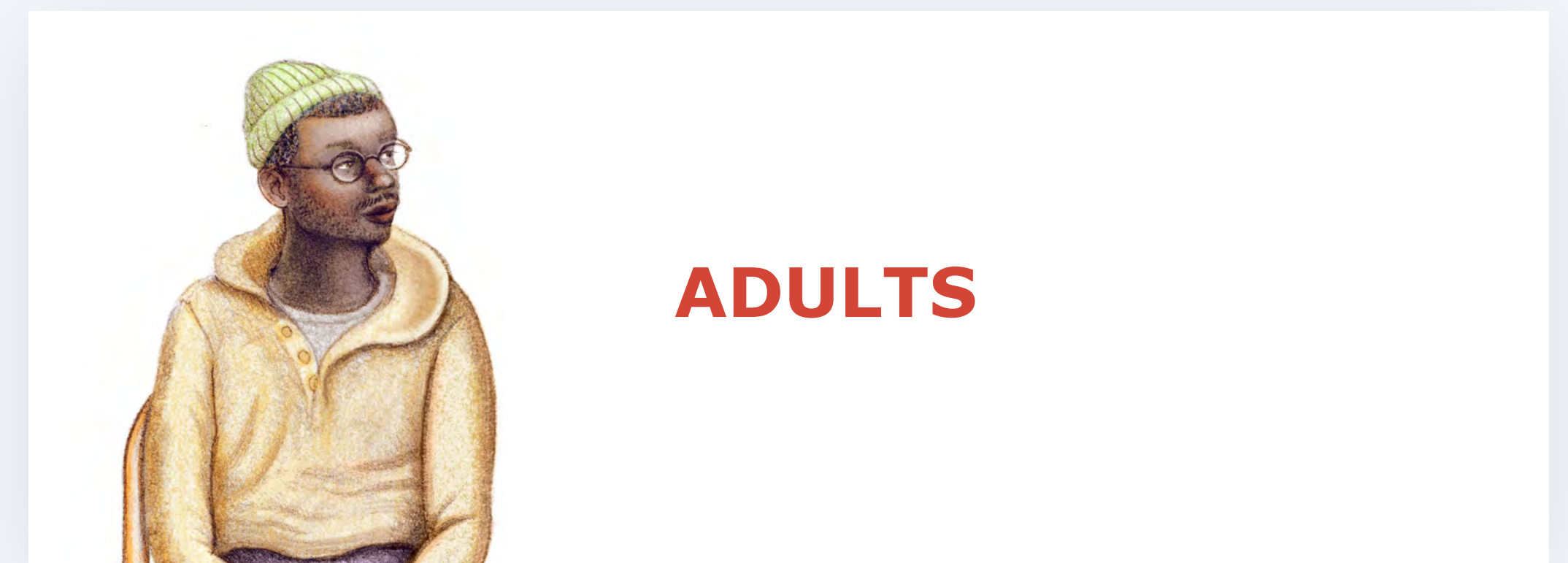
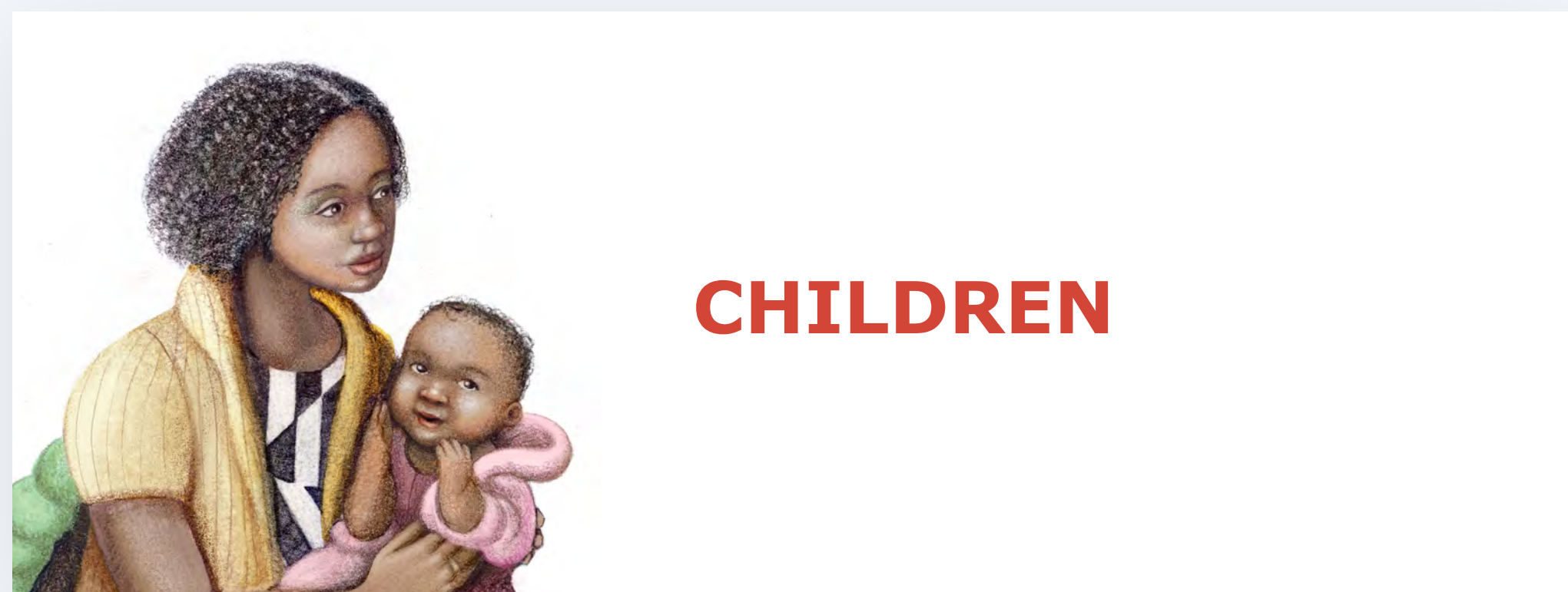
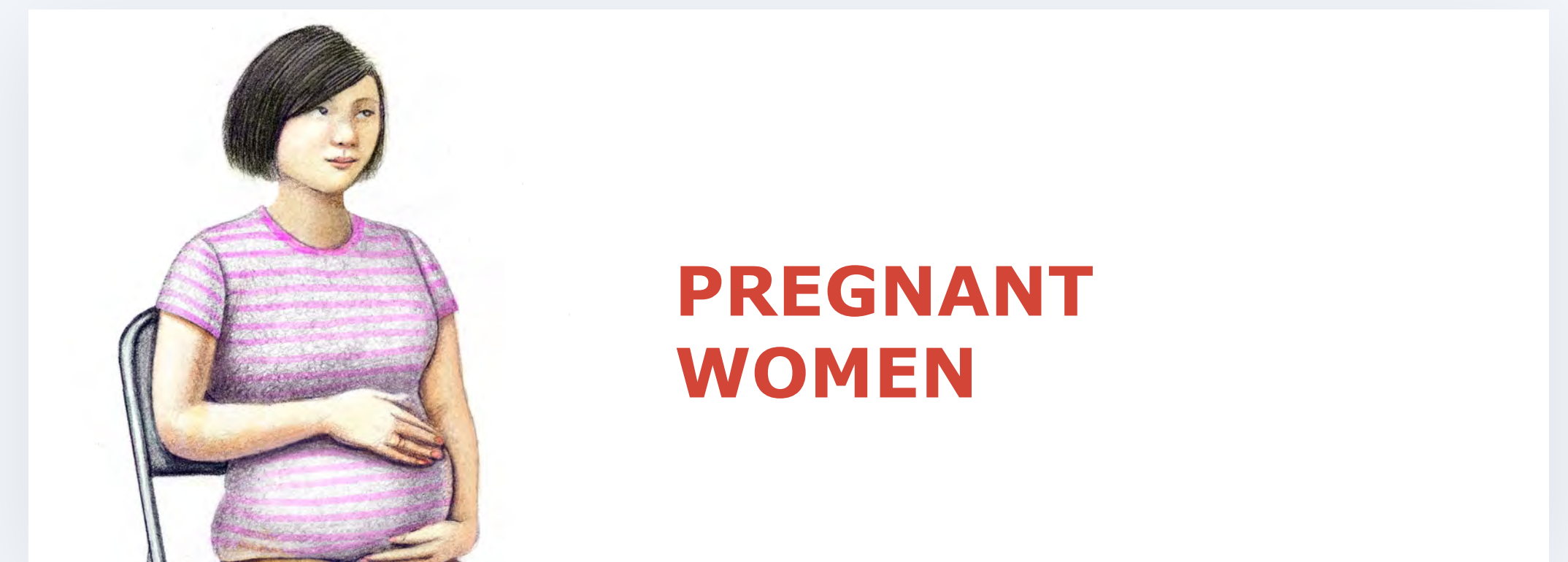
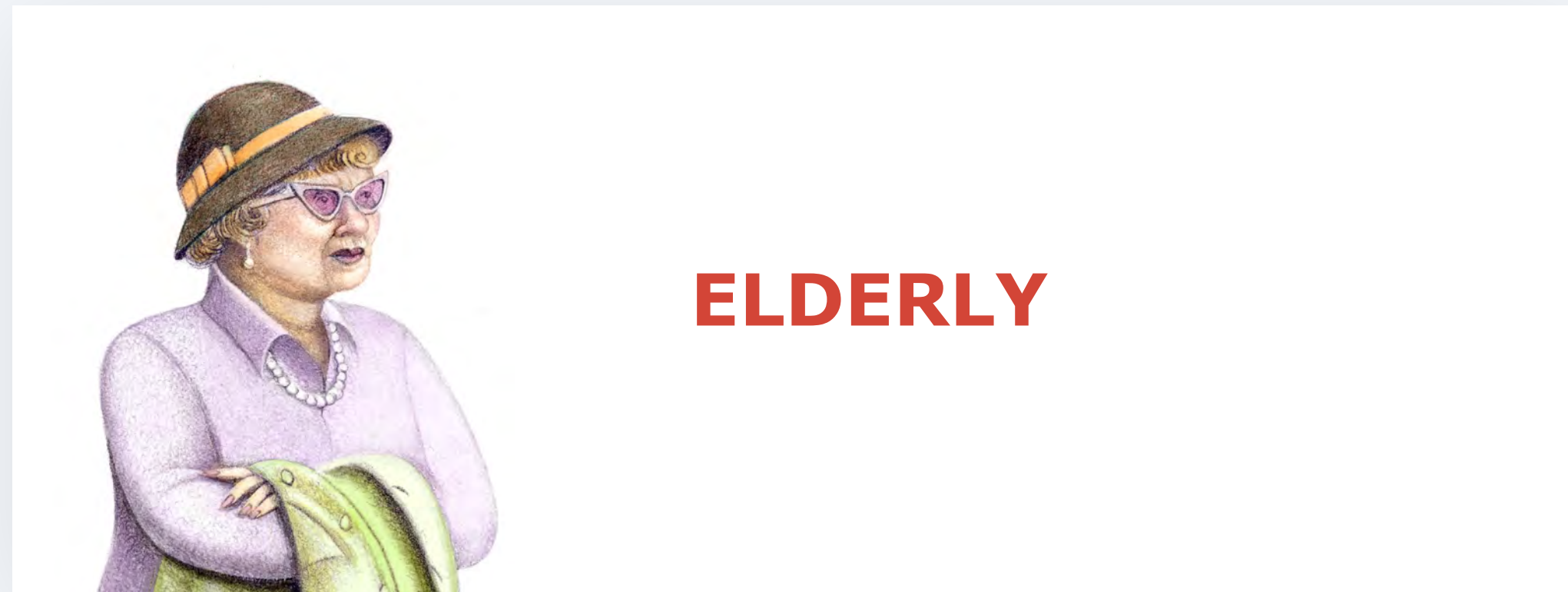
Immunogenicity

