

INFANRIX® IPV

NAME OF THE DRUG

INFANRIX® IPV vaccine is a combined diphtheria, tetanus, acellular pertussis (DTPa) and inactivated poliovirus vaccine.

DESCRIPTION

INFANRIX® IPV vaccine is a sterile suspension which contains diphtheria toxoid (D), tetanus toxoid (T), three purified antigens of *Bordetella pertussis* [pertussis toxoid (PT), pertussis filamentous haemagglutinin (FHA) and pertussis 69 kilodalton outer membrane protein (69kDa OMP) (pertactin)] and three types of inactivated polio viruses (type 1: Mahoney strain; type 2: MEF-1 strain; type 3: Saukett strain).

The diphtheria and tetanus toxoids are obtained by formaldehyde treatment of purified *Corynebacterium diphtheriae* and *Clostridium tetani* toxins. The acellular pertussis vaccine components are obtained by extraction and purification from phase I *Bordetella pertussis* cultures, followed by irreversible detoxification of the pertussis toxin by glutaraldehyde and formaldehyde treatment, and formaldehyde treatment of FHA and pertactin. The three polioviruses are cultivated on a continuous VERO cell line, purified and inactivated with formaldehyde.

A 0.5mL dose of vaccine contains not less than 30IU (25Lf U) of diphtheria toxoid, not less than 40IU (10Lf U) of tetanus toxoid, 25µg of adsorbed PT, 25µg of adsorbed pertussis FHA, 8µg of adsorbed pertactin, 40 D-antigen units of type 1 (Mahoney), 8 D-antigen units of type 2 (MEF-1) and 32 D-antigen units of type 3 (Saukett) polioviruses. The final vaccine also contains the excipients aluminium hydroxide, sodium chloride and water for injections. The vaccine also contains the following residues: medium 199, polysorbate 80, formaldehyde, glycine, potassium chloride, sodium phosphate dibasic dihydrate, potassium phosphate monobasic, neomycin sulfate and polymyxin B sulfate.

The manufacture of this product includes exposure to bovine derived materials. No evidence exists that any case of vCJD (considered to be the human form of bovine spongiform encephalopathy) has resulted from the administration of any vaccine product.

INFANRIX[®] *IPV* vaccine meets the World Health Organisation requirements for manufacture of biological substances, of diphtheria, tetanus, pertussis and combined vaccines, and of inactivated poliomyelitis vaccines.

PHARMACOLOGY

Clinical Trials

More than 1,800 doses of *INFANRIX*[®] *IPV* have been administered in clinical studies evaluating use in primary vaccination schedules. In addition, 721 doses have been administered as a single booster dose in infants and children ranging from 15 months to 13 years.

Immune response to the DT components:

One month after a 3 dose primary vaccination course with *INFANRIX*[®] *IPV*, more than 99% of vaccinated infants had antibody titres of ≥ 0.1 IU/mL to both tetanus and diphtheria.

Following administration of a booster dose of *INFANRIX*[®] *IPV*, more than 99.5% of children had antibody titres of ≥ 0.1 IU/mL for both antigens.

Antibody titres ≥ 0.1 IU/mL are deemed to correlate with seroprotection against diphtheria and tetanus.

Immune response to the Pa component:

One month after the 3-dose primary vaccination course with *INFANRIX*[®] *IPV*, 100% of infants were seropositive (antibodies ≥ 5 EL.U/mL) for the three pertussis components (PT, FHA, pertactin). Overall response rates, for each of the three individual pertussis antigens were $\geq 94\%$. A vaccine response was defined as induction of antibodies to the individual pertussis antigens, taking into account the age and the pre-vaccination serological status of the subject.

In booster studies, a vaccine response was seen in $\geq 96.6\%$ of vaccinees against the pertussis antigens; lower response rates were seen in studies where the pre-vaccination levels of antibodies were high. A vaccine response was defined as a post-vaccination titre $\geq 2x$ the pre-vaccination titre for subjects initially seropositive, and a titre \geq the assay cut-off (5 EL.U/ml) for subjects initially seronegative. All subjects were seropositive one month after this dose.

