INTANZA®, THE FIRST MICRO-NEEDLE VACCINE AGAINST INFLUENZA

“EFFECTIVE FLU PROTECTION WITH A SIMPLE TOUCH”

INTANZA®, THE LATEST INNOVATION FROM SANOFI PASTEUR

• Intanza® is the first influenza vaccine administered intradermally by micro-injection.¹

• Intanza® is a trivalent seasonal vaccine indicated for the prevention of influenza in adult populations (aged 18 and over).¹

• Intanza® is an innovative micro-needle vaccine that targets the dermis, a highly immunogenic area, and that provides an effective and safe protection against influenza. This novel patient-friendly vaccine is considered by vaccinators to be very convenient and easy-to-use, and is widely accepted by patients.²

• Intanza® was developed and licensed by the world’s influenza vaccine leader, Sanofi Pasteur, and is being marketed under two dosages:¹
  • Intanza® 9µg for adults 18 to 59,
  • Intanza® 15µg for adults 60 and over.

INTANZA® TAKES FULL ADVANTAGE OF THE INTRADERMAL ROUTE

• Immunization via the intradermal (ID) route involves the introduction of vaccine antigens directly into an upper layer (only 1.5 to 2 mm deep) of the skin, the dermis.³

• The ID route exploits the unique immune potential of the skin and is an highly attractive alternative to the standard intramuscular (IM) and subcutaneous (SC) routes:⁴
  • The dermis is a key component of the immune system rich in specialized immune cells—called “dendritic cells”—that are essential to effectively stimulating an immune response.⁴,⁵ These dendritic cells are both efficient and specialized in antigen presentation, and they control the magnitude, quality and memory of the ensuing immune response.⁶
  • The ID route provides the vaccine with direct, easy and efficient access to the dermal layer of the skin and, consequently, to the immune system.⁴

* Intanza® vaccine is also commercialized under the brand name of IDflu® in some countries of the world.¹ It was granted marketing licensure in the European Union on February 26th 2009 and is intended for distribution worldwide except in the U.S.
INTANZA® OFFERS EFFECTIVE AND SAFE PROTECTION AGAINST INFLUENZA

- Both Intanza® dosages (9µg or 15µg /dose) provide effective influenza seroprotection against all seasonal influenza strains tested:
  - Intanza® 9µg for adults 18–59 years offers seroprotective immune response at rates comparable to those achieved with intramuscular (IM) influenza vaccination (15µg), with less antigen.
  - Intanza® 15µg for adults aged 60 and over offers seroprotective immune response at rates at least equivalent to those achieved with IM influenza vaccination (15µg), with the same antigen content:
    - Intanza® 15µg has proven to elicit an immune response that is superior to that induced by an IM reference seasonal influenza vaccine, for all 3 strains, in a Phase III randomized controlled clinical trial.
    - Intanza® 15µg has also proven to elicit the same immune response (in terms of Geometric Mean Titers) as MF-59 adjuvanted IM seasonal vaccine in a randomized comparative Phase III trial.
- Intanza® benefits from a favorable safety profile, as demonstrated in clinical trials:
  - Intanza®'s systemic safety profile is the same as that of IM seasonal influenza split vaccines.
  - Intanza® is well-tolerated:
    - Local reactions at the point of injection are those anticipated as a result of the inflammatory or immunological response beneath the skin's surface.
    - Local site reactions are generally mild and are all transient. Most of them resolve spontaneously within 1 to 3 days after onset.
    - These local reactions do not increase with repeated administrations (consecutive annual vaccination).
    - Finally, more than 96% of study participants consider local site reactions as totally or very acceptable.

The high immune response observed with Intanza® 15µg vaccine in adults aged 60 and over is all the more a matter of interest as the natural weakening of the immune system with ageing renders individuals from this age-group not only more susceptible to infections and to complications from influenza, but also reduces the immune response to influenza vaccination compared with younger adults.

While influenza vaccination, by preventing direct outcomes of influenza infection and complications including hospitalization and death, but also indirect outcomes such as death from other causes or acceleration of the worsening of their health status, is of great benefit in the elderly, there remains a significant need for more seroprotective vaccines—i.e. as Intanza® 15µg—for this specific adult population, aged 60 years and over.
• Intanza® improves individual acceptance of vaccination: 
  
  - High patient satisfaction level:
    - As demonstrated in clinical trials, more than 96% of individuals vaccinated with Intanza® were satisfied or very satisfied with the micro-injection system vaccine. 
  