Safety Profile

Convenience

SUMMARY

[SmPC >](#)

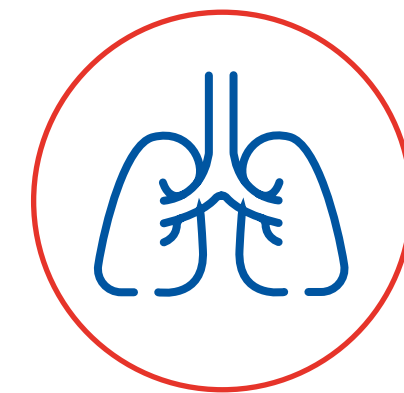


Tap to see the risks for each type of patient



Patients aged 65+ can be at greater risk of severe complications¹⁻³

ELDERLY



Up to **1 in 3** older adults hospitalised with influenza **develop pneumonia**¹



Older adults remain at **higher risk for stroke** for up to **2 months** after an influenza infection²



After flu-related hospitalisation, **23%** of older adults experience a **functional decline** in daily activities^{3,a}

^aFunction was assessed using the Barthel index and was assessed pre-admission (retrospectively) to reflect function 2 weeks before the onset of current illness, on admission, and 30 days post-discharge.³

**You have the power to help protect your patients,
aged 6 months and up, against flu with Vaxigrip®⁴**



View References



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2. Warren-Gash C, Blackburn R, Whitaker H, McMenamin J, Hayward AC. Laboratory-confirmed respiratory infections as triggers for acute myocardial infarction and stroke: a self-controlled case series analysis of national linked datasets from Scotland. *Eur Respir J*. 2018;51(3):1701794. doi:10.1183/13993003.01794-2017
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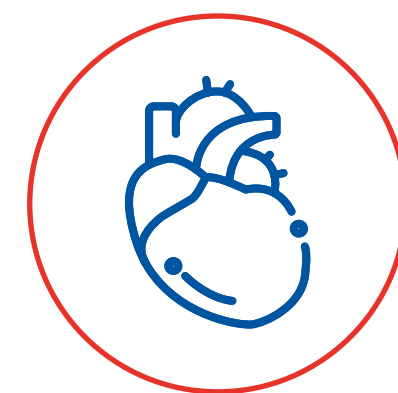


Even patients who do not have a pre-existing heart condition are susceptible to post-flu heart complications^{1,2}

PATIENTS WITH CARDIOVASCULAR DISEASE



In a study of the correlation between influenza and cardiovascular events, within 1 week of influenza infection, adults were¹:



10x more likely to have a **heart attack** after a flu infection¹

In subjects at least 40 years of age or older (n=1227)¹



8x more likely to have a **stroke** after a flu infection¹

In subjects at least 40 years of age or older (n=762)¹

The risk for severe cardiovascular complications increases dramatically in the days following influenza infection for these patients^{1,2}

**You have the power to help protect your patients,
aged 6 months and up, against flu with Vaxigrip®³**



View References

References

1. Warren-Gash C, Blackburn R, Whitaker H, McMenamin J, Hayward AC. Laboratory-confirmed respiratory infections as triggers for acute myocardial infarction and stroke: a self-controlled case series analysis of national linked datasets from Scotland. *Eur Respir J*. 2018;51(3):1701794. doi:10.1183/13993003.01794-2017
2. Kwong JC, Schwartz KL, Campitelli MA, et al. Acute myocardial infarction after laboratory-confirmed influenza infection. *N Engl J Med*. 2018;378(4):345-353. doi:10.1056/NEJMoa1702090
3. Vaxigrip® Summary of Product Characteristics 2025.



Diabetes can put your patients at greater risk of influenza complications¹⁻³

PATIENTS WITH DIABETES

In a study evaluating the existence of an increased risk of influenza complications among patients with diabetes in Montreal, patients with diabetes were¹:



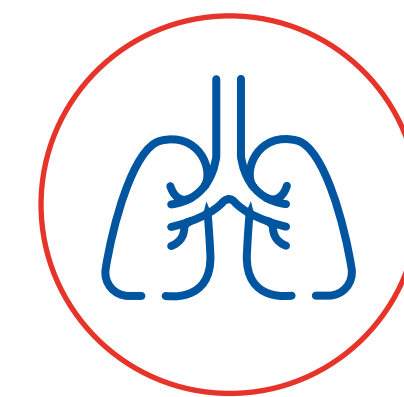
3x more likely to be **hospitalised** during influenza pandemics¹

(N=162; 95% CI=2.04 to 4.71)

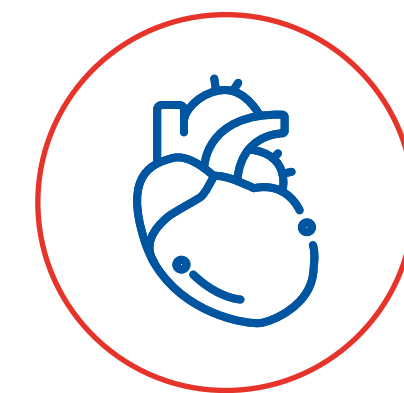
4x more likely to be **admitted to the ICU** once hospitalised¹

(N=162; 95% CI=1.38 to 13.8)

In a retrospective cohort analysis of a United States health plan, patients with type 2 diabetes mellitus during influenza infection were^{4,a}:



7x more likely to develop **pneumonia** when getting influenza⁴ (95% CI: 3.5 to 15.3)



8x more likely to develop **ischemic heart disease** after influenza infection compared to people without diabetes⁴