Protective efficacy of the Pa component:

As the immune response to pertussis antigens following *INFANRIX*[®] *IPV* administration is equivalent to that of *INFANRIX*[®], it can be assumed that the protective efficacy of the two vaccines will also be equivalent.

The clinical protection of the DTPa component, against WHO-defined typical pertussis (≥ 21 days of paroxysmal cough) was demonstrated in:

- a prospective blinded household contact study was performed in Germany (3, 4, 5 months schedule). Based on data collected from secondary contacts in households where there was an index case with typical pertussis, the protective efficacy of the vaccine was calculated to be 88.7%.
- a US National Institute of Health (NIH) sponsored efficacy study was performed in Italy (2, 4, 6 months schedule). This study determined the vaccine efficacy to be 84%. In a follow-up of the same cohort, the efficacy was confirmed for up to 4 years of age.

Immune response to the IPV component:

One month after the 3 dose primary vaccination course with *INFANRIX[®] IPV*, the overall seropositivity for each of the three polio serotypes (type 1, 2 and 3) was $\geq 99.5\%$. Antibody titres ≥ 8 are deemed to correlate with seroprotection against poliomyelitis.

Following administration of a booster dose of *INFANRIX[®] IPV*, 100% of children were seropositive for the three polio serotypes.

In all booster trials, vaccination with *INFANRIX[®] IPV* induced a marked increase in antibody levels with respect to pre-booster values.

Geometric Mean Antibody Titres (GMTs) following primary immunisation with *INFANRIX[®] IPV* vaccine in children at 7 months of age

Antigen	Primary immunisation GMT [95% confidence interval]
Diphtheria Toxoid (N=203)	1.83 [1.69 – 1.98]
Tetanus Toxoid (N=193)	3.72 [3.47 – 3.99]
Pertussis Toxoid (N=198)	87.2 [81.7 – 93.0]
Pertussis FHA (N=188)	91.1 [80.6 – 102.9]
Pertactin (N=188)	166.6 [151.6 – 183.1]
Poliovirus Type 1 (N=174)	374.5 [326.8 – 429.1]
Poliovirus Type 2 (N=175)	406.1 [352.9 – 467.2]
Poliovirus Type 3 (N=175)	1115.0 [978.4 – 1270.6]

Note: Primary immunisation with DTPa-IPV vaccine at 3, 4.5, 6 months
 IU = International Units; EL.U = ELISA Units; N = Number of subjects
 Assay cut-offs for each antigen are as follows: D & T: $\geq 0.1\text{IU/mL}$; PT, FHA & PRN: 5EL.U/mL ;
 POLIO types 1,2,3: ≥ 8 .
 The cut-off values for diphtheria, tetanus and polio correlate with seroprotection. Currently there are no known serological correlates for protection for the pertussis antigens.

Geometric Mean Antibody Titres (GMTs) from a study of booster immunisation with INFANRIX[®] IPV at 4-6 years of age, following primary immunisation

Antigen	Booster immunisation GMT (95% confidence interval)	
	Pre-booster	Post-booster
Diphtheria Toxoid (N=201 [pre] and 208 [post])	0.08 (0.07-0.09)	6.24 (5.39 – 7.23)
Tetanus Toxoid (N=200 [pre] and 208 [post])	0.15 (0.12-0.17)	9.96 (8.79-11.28)
Pertussis Toxoid (N= 200 [pre] and 208 [post])	3.6 (3.2-4.0)	63.2 (56.1-71.2)
Pertussis FHA (N=201 [pre] and 208 [post])	30.0 (24.9-36.2)	735.2 (653.4-827.4)
Pertactin (N=201 [pre] and 208 [post])	27.2 (23.0-32.3)	995.6 (863.5-1147.9)
Poliovirus Type 1 (N=193 [pre] and 193 [post])	65.3 (49.9-85.4)	2096.0 (1817.6-2417.0)
Poliovirus Type 2 (N=194 [pre] and 197 [post])	41.4 (32.0-53.5)	1702.4 (1482.1-1955.4)
Poliovirus Type 3 N=192 [pre] and 189 [post])	23.5 (19.3-28.7)	2542.6 (2122.0-3046.5)