  - Painless injection:
    - Micro-needle placement into the skin was reported by most of vaccinees as pain free on a verbal pain description scale during a trial (645 volunteers, 2,524 injections).
    - 89.1% of adults aged 60 or over and 80.3% of 18-59 year old adults vaccinated with Intanza® said they had “no or hardly any pain” at the time of injection. 
      Questionnaire administered at the time of injection using a verbal Rating Scale N=2,606 and N=1,796 respectively
  
  - High acceptability for revaccination with Intanza®:
    - 90 % of adults aged 60 or over and more than 80% of adults aged 18-59 vaccinated with Intanza® indicated their preference for a revaccination with the same vaccine the following year.

• Intanza®’s micro-injection system allows successful intradermal injection with a simple touch:
  
  - This innovative vaccine facilitates influenza antigen administration and is appreciated by health care professionals.

• Intanza® was designed to encourage more people to be vaccinated and to help vaccinators protect their patients against flu:
  
  - The added comfort, ease-of-use and reassuring profile offered by Intanza®—for both patients and vaccinators—may lead to more successful vaccination campaigns.
  
  - These advantages have the potential to improve the vaccine coverage rates among the elderly and among the younger adult population and, consequently, to help protect more people, thereby reducing the health and economic burden of influenza.

The World Health Organization (WHO) strongly emphasizes the importance of raising public awareness of influenza and its complications as well as the beneficial effects of influenza vaccination. Despite WHO recommendations for the implementation of strategies to increase vaccination coverage for all people at high risk, including the elderly and persons with underlying conditions (with a low-end goal of 75% coverage for the elderly population), influenza vaccines are still underused and the disease continues to be a global health problem.

Influenza vaccination offers approximately 70-90% protection against clinical disease in healthy adults aged 18-59, provided there is a good match between the vaccine antigens and circulating viruses. The benefits of influenza vaccination in this healthy adult group—including health-care workers—justify the economic costs involved since vaccination prevents absenteeism and loss of productivity while reducing illness rates and the burden of disease.

The fear or the dislike of needles may represent a potential barrier for all adults—whether healthy or at-risk—and may keep them from being vaccinated. Patients not only need to be convinced of the benefit of being vaccinated, but also reassured about the process of receiving an influenza vaccination.
INTANZA®’S MICRO-INJECTION SYSTEM PROVIDES EASY AND RELIABLE INTRADERMAL IMMUNIZATION

- Intanza®’s innovative pre-filled micro-injection system overcomes the technical difficulties that have so far limited the use of the ID route.\(^5\)

- Intanza®’s micro-injection system is convenient, intuitive and easy to use:\(^2,15\)
  - No specific training for successful injection.\(^15\)
  - Simple application, perpendicular, to the skin in the deltoid region.\(^1\)
  - No air purging.\(^1\)
  - The vein test is unnecessary.\(^1\)

- Intanza®’s micro-injection system allows reliable and precise vaccine administration:\(^15\)
  - The antigen is accurately and consistently deposited \(^2,15\) in the dermal layer of the skin, irrespective of the patient’s physical characteristics (age, gender, ethnicity, body mass index).\(^5,15\)

INTANZA®’S MICRO-INJECTION SYSTEM OFFERS ADDED COMFORT FOR PATIENTS AND FOR VACCINATORS

- Shorter needle length, thinner needle gauge and smaller volume administered:\(^1,2,15\)
  - Shorter needle length and thinner gauge:
    - Intanza®’s micro-injection needle has a length of only 1.5 mm [10 to 16 times shorter than the 16 mm or 25 mm needles commonly used for IM vaccinations] and is inserted perpendicularly into the skin.\(^1,15\)
    - Intanza®’s micro-injection needle is quite thin; at 30 gauge, it is approximately 40% thinner than commonly used IM needles.\(^15\)
  - Smaller volume administered:
    - Intanza®’s micro-injection system allows the precise administration of the right amount of antigen in a very small volume of vaccine (0.1 mL) – five times less than that required for the regular IM route.\(^1,2\)

- Intanza®’s micro-injection system is safe for vaccinators and vaccinees:\(^15\)
  - Intanza®’s micro-injection system provides user protection, owing to an integrated needle-shielding system that is manually activated immediately after injection.
    - Minimises the risk of needle-stick injury, contamination and illicit re-use.\(^1,15\)
  - Intanza®’s micro-injection needle is inserted no further than the dermal layer.
    - No risk of hitting a vein or a nerve.\(^7,15\)
Sources:

1. SmPC Intanza® 9μg and 15μg
5. Lambert PH, Laurent PE. Intradermal vaccine delivery: Will new delivery systems transform vaccine administration, Vaccine 2008; 26:3197–208
16. Sanofi Pasteur Internal clinical data (Source Pain Data GID15, GID17 and GID23)
17. Sanofi Pasteur internal data: Quantitative market research performed in 7 countries involving 940 physicians and 906 vaccine recipients and Market research in France performed on more than 1700 vaccine recipients and 260 general practitioners

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