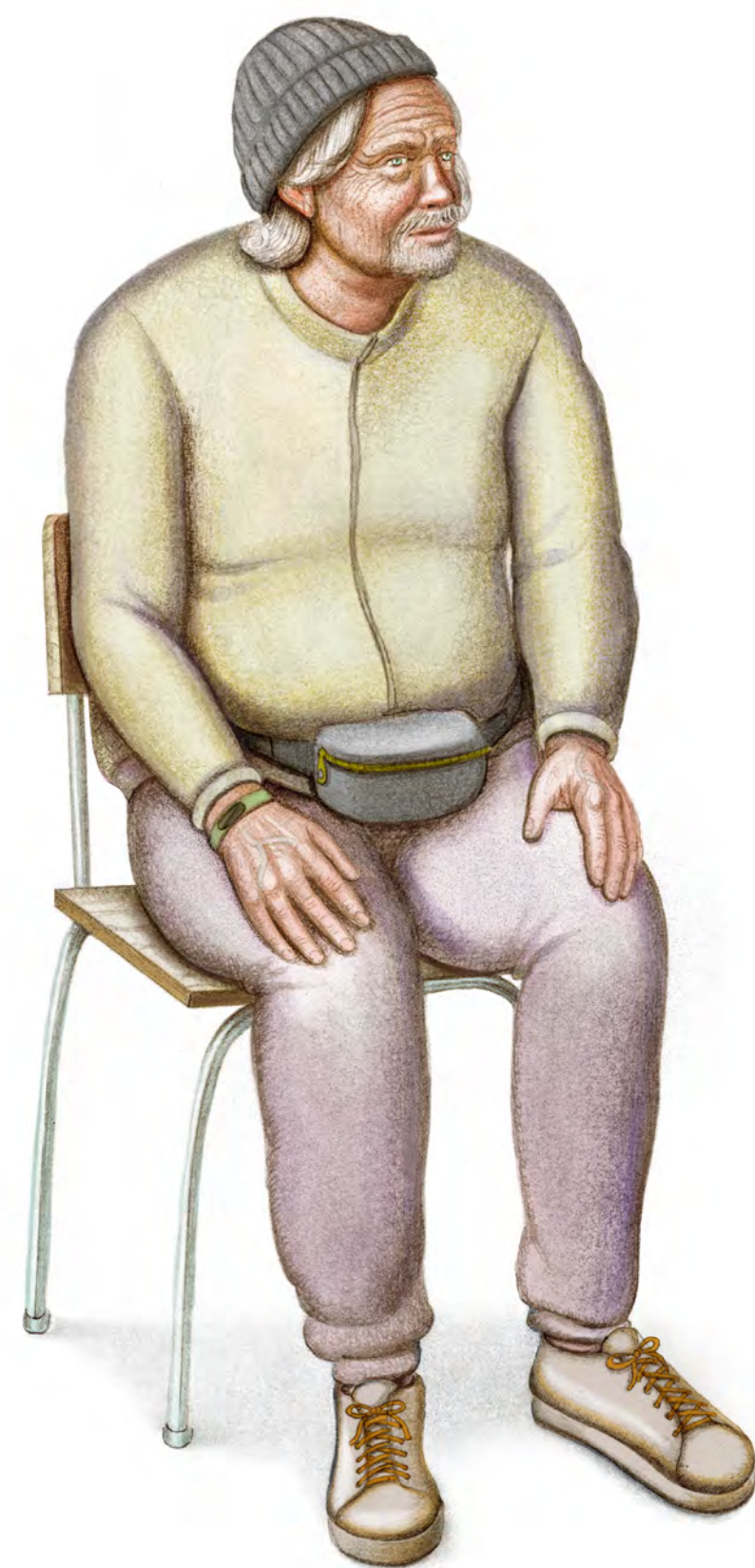
(95% CI: 1.05 to 2.36)



74% more likely to experience **abnormal glycemic events** post-influenza⁴

(95% CI: 2.15 to 3.74, $P<0.05$)

^aPeri-influenza period was 2 weeks before and 4 weeks after influenza diagnosis.⁴



CI=confidence interval.

You have the power to help protect your patients, aged 6 months and up, against flu with Vaxigrip^{®5}



View References



References

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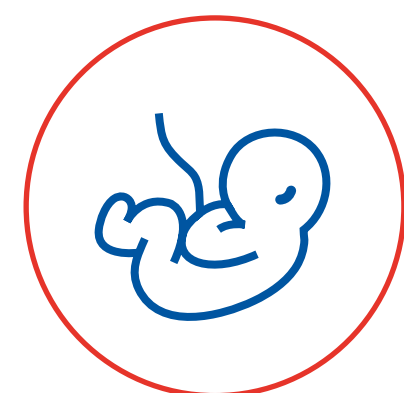
Pregnant women and their developing babies are at increased risk for serious consequences of influenza infection¹⁻³

PREGNANT WOMEN



According to the World Health Organization, with the A(H1N1)pdm09 strain from the 2009 influenza pandemic pregnant women in New York City were³:

- **7x** more likely to be **hospitalised**³



In a systematic review of 21 global studies published between <2000 and 2010⁴:

- Up to **4x** higher risk of **fetal death**⁴
- Up to **4x** higher risk of **preterm birth**⁴

In 168 pregnancy outcomes during the 2009 influenza pandemic in the United States⁵:

- **44%** of babies born during their mothers' hospitalisations for influenza had low birth weights⁵

You have the power to help protect your patients,
aged 6 months and up, against flu with Vaxigrip®⁶



[View References](#)



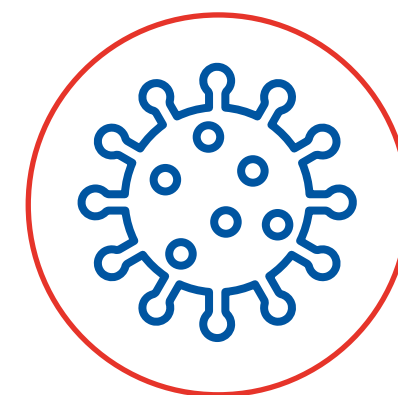
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6. Vaxigrip® Summary of Product Characteristics 2025.



Children can contribute to community spread due to high attack rates and because they shed the influenza virus longer than adults. They are also at risk of complications¹⁻³

CHILDREN



Influenza has an annual **attack rate** estimated at **20% to 30%** in children compared to **5% to 10%** in adults globally¹



High hospitalisation rates among pre-school-aged children are comparable to rates of hospitalisation among people 50 to 64 years of age¹

You have the power to help protect your patients, aged 6 months and up, against flu with Vaxigrip®⁴



[View References](#)

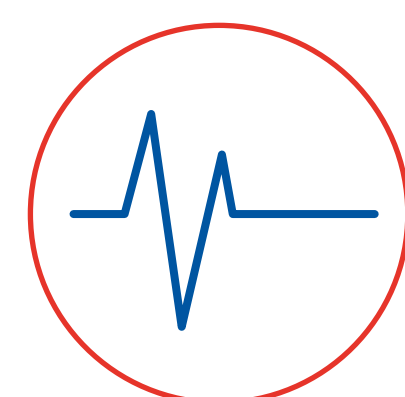
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3. Ng S, Lopez R, Kuan G, et al. The timeline of influenza virus shedding in children and adults in a household transmission study of influenza in Managua, Nicaragua. *Pediatr Infect Dis J*. 2016;35(5):583-586. doi:10.1097/INF.0000000000001083
4. Vaxigrip® Summary of Product Characteristics 2025.

Of the estimated 1 billion people affected by influenza every season, adults experience an estimated attack rate of 5% to 10%^{1,2}



ADULTS



During the 2019-2020 flu season in the United States,

39% of all **flu-related deaths** occurred among adults aged 18 to 64, a group for which influenza vaccine coverage is often low³



The 2019 to 2020 rates of flu-related **hospitalisation** for adults aged 18 to 49 were the highest seasonal rates seen since the 2017 to 2018 season³

You have the power to help protect your patients, aged 6 months and up, against flu with Vaxigrip®⁴



[View References](#)



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2. Weekly epidemiological record. World Health Organization. 23 November 2012. Accessed 5 July 2022. <https://apps.who.int/iris/bitstream/handle/10665/241925/WER8723.PDF?sequence=1&isAllowed=y>
3. Estimated flu-related illnesses, medical visits, hospitalizations, and deaths in the United States — 2019–2020 flu season. Centers for Disease Control and Prevention. 1 October 2021. Accessed 5 July 2022. <https://www.cdc.gov/flu/about/burden/2019-2020.html>
4. Vaxigrip® Summary of Product Characteristics 2025.

Sanofi is committed to demonstrating protection beyond flu for its flu vaccines^a

INFLUENZA

Burden

Patients at Risk

**Protection
Beyond Flu**

VAXIGRIP®

Proven Efficacy

Immunogenicity

Safety Profile

Convenience

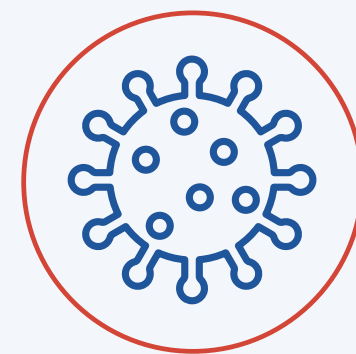
SUMMARY

SmPC >

Consider more support for your influenza vaccines than just immunogenicity trials

Protection Beyond Flu^a

OUTCOMES¹⁻⁴



INFECTION DATA

on lab-confirmed
flu cases

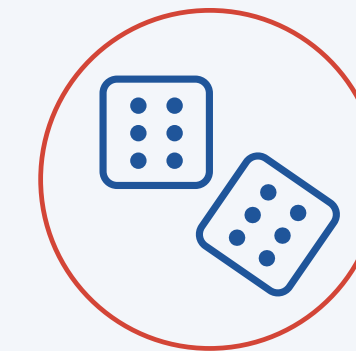


HOSPITALISATION ENDPOINTS

to prove impact on
severe complications

Immunogenicity data^{5,6}

METHODOLOGY¹⁻⁴



RANDOMISED STUDIES

in clinical
and real-world
settings



STANDARD OF CARE^b

as the
comparator



CONSISTENT RESULTS

across multiple
seasons and
study designs

^aBeyond influenza and its complications.