Note: Primary immunisation with DTPa-containing vaccines at 3, 5 and 11 months of age

N = Number of subjects; IU = International Units; EL.U = ELISA Units

Assay cut-offs for each antigen are as follows: D & T: $\geq 0.11\text{IU/mL}$; PT, FHA & PRN: 5EL.U/mL ; POLIO types 1,2,3: ≥ 8 .

The cut-off values for diphtheria, tetanus and polio correlate with seroprotection. Currently there are no known serological correlates for protection for the pertussis antigens.

Geometric Mean Antibody Titres (GMTs) from a study of booster immunisation with INFANRIX® IPV at 5-6 years of age, following primary and first booster immunisation

Antigen	Booster immunisation GMT (95% confidence interval)	
	Pre-booster	Post-booster
Diphtheria Toxoid (N=72 [pre] and 73 [post])	0.12 (0.09 – 0.15)	6.19 (4.83 – 7.93)
Tetanus Toxoid (N=72 [pre] and 73 [post])	0.25 (0.20 – 0.32)	13.58 (11.30 – 16.31)
Pertussis Toxoid (N=72 [pre] and 66 [post])	3.6 (3.0 – 4.3)	84.7 (62.5 – 114.9)
Pertussis FHA (N=70 [pre] and 72 [post])	31.8 (22.1 – 45.9)	1051.1 (898.3 – 1299.8)
Pertactin (N=72 [pre] and 73 [post])	16.8 (12.7 – 22.3)	820.1 (656.8 – 1024.0)
Poliovirus Type 1 (N=72)	15.6 (11.7 – 20.8)	1533.2 (1156.6 – 2032.2)
Poliovirus Type 2 (N=72 [pre] and 71 [post])	21.8 (16.3 – 29.0)	1053.4 (819.7 – 1353.6)
Poliovirus Type 3 (N=71)	44.4 (31.9 – 61.7)	1740.7 (1315.7 – 2303.0)

Note: Primary and first booster immunisation with DTPw-IPV or DTPw-IPV/Hib vaccine

N = Number of subjects; IU = International Units; EL.U = ELISA Units

Assay cut-offs for each antigen are as follows: D & T: $\geq 0.1IU/mL$; PT, FHA & PRN: $5EL.U/mL$; POLIO types 1,2,3: ≥ 8 .

The cut-off values for diphtheria, tetanus and polio correlate with seroprotection. Currently there are no known serological correlates for protection for the pertussis antigens.

INDICATIONS

INFANRIX® IPV is indicated for use in a three dose primary schedule for immunisation of infants from 6 weeks of age and over, against diphtheria, tetanus, pertussis and poliomyelitis.

INFANRIX® IPV is also indicated as a single booster dose for children, up to and including 6 years of age, who have previously been immunised against DTP and polio.

CONTRAINDICATIONS

INFANRIX® IPV should not be administered to subjects with known hypersensitivity to the active substances or to any of the excipients or residues (see Description).

INFANRIX[®] *IPV* should not be administered to subjects having shown signs of hypersensitivity after previous administration of diphtheria, tetanus, pertussis, or inactivated polio vaccines.

INFANRIX[®] *IPV* is contraindicated if the child has experienced an encephalopathy of unknown aetiology, occurring within 7 days following previous vaccination with a pertussis containing vaccine. In these circumstances pertussis vaccination should be discontinued and the vaccination should be continued with diphtheria-tetanus and polio vaccines.

PRECAUTIONS

***INFANRIX*[®] *IPV* should under no circumstances be administered intravenously.**

It is good clinical practice that immunisation should be preceded by a review of the medical history (especially with regard to previous immunisation and possible occurrence of undesirable events) and a clinical examination.