^bStandard of care is defined as standard-dose influenza vaccines.





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6. U.S. Department of Health and Human Services. Guidance for industry. Clinical data needed to support the licensure of seasonal inactivated influenza vaccines. Updated May 2007. Accessed 18 July, 2022. <https://www.fda.gov/files/vaccines%2C%20blood%20%26%20biologics/published/Guidance-for-Industry--Clinical-Data-Needed-to-Support-the-Licensure-of-Seasonal-Inactivated-Influenza-Vaccines.pdf>
7. Vaxigrip® Summary of Product Characteristics 2025.

INFLUENZA

Burden

Patients at Risk

Protection
Beyond Flu

VAXIGRIP®

Proven Efficacy

Immunogenicity

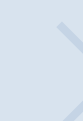
Safety Profile

Convenience

SUMMARY

SmPC

SmPC >



INFLUENZA

Burden

Patients at Risk

Protection
Beyond Flu

VAXIGRIP®

Proven Efficacy

Immunogenicity

Safety Profile

Convenience

SUMMARY

SmPC >

IN ADULTS WITH CARDIOVASCULAR DISEASE

Vaxigrip® is the only standard-dose influenza vaccine with statistically significant data from an RCT demonstrating protection against cardiovascular disease outcomes across geographies and seasons¹



Primary and secondary endpoints evaluating Vaxigrip® vs placebo at 12 months post-randomisation¹

Composite of all-cause death, myocardial infarction, or stent thrombosis



28% reduction¹

(HR=0.72; 95% CI: 0.52-0.99, P=0.040)¹

All-cause death



41% reduction¹

(HR=0.59; 95% CI: 0.39-0.89, P=0.010)¹

Cardiovascular death



41% reduction¹

(HR=0.59; 95% CI: 0.39-0.90, P=0.014)¹

Injection-site reactions were more frequent with Vaxigrip®. No differences between groups in self-reported systemic reactions or investigator-reported adverse events and serious adverse events¹

■ Primary Endpoint
■ Secondary Endpoint^a

STUDY DESIGN

INFLUENZA VACCINES VS PLACEBO

RCT=randomised controlled trial.

^aAdditional endpoints included myocardial infarction (HR=0.86; 95% CI=0.50-1.46; P=0.57) and stent thrombosis (HR=1.94; 95% CI=0.48-7.76; P=0.34).¹

View References



Study design¹

IAMI trial was a prospective, double-blind, randomised, controlled trial conducted in 8 countries for influenza seasons. These countries included Sweden, Denmark, Norway, Latvia, the UK, the Czech Republic, Bangladesh, and Australia.

Between October 1, 2016 and March 1, 2020, more than 2500 adults (the minimum age of eligibility was 18 years and the mean age was 60.1 [+/- 11.0]) were hospitalised with acute myocardial infarction (MI) or, in fewer than 1% of cases, high-risk stable coronary heart disease. Half were assigned to receive the year's standard influenza vaccine and the other half a saline placebo within 72 hours of admission or a revascularization procedure.

IAMI=influenza vaccination after myocardial infarction.

RCT=randomised controlled trial.

Additional endpoints included myocardial infarction (HR=0.86; 95% CI=0.50-1.46; *P*=0.57) and stent thrombosis (HR=1.94; 95% CI=0.48-7.76; *P*=0.34).¹

[View References](#)



Reference

1. Fröbert O, Götberg M, Erlinge D, et al. Influenza vaccination after myocardial infarction: a randomized, double-blind, placebo-controlled, multicenter trial. *Circulation*. 2021;144(18):1476-1484. doi:10.1161/CIRCULATIONAHA.121.057042

RCT=randomised controlled trial.

Additional endpoints included myocardial infarction (HR=0.86; 95% CI=0.50-1.46; *P*=0.57) and stent thrombosis (HR=1.94; 95% CI=0.48-7.76; *P*=0.34).¹

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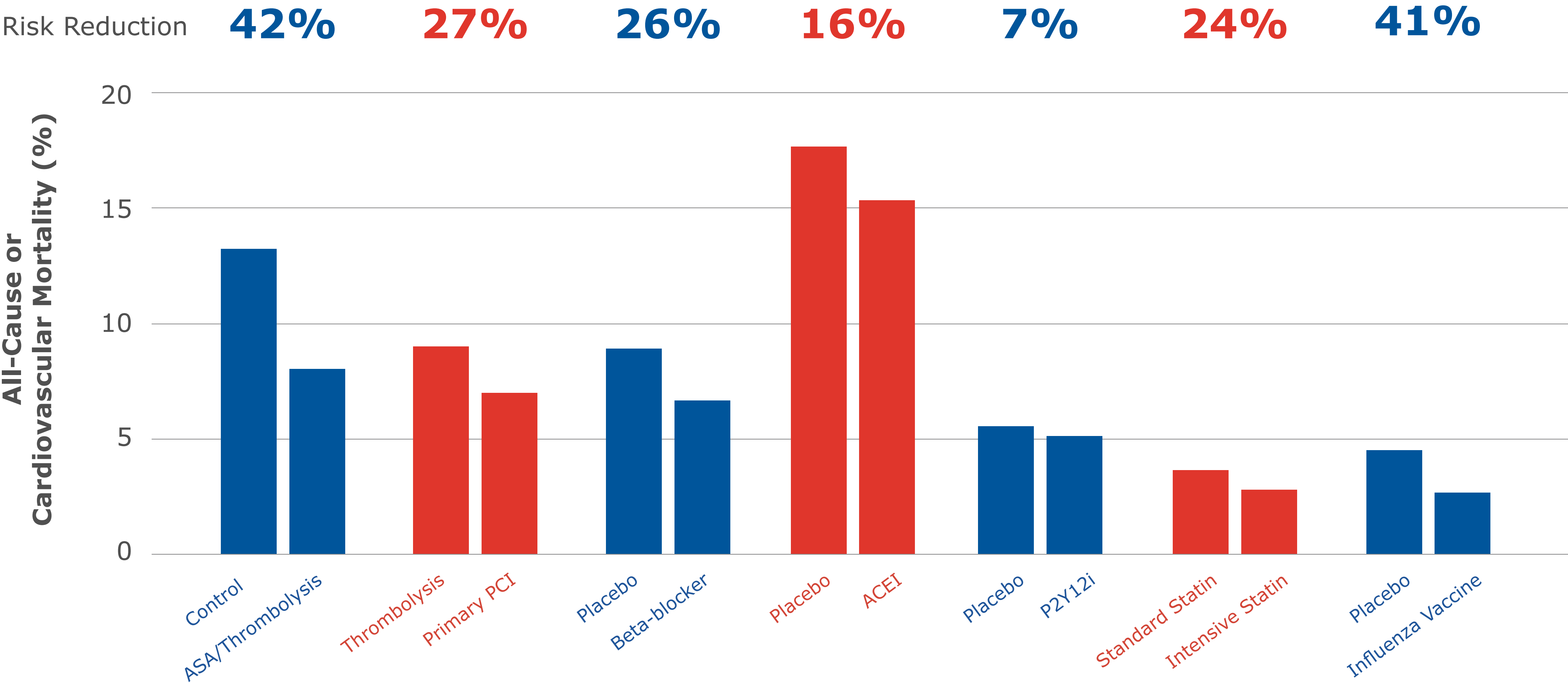


Studies suggest that influenza vaccination after myocardial infarction benefits patients similarly to other standard therapies in preventing all-cause and cardiovascular mortality¹

Influenza vaccination is well tolerated and its domain shows similar performance as other commonly used preventative therapies in reduction of cardiovascular mortality¹



Cumulative impact of evidence-based medical therapies after myocardial infarction on all-cause or cardiovascular mortality^{1,a}



^aRelative risk reductions for different pharmacotherapies cannot be directly compared across studies given different study designs and background risk of study populations.¹
ACEI=angiotensin-converting enzyme inhibitor; ASA=aspirin; PCI=percutaneous coronary intervention.

[View References](#)

Reference

1. Michos ED, Udell JA. Am I getting the influenza shot too? Influenza vaccination as post-myocardial infarction care for the prevention of cardiovascular events and death. *Circulation*. 2021;144(18):1485-1488. doi: 10.1161/CIRCULATIONAHA.121.057534

Vaxigrip® has data demonstrating efficacy^a for the broadest range of patients¹⁻³

INFLUENZA

Burden

Patients at Risk

Protection
Beyond Flu

VAXIGRIP®

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SUMMARY

[SmPC >](#)



PREGNANT WOMEN AND THEIR INFANTS

The only influenza vaccine indicated for passive protection of infants up to 6 months of age following vaccination of pregnant women.¹



CHILDREN

Demonstrated efficacy and reduction of complications in children 6 to 35 months old.^{1,4}



Tap to see efficacy for each population



References

1. Vaxigrip® Summary of Product Characteristics 2025.
2. Fröbert O, Götberg M, Erlinge D, et al. Influenza vaccination after myocardial infarction: a randomized, double-blind, placebo-controlled, multicenter trial. *Circulation*. 2021;144(18):1476-1484. doi:10.1161/CIRCULATIONAHA.121.057042
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^aIn pregnant women, children and patients with cardiovascular disease.

^bIn elderly patients, adults, and patients with diabetes.

IN PREGNANT WOMEN AND THEIR INFANTS <6 MONTHS OLD

Vaxigrip® is the only influenza vaccine indicated for passive protection of infants up to 6 months of age following vaccination of pregnant women¹

- Offers proven protection of influenza¹
- Offers protection of infants until 6 months of age¹



Lab-confirmed influenza in
pregnant women with Vaxigrip®



50%
reduction²
(95% CI: 14.5-71.2)

STUDY DESIGN

Pooled results for maternal vaccination and lab-confirmed
influenza in **infants <6 months** with Vaxigrip®



35%
reduction³
(95% CI: 19-47)

STUDY DESIGN

Clinical studies evaluated Vaxigrip® to determine efficacy results.¹⁻³
CI=confidence interval.

[View References](#)

Study design²

Two double-blind, randomised, placebo-controlled trials of trivalent inactivated influenza vaccine (IIV3) in South Africa.

One trial in 2011 included 194 pregnant women who were infected with HIV. In this trial, 100 were randomly assigned to the IIV3 group and 94 were assigned to the placebo group.

The second trial in 2012 included 2116 pregnant women who were not infected with HIV. In this trial, 1062 were randomly assigned to the IIV3 group and 1054 were assigned to the placebo group.

The immunogenicity, safety, and efficacy of IIV3 in these women and their infants were evaluated until 24 weeks after birth. Immune responses were measured with an HAI assay, and influenza was diagnosed by means of RT-PCR assays.

HAI=haemagglutination inhibition; RT-PCR=reverse transcription polymerase chain reaction.

Study design³

Pooled analysis of 3 randomised controlled trials:

- Nepal (2011-2013; N=3693), enrolling pregnant women at gestational age 17-34 weeks
- Mali (2011-2013; N=4193), enrolling pregnant women at or above gestation age 28 weeks
- South Africa (2011-2012; N=2116), enrolling pregnant women at gestation age 20-36 weeks

In each of the studies, women were randomly assigned 1:1 to receive trivalent inactivated influenza vaccine or saline placebo.

Outcomes analysed included overall vaccine efficacy of maternal influenza immunisation; duration of maternal and infant protection; effect of gestational age on vaccine efficacy; adverse birth outcomes (including low birth weight, stillbirth, preterm birth, and small for gestational age); and infant growth up to 6 months of age.



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Vaxigrip® helps protect children 6 to 35 months old from influenza¹

Demonstrated efficacy in 5400 young children against all
strains contained within the vaccine^{1,a}



Proven reduction against
lab-confirmed influenza^{1,b}

**Any A or
B strain**



52%
reduction¹

(95% CI: 40-62)

**Viral strains similar to
those in Vaxigrip®**



69%
reduction¹

(95% CI: 52-81)

Proven reduction against
lab-confirmed **severe** influenza^{1,b}

**Any A or
B strain**



57%
reduction¹

(95% CI: 37-71)

**Viral strains similar to
those in Vaxigrip®**



72%
reduction¹

(95% CI: 44-87)

CI=confidence interval.

^aTwo doses (0.5 mL) of Vaxigrip® (n=2722) or placebo (n=2717) 28 days apart.¹

^bPredefined complementary analysis. Randomised placebo controlled trial over four seasons.¹

EFFICACY AGAINST COMPLICATIONS

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Reference

1. Vaxigrip® Summary of Product Characteristics 2025.

Vaxigrip®
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IN CHILDREN 6 TO 35 MONTHS OLD

Vaxigrip® showed a reduction in flu-related complications¹

Relative risk in laboratory-confirmed influenza of Vaxigrip® vs placebo¹



Acute lower respiratory infection



78%
reduction¹

(RR=21.76%; 95% CI: 6.46-58.51)
Vaxigrip® (n=5); placebo (n=23)

Acute otitis media



69%
reduction¹

(RR=31.28%; 95% CI: 8.96-89.34)
Vaxigrip® (n=5); placebo (n=16)

Healthcare medical visits, including hospitalisations



59%
reduction¹

(RR=40.80%; 95% CI: 29.62-55.59)
Vaxigrip® (n=59); placebo (n=145)

Antibiotic use



61%
reduction¹

(RR=39.20%; 95% CI: 26.89-56.24)
Vaxigrip® (n=43); placebo (n=110)

STUDY DESIGN

CI=confidence interval; RR=relative risk.

[View References](#)

Study design^{1,2}

5436 healthy children aged 6 to 35 months were enrolled in a phase 3, randomised, multicentre, placebo-controlled trial to examine the vaccine efficacy of IIV4 in preventing laboratory-confirmed influenza in age subgroups and determine the relative risk for IIV4 vs placebo for severe outcomes, healthcare medical visits, and parental absenteeism from work associated with laboratory-confirmed influenza within 15 days after onset of the influenza-like illness. This study was conducted over 4 influenza seasons in the Northern and Southern Hemispheres from March 2014 to July 2016.

IIV4=quadrivalent split-virion inactivated influenza vaccine.

References

1. Pepin S, Samson SI, Alvarez FP. Impact of a quadrivalent inactivated influenza vaccine on influenza-associated complications and health care use in children aged 6 to 35 months: Analysis of data from a phase III trial in the Northern and Southern Hemispheres. *Vaccine*. 2019;37(13):1885-1888. doi:10.1016/j.vaccine.2019.01.059
2. Pepin S, Dupuy M, Borja-Tabora CFC, et al. Efficacy, immunogenicity, and safety of a quadrivalent inactivated influenza vaccine in children aged 6–35 months: a multi-season randomised placebo controlled trial in the northern and southern hemispheres. *Vaccine*. 2019;37(13):1876-1884. doi:10.1016/j.vaccine.2018.11.074

Vaxigrip® demonstrated immunogenicity in adults¹

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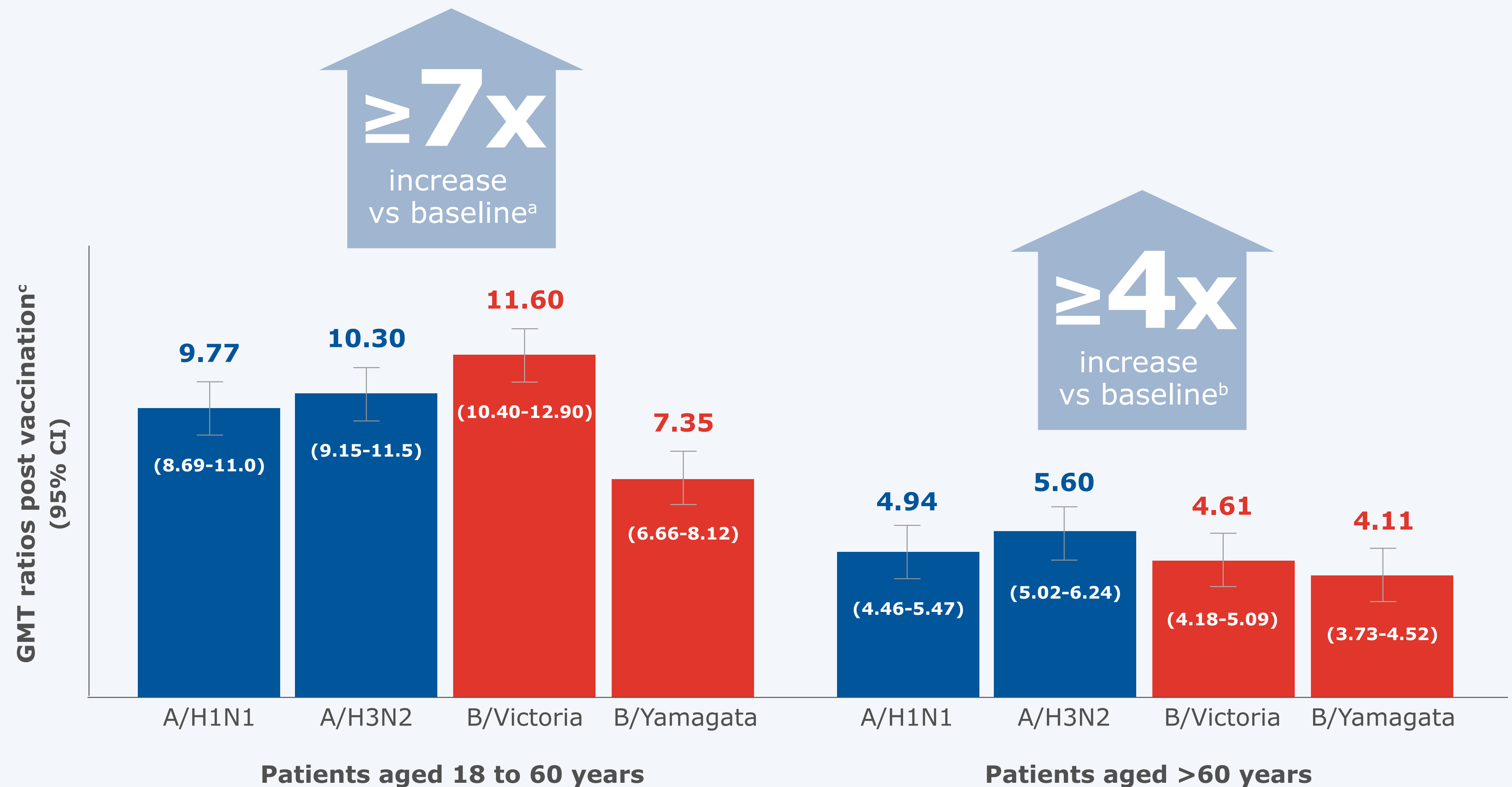
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HAI antibody responses with Vaxigrip® at day 21 vs baseline^{1,a}