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of a rare anaphylactic reaction following the administration of the vaccine.

If any of the following events are known to have occurred in temporal relation to receipt of whole cell or acellular pertussis-containing vaccine, the decision to give further doses of vaccine containing the pertussis component should be carefully considered. There may be circumstances, such as a high incidence of pertussis, when the potential benefits of vaccination outweigh the possible risks, particularly since these events are not associated with permanent sequelae.

- Temperature of $\geq 40.0^{\circ}\text{C}$ within 48 hours, not due to another identifiable cause.
- Collapse or shock-like state (hypotonic-hyporesponsive episode) within 48 hours of vaccination.
- Persistent, inconsolable crying lasting ≥ 3 hours, occurring within 48 hours of vaccination.
- Convulsions with or without fever, occurring within 3 days of vaccination.

In children with progressive neurological disorders, including infantile spasms, uncontrolled epilepsy or progressive encephalopathy, it is better to defer pertussis (Pa or Pw) immunisation until the condition is corrected or stable. However, the decision to give

pertussis vaccine must be made on an individual basis after careful consideration of the risks and benefits.

A history of febrile convulsions, a family history of convulsions, a family history of Sudden Infant Death Syndrome (SIDS) or a family history of an adverse event following DTPa and/or IPV vaccination do not constitute contra-indications.

As with other vaccines, the administration of *INFANRIX*[®] IPV should be postponed in subjects suffering from acute severe febrile illness. The presence of a minor infection, however, is not a contraindication.

INFANRIX[®] IPV should be administered with caution to subjects with thrombocytopenia or a bleeding disorder since bleeding may occur following an intramuscular administration to these subjects. Firm pressure should be applied to the injection site (without rubbing) for at least two minutes.

INFANRIX[®] IPV contains traces of neomycin sulfate and polymyxin sulfate. The vaccine should be used with caution in patients with known hypersensitivity to one of these antibiotics.

Human Immunodeficiency Virus (HIV) infection is not considered a contra-indication to *INFANRIX*[®] IPV vaccination. However in patients with immunodeficiency or in patients receiving immunosuppressive therapy, the expected immunologic response may not be achieved. No data currently exist on use of *INFANRIX*[®] IPV in these patients.

Use During Pregnancy:

Adequate human data on use during pregnancy and adequate animal reproduction studies are not available.

Use During Lactation:

Adequate human data on use during lactation and adequate animal reproduction studies are not available.

Interactions with other drugs

It is current practice in paediatric vaccination to co-administer different vaccines during the same session. Injectable vaccines should always be given at different injection sites.

INFANRIX[®] IPV can be administered concomitantly with hepatitis B vaccine, and/or *Haemophilus influenzae* type b vaccine, the injections being administered at different

injection sites. Routine simultaneous administration of Hib vaccine and hepatitis B vaccine may be performed for children who are at the recommended age to receive these vaccines.

Concomitant administration of *INFANRIX*[®] *IPV* and the PRP-OMP type Hib vaccine, measles, mumps and rubella combined vaccine, and varicella vaccine has not been assessed in clinical studies. The Australian Immunisation Handbook 2000 accepts that these vaccines may be given at the same time if separate injection sites are used.

INFANRIX[®] *IPV* should not be mixed with other vaccines in the same syringe.

ADVERSE REACTIONS

Clinical Trial Experience

Adverse reactions associated with *INFANRIX*[®] *IPV* vaccination have been evaluated in 13 clinical trials, with more than 2,400 doses administered. Adverse event data were actively collected using diary cards and by questioning the parents at clinic visits.