CI=confidence interval; GMT=geometric mean titre; HAI=haemagglutination inhibition.

^aN=833 for 18-60 years of age group.¹

^bN=832 for over 60 years of age group.¹

^cGeometric mean of individual titre ratios (post-/pre-vaccination titres).¹

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- 1.** Vaxigrip® Summary of Product Characteristics 2025.

CI=confidence interval; GMT=geometric mean titre; NA1=haemagglutination inhibition.
^aN=833 for 18-60 years of age group.¹
^bN=832 for over 60 years of age group.¹
^cGeometric mean of individual titre ratios (post-/pre-vaccination titres).¹

[View References](#)

Vaxigrip® is well tolerated with a good safety profile¹

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Overall, the most common adverse events observed during clinical trials were injection-site reactions, headache, myalgia, and malaise.¹

Most adverse reactions are mild and short-lived¹



**YOUNG CHILDREN
6 TO 35 MONTHS**



**CHILDREN
3 TO 17 YEARS**



**ADULTS
AND ELDERLY**



Click for safety profiles of specific populations



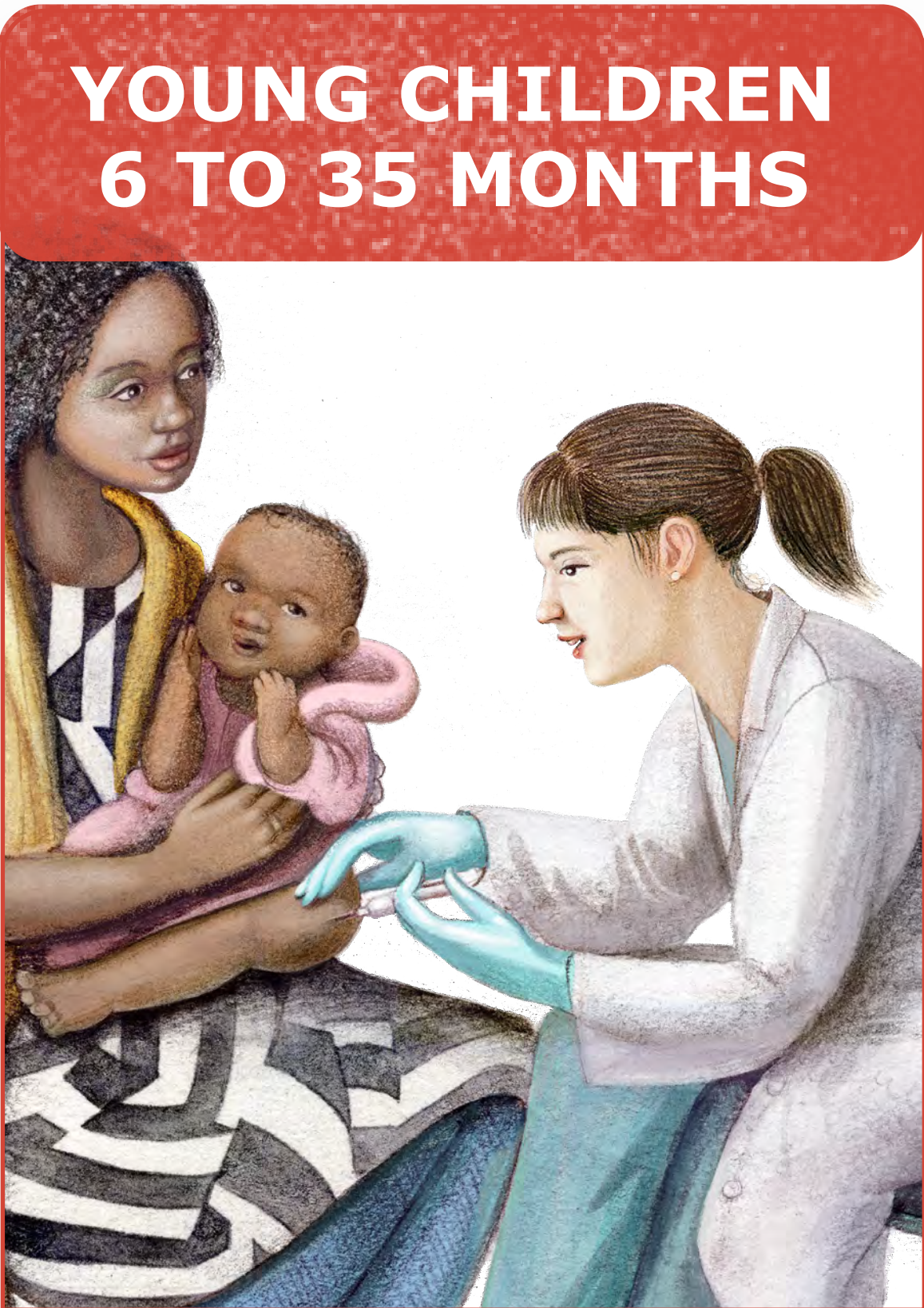
Reference

1. Vaxigrip® Summary of Product Characteristics 2025.



Vaxigrip® is well tolerated with a good safety profile¹

Most adverse reactions are mild and short-lived¹



VERY COMMON ADVERSE REACTIONS¹

- | | | |
|-----------------|-------------------|----------------------------------|
| • Headache | • Abnormal crying | • Injection-site pain/tenderness |
| • Vomiting | • Malaise | • Injection-site erythema |
| • Myalgia | • Fever | |
| • Irritability | • Drowsiness | |
| • Appetite loss | | |

COMMON ADVERSE REACTIONS¹

- | | | |
|-----------------------------|---------------------------|-----------------------------|
| • Shivering | • Injection-site swelling | • Injection-site ecchymosis |
| • Injection-site induration | | |

[View References](#)

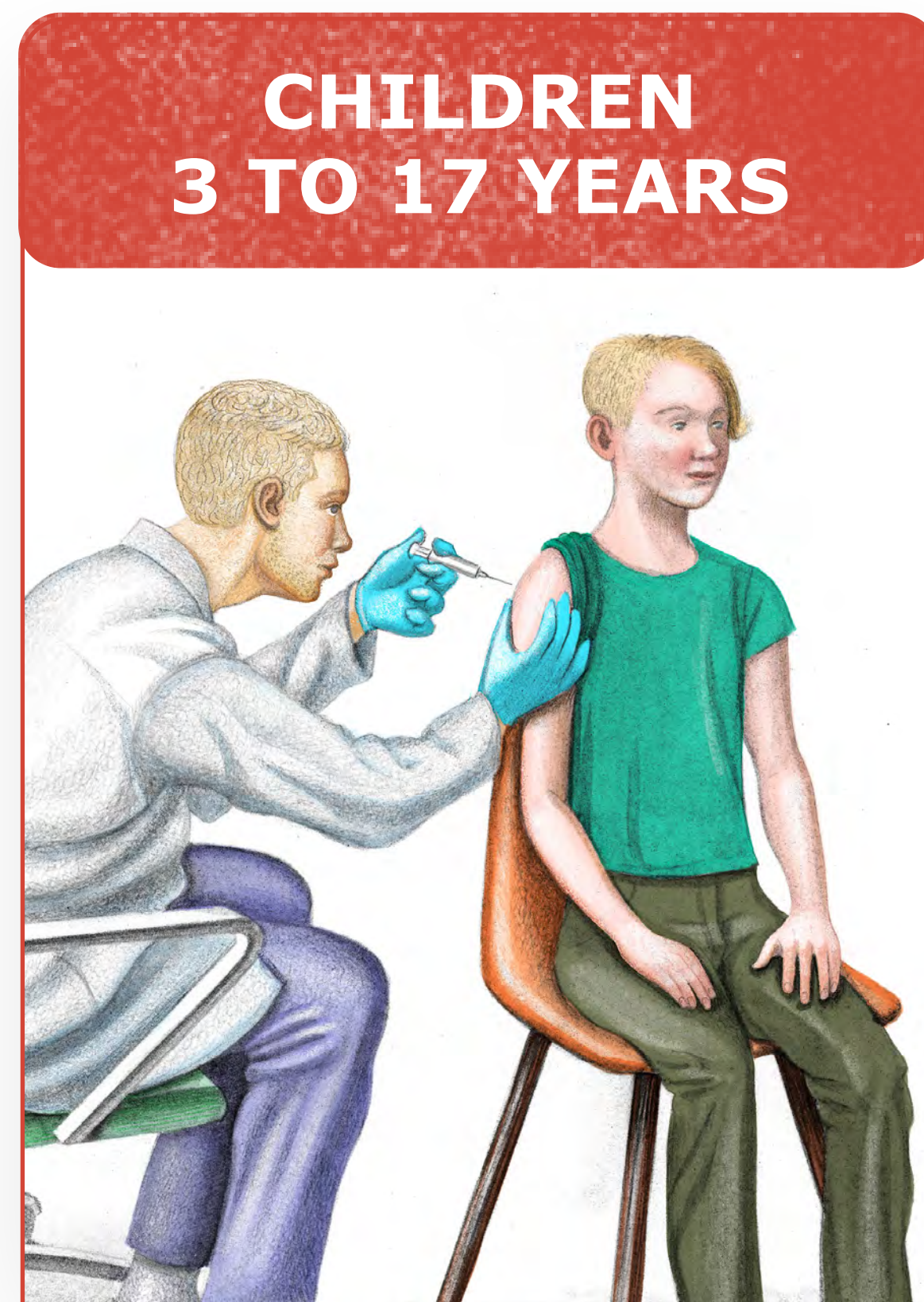
Reference

1. Vaxigrip® Summary of Product Characteristics 2025.



Vaxigrip® is well tolerated with a good safety profile¹

Most adverse reactions are mild and short-lived¹



VERY COMMON ADVERSE REACTIONS¹

- Headache
- Myalgia
- Malaise
- Shivering
- Injection-site pain
- Injection-site swelling
- Injection-site erythema
- Injection-site induration

COMMON ADVERSE REACTIONS¹

- Fever
- Injection-site ecchymosis

[View References](#)

Reference

- 1. Vaxigrip® Summary of Product Characteristics 2025.



Vaxigrip® is well tolerated with a good safety profile¹

Most adverse reactions are mild and short-lived¹

ADULTS AND ELDERLY



VERY COMMON ADVERSE REACTIONS¹

- Headache
- Myalgia
- Malaise
- Injection-site pain

COMMON ADVERSE REACTIONS¹

- Shivering
- Fever
- Injection-site erythema
- Injection-site swelling
- Injection-site induration

[View References](#)

Reference

1. Vaxigrip® Summary of Product Characteristics 2025.

Vaxigrip® is simple and convenient

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**EASY DOSING
FOR ALL PATIENTS**



**EASY
TO USE**



**EASY
TO STORE**

 Tap to see each feature



Vaxigrip® is simple and convenient



**SAME DOSING FOR
ALL PATIENTS**

- **1x 0.5-mL** dose for adults and children >6 months^{1,2}
- **2x 0.5-mL** doses ≥ 4 weeks apart for children <9 years of age not previously vaccinated^{1,2}

[View References](#)

References

1. Vaxigrip® vaccine. Public Assessment Report, November 2016. Accessed July 18, 2022.
https://file.wuxuwang.com/hma/DE_H_1949_001_PAR.pdf
2. Vaxigrip® Summary of Product Characteristics 2025.



Vaxigrip® is simple and convenient



**EASY
TO USE**

- **Easy-to-open pack^a** with direct access to a single-use prefilled syringe¹
- **Intramuscular or subcutaneous administration** to adapt to your patients' needs¹

^aFor countries using the compact box.

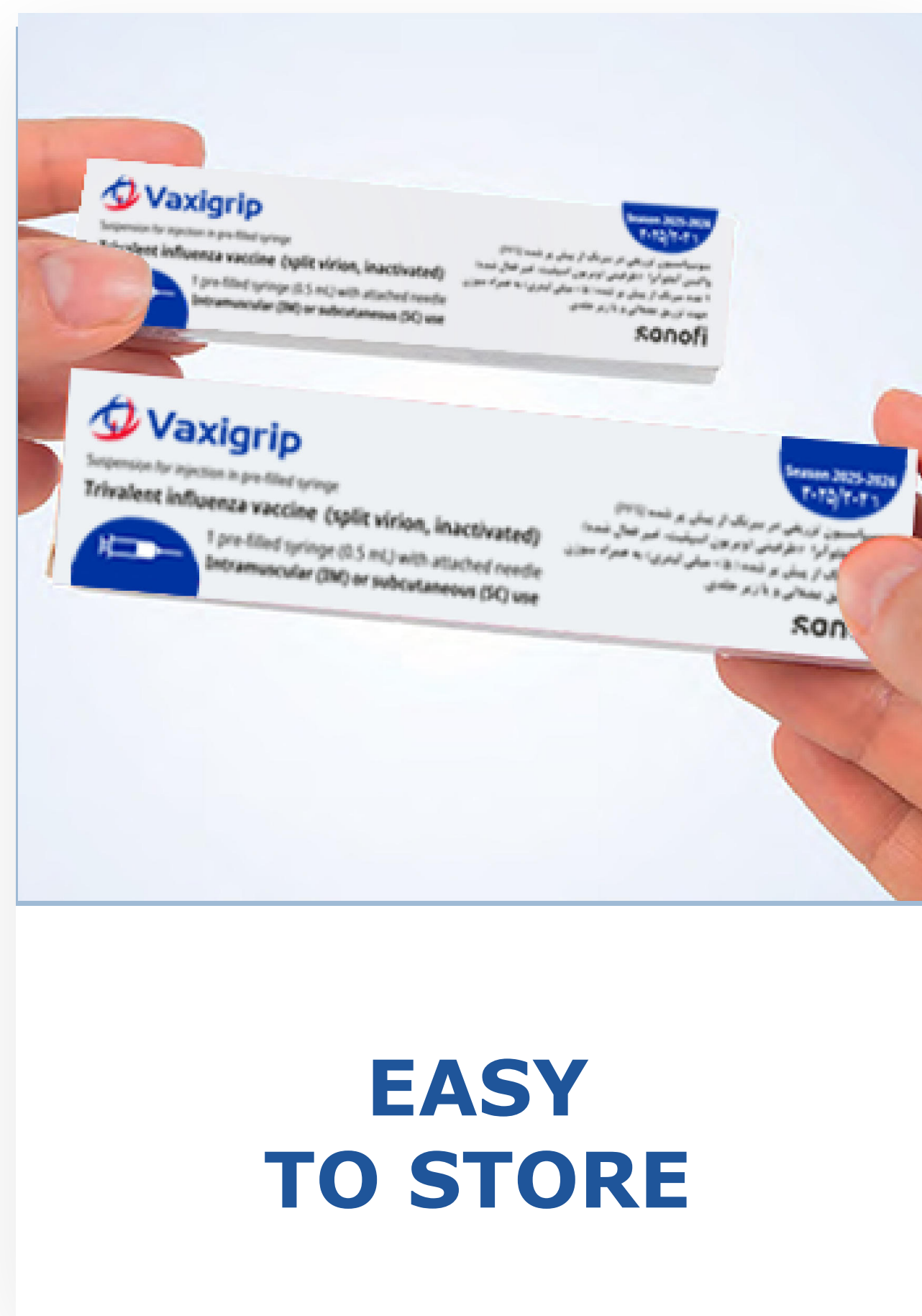
[View References](#)

Reference

1. Vaxigrip® Summary of Product Characteristics 2025.



Vaxigrip® is simple and convenient



- **100% eco-friendly**, space-saving packaging helps reduce waste and minimises storage requirements^{1,a}
- **~50% reduction** in storage compared to previous standard packaging (48 cm³)¹
- **~31% reduction** in CO₂ emissions by transport freight¹

^aOne of the smallest boxes available.

[View References](#)

Reference

- 1. Data on file, Sanofi Pasteur Inc.

VAXIGRIP® HAS DATA DEMONSTRATING EFFICACY^a FOR THE BROADEST RANGE OF PATIENTS¹⁻³

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The only standard-dose influenza vaccine with statistically significant data from an RCT demonstrating **protection against cardiovascular disease** outcomes across geographies and seasons²



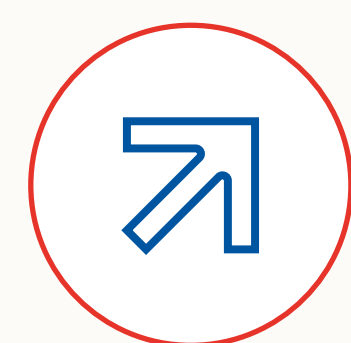
The only influenza vaccine indicated for **passive protection of infants up to 6 months of age following vaccination of pregnant women**¹



Demonstrated efficacy and **reduction of flu-related complications** in children 6 to 35 months old^{1,4}



Well tolerated with a proven safety record and more than 2 billion doses of Vaxigrip/Vaxigrip® distributed worldwide^{1,5}



Protection beyond flu is the new bar for our flu vaccines, and Sanofi is advancing the future of protection beyond flu with Vaxigrip®, Efluelda, Supemtek, and more^{2,6-11}

RCT=randomised controlled trial.