Events are listed within body systems and categorised by frequency according to the following definitions:

Frequencies per dose are defined as follows:

Very common: $\geq 10\%$

Common: $\geq 1\%$ and $< 10\%$

Uncommon: $\geq 0.1\%$ and $< 1\%$

Rare: $\geq 0.01\%$ and $< 0.1\%$

Very rare: $< 0.01\%$

Primary vaccination with *INFANRIX*[®] *IPV*

*Incidence (%) of general solicited symptoms reported within 48 hours following primary immunisation of infants with *INFANRIX*[®] *IPV* at a 3, 4.5, 6 month schedule*

Solicited Symptoms	% incidence (N = 726)
<i>Local Reactions:</i>	
Pain at the injection site	16.3
Redness (>20mm)	4.4
Swelling (>20mm)	3.4
<i>General Symptoms:</i>	
Fever: Any [#]	6.1

Grade 3 [@]	0.1
Loss of appetite	10.7
Restlessness	22.7
Unusual crying	18.2
Vomiting	6.5
Diarrhoea	11.6

N = Total number of doses administered over a 3 dose primary vaccination course

= A temperature of $\geq 37.5^{\circ}\text{C}$ (axillary or oral) or $\geq 38^{\circ}\text{C}$ (rectal)

@ = A temperature of $> 39^{\circ}\text{C}$ (axillary or oral) or $> 39.5^{\circ}\text{C}$ (rectal)

The following events were also reported in temporal association with vaccination in clinical trials evaluating the 3 dose primary vaccination schedules. It should be noted that causality has not necessarily been established for these events.

Events are listed within body systems and categorised by frequency according to the following definitions:

Frequencies per dose are defined as follows:

Very common: $\geq 10\%$

Common: $\geq 1\%$ and $< 10\%$

Uncommon: $\geq 0.1\%$ and $< 1\%$

Rare: $\geq 0.01\%$ and $< 0.1\%$

Very rare: $< 0.01\%$

Body as a whole: *Uncommon*: bacterial infection, fungal infection, viral infection, herpes zoster (chicken pox), moniliasis

Cardiovascular: *Uncommon*: haematoma

Central Nervous System: *Very Common*: Somnolence

Dermatological: *Uncommon*: rash³, dermatitis, dermatitis contact, eczema, rash erythematous, urticaria

Gastrointestinal: *Common*: tooth ache; vomiting, *Uncommon*: dyspepsia, hiccup, abdominal pain, gastroenteritis, gastro-oesophageal reflux, constipation, flatulence

Injection site: *Very common*: redness, local swelling at injection site ($\leq 50\text{mm}$), fever ($> 38^{\circ}\text{C}$)

Common: injection site mass ($> 50\text{mm}$), asthenia¹, injection site reactions including induration

Uncommon: diffuse swelling of the injected limb, sometimes involving the adjacent joint¹, fever ($\geq 39.5^{\circ}\text{C}$)

Nervous System: *Uncommon*: insomnia

Psychiatric: *very common*: irritability

Respiratory: *Common*: rhinitis, pharyngitis, upper respiratory tract infection

Uncommon: asthma, coughing³, pneumonia, respiratory disorder, bronchitis³

Special senses: *Common:* otitis media; *Uncommon:* conjunctivitis

Urogenital: *Uncommon:* pyelonephritis

Booster vaccination with *INFANRIX*[®] IPV at 4-6 years of age

*Incidence (%) of solicited symptoms reported within 48 hours from a study of booster immunisation with *INFANRIX*[®] IPV at 4-6 years of age*

	following primary immunisation (study A)	following primary and first booster immunisation (study B)
Solicited Symptoms	% incidence (*N = 210)	% incidence (*N = 73)
Local Reactions:		
Pain at the injection site:		
Any	71.4	82.2
Grade 3	2.9	5.5
Redness:		
Any	61.0	65.8
>50mm	25.7	9.6
Swelling:		
Any	53.3	52.1
>50mm	13.3	5.5
General Symptoms:		
Fever:		
Any [#]	21.0	9.6
Grade 3 [@]	0.5	0.0
Irritability	16.7	13.7
Vomiting	not solicited	1.4
Diarrhoea	not solicited	2.7
Loss of appetite	19.0	12.3
Restlessness	not solicited	6.8
Sleeping more than usual/drowsiness	24.8	17.8

Note: Study A: Primary immunisation with DTPa-containing vaccines at 3, 5, 11 months of age; Study B: Primary and first booster immunisation with DTPw-IPV or DTPw-IPV/Hib vaccine. The occurrence and severity of symptoms was assessed using diary cards listing the events tabulated. "Not solicited" indicates that the event was not listed on the diary card for evaluation.