^a In pregnant women, children, and patients with cardiovascular disease.¹⁻³

You have the power to help protect your patients, aged 6 months and up, against flu with Vaxigrip®¹

References



1. Vaxigrip® Summary of Product Characteristics 2025.
2. Fröbert O, Götberg M, Erlinge D, et al. Influenza vaccination after myocardial infarction: a randomized, double-blind, placebo-controlled, multicenter trial. *Circulation*. 2021;144(18):1476-1484. doi:10.1161/CIRCULATIONAHA.121.057042
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4. Pepin S, Samson SI, Alvarez FP, Dupuy M, Gresset-Bourgeois V, De Bruijn I. Impact of a quadrivalent inactivated influenza vaccine on influenza associated complications and health care use in children aged 6 to 35 months: analysis of data from a phase III trial in the northern and southern hemispheres. *Vaccine*. 2019;37(13):1885-1888. doi:10.1016/j.vaccine.2019.01.059
5. Sanofi. Periodic Benefit Risk Evaluation Report. 4 May, 2020.
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7. Supemtek Quadrivalent Influenza Vaccine [Summary of Product Characteristics]. Sanofi Pasteur Inc; 2021.
8. DiazGranados CA, Dunning AJ, Kimmel M, et al. Efficacy of high-dose versus standard-dose influenza vaccine in older adults. *N Engl J Med*. 2014;371(7):635-645. doi:10.1056/NEJMoa1315727
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10. Izurieta HS, Lu M, Kelman J, et al. Comparative effectiveness of influenza vaccines among US Medicare beneficiaries ages 65 years and older during the 2019-2020 season. *Clin Infect Dis*. 2021;73(11):e4251-e4259. doi:10.1093/cid/ciaa1727
11. Lee JKH, Lam GKL, Shin T, Samson SI, Greenberg DP, Chit A. Efficacy and effectiveness of high-dose influenza vaccine in older adults by circulating strain and antigenic match: an updated systematic review and meta-analysis. *Vaccine*. 2021;39(suppl1):A24-A35. doi:10.1016/j.vaccine.2020.09.004



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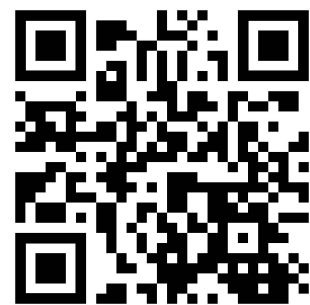
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ABRIDGED PRESCRIBING INFORMATION
INDICATIONS AND USAGE Vaxigrip is indicated for the prevention of influenza disease caused by the two influenza A virus subtypes and the influenza B virus type contained in the vaccine for:
- active immunisation of adults, including pregnant women, and children from 6 months of age and older,
- passive protection of infant(s) from birth to less than 6 months of age following vaccination of pregnant women
The use of Vaxigrip should be based on official recommendations on vaccination against influenza.
Posology and method of administration: Posology **Adults:** one dose of 0.5 mL.
Paediatric population - Children from 6 months to 17 years of age: one dose of 0.5 mL. For children less than 9 years of age who have not previously been vaccinated, a second dose of 0.5 mL should be given after an interval of at least 4 weeks.
- Infants less than 6 months of age: the safety and efficacy of Vaxigrip administration (active immunisation) have not been established. No data are available.
Regarding passive protection: one 0.5 mL dose given to pregnant women may protect infants from birth to less than 6 months of age
. QUALITATIVE AND QUANTITATIVE COMPOSITION
Influenza virus (inactivated, split) of the following strains*:
A/Victoria/4897/2022 (H1N1)pdm09-like strain (A/Victoria/4897/2022, IVR-238) 15 micrograms HA**
A/Croatia/10136RV/2023 (H3N2)-like strain (A/Croatia/10136RV/2023, X-425A) 15 micrograms HA**
B/Austria/1359417/2021-like strain (B/Michigan/01/2021, wild type) 15 micrograms HA**
Per 0.5 mL dose
* propagated in fertilised hens’ eggs from healthy chicken flocks
** haemagglutinin
This vaccine complies with the WHO recommendations (Northern Hemisphere) and EU decision for the 2025/2026 season.
FORMS AND STRENGTHS Suspension for injection in pre-filled syringe, For 0.5 mL dose. **CONTRAINDICATIONS** Hypersensitivity to the active substances, to any of the excipients listed in Section 6.1 or to any component that may be present as traces such as eggs (ovalbumin, chicken proteins), neomycin, formaldehyde and octoxinol-9. **WARNINGS AND PRECAUTIONS:** Talk to your doctor or pharmacist before using Vaxigrip. You should tell your doctor before vaccination if you or your child have:
• A poor immune response (immunodeficiency or taking medicines affecting the immune system),
• Bleeding problem or bruising easily. If you or your child have an acute illness with fever, the vaccination should be postponed until the fever is resolved. Your doctor will decide if you or your child should receive the vaccine. Fainting can occur (mostly in adolescents) following, or even before, any needle injection. Therefore tell your doctor or nurse if you or your child fainted with a previous injection. As with all vaccines, Vaxigrip may not fully protect all persons who are vaccinated.
Not all babies less than 6 months of age born to pregnant women vaccinated during pregnancy will be protected. **ADVERSE REACTIONS Clinical Trial** The safety profile of Vaxigrip is based on data from 46 clinical studies in which approximately 17 900 participants from 6 months of age received Vaxigrip or Vaxigrip, and data from post-marketing surveillance. Most of adverse reactions usually occurred within the first 3 days after vaccination and resolved spontaneously within 1 to 3 days after onset. The intensity of most these reactions was mild to moderate. The most frequently reported adverse reaction after vaccination, in all populations including the whole group of children from 6 to 35 months of age, was injection site pain. Adult and elderly
The safety profile is based on data:- from clinical studies in more than 8 000 adults (5064 for Vaxigrip, 3040 for Vaxigrip) and more than 5 800 elderly over 60 years of age (4 468 for Vaxigrip, 1392 for Vaxigrip),
- from worldwide post-marketing surveillance in the overall population. In adults, the most frequently reported adverse reactions after vaccination were injection site pain (52.8%), headache (27.8%), myalgia (23.0%), malaise (19.2%). In the elderly, the most frequently reported adverse reactions after vaccination were injection site pain (25.8%), headache (15.6%), myalgia (13.9%).
Interactions with Other medicinal products Vaxigrip could be given at the same time as other vaccines if needed. Data showing that Vaxigrip can be administered concomitantly with other vaccines are available for the following vaccines: a pneumococcal polysaccharide vaccine, a tetanus, diphtheria, pertussis, polio vaccine (Tdap-IPV, Repevax), and a zoster vaccine. If Vaxigrip is given at the same time as other vaccines, separate injection sites and separate syringes should be used. The immunological response may be reduced if the patient is undergoing immunosuppressant treatment. **USE IN SPECIFIC POPULATIONS Pregnancy** Pregnant women are at high risk of influenza complications, including premature labour and delivery, hospitalization, and death: pregnant women should receive an influenza vaccine. Vaxigrip can be used in all stages of pregnancy. **Breastfeeding** Vaxigrip may be used during breast-feeding. **Fertility** No fertility data are available in Humans. One animal study with did not indicate harmful effects on female fertility. **CLINICAL PHARMACOLOGY Mechanism of Action:** Vaxigrip provides active immunisation against three influenza virus strains (two A subtypes and one B type) contained in the vaccine. Vaxigrip induces humoral antibodies against the haemagglutinins within 2 to 3 weeks. These antibodies neutralise influenza viruses.. **HOW SUPPLIED** Vaxigrip is a suspension for injection presented in a pre-filled syringe of 0.5 mL, with attached needle, with separate needle or without needle, in box of 1. **STORAGE** Store in a refrigerator (2°C – 8°C). Do not freeze. Keep the syringe in the outer carton in order to protect from light.

Last date of text revision: 05-2025
Disclaimer this information is provided for scientific and medical purpose only.
Sanofi doesn’t recommend the use of its products in any manner inconsistent with that described in the full prescribing information available in our country.
To report an adverse event or if you have any medical enquiry in Iran , please call +982127605000 EXT:3
or email us at:
ae.ptc@rouginedarou.com for adverse events and product technical complaints
medicalinfo@rouginedarou.com for medical enquiries



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To report an adverse event or if you have any medical enquiry in Iran, please call +982127605000 EXT:3 or email us at:
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medicalinfo@rouginedarou.com for medical enquiries



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