**N = Number of subjects*

= A temperature of $\geq 37.5^{\circ}\text{C}$ (axillary or oral) or $\geq 38^{\circ}\text{C}$ (rectal)

@ = A temperature of $> 39^{\circ}\text{C}$ (axillary or oral) or $> 39.5^{\circ}\text{C}$ (rectal)

The following events were also reported in temporal association with vaccination in clinical trials evaluating booster vaccination schedules. It should be noted that causality has not necessarily been established for these events.

Events are listed within body systems and categorised by frequency according to the following definitions:

Frequencies per dose are defined as follows:

Very common: $\geq 10\%$

Common: $\geq 1\%$ and $< 10\%$

Uncommon: $\geq 0.1\%$ and $< 1\%$

Rare: $\geq 0.01\%$ and $< 0.1\%$

Very rare: $< 0.01\%$

Injection site: *Very common:* local swelling at the injection site (≤ 50 mm)

Common: local swelling at the injection site (>50 mm)¹, injection site reactions including induration.*

Uncommon: diffuse swelling of the injected limb, sometimes involving the adjacent joint¹

Body as a whole: *Common:* asthenia, malaise; *Uncommon:* viral infection

Blood and lymphatic system disorders: *rare:* Lymphadenopathy

Dermatological: *Common:* pruritis

Uncommon: dermatitis allergic

Rare: urticaria,

Gastrointestinal: *common:* nausea, vomiting, diarrhoea

Uncommon: abdominal pain

Musculoskeletal: *Uncommon:* myalgia

Nervous system disorders: *Very common:* Headache (age range 6-13 years old), somnolence

Psychiatric disorders: *Very common:* restlessness, crying abnormally

Respiratory: *Common:* coughing³, rhinitis, pharyngitis; *Uncommon:* bronchitis³

Special senses: *Common:* otitis media

Post-marketing Experience

During post marketing surveillance, other reactions have been reported in temporal association with *INFANRIX*[®] *IPV* or with other DTPa-containing vaccines. None of the reactions were reported with a frequency higher than 0.01%.

Note that exact incidence rates cannot be calculated under post-marketing experience.

Administration site conditions: *very rare:* injection site mass, swelling of the entire injected limb, injection site vesicles.

Body as a whole: *very rare:* Allergic reactions (including rash and pruritus), including anaphylactic³ and anaphylactoid reactions (including urticaria),

Blood and lymphatic system disorders: Thrombocytopenia²

Dermatological: *very rare:* angioneurotic oedema.³

Neurological disorders: *very rare:* cConvulsions (with or without fever) within 2 to 3 days of vaccination, collapse or shock-like state (hypotonic-hyporesponsiveness episode).

Respiratory disorders: Apnoea³

¹Children primed with acellular pertussis vaccines are more likely to experience swelling reactions after booster administration in comparison with children primed with whole cell vaccines. Local swelling at the injection site (>50 mm) and diffuse swelling may be more frequent (very common and common, respectively) when the booster dose is administered between 4 and 6 years. These reactions resolve over an average of 4 days.

²Reported with D and T vaccines

³Reported with GSK's DTPa containing vaccines

DOSAGE AND ADMINISTRATION

All parenteral drug and vaccine products should be inspected visually for any particulate matter or discolouration prior to administration. Before use of *INFANRIX® IPV*, the vaccine should be well shaken to obtain a homogenous turbid suspension. Discard the vaccine if it appears otherwise. The vaccine should be administered immediately after opening.

Dosage

Each dose consists of a 0.5mL ready to use sterile suspension.

Overdosage

Cases of overdose have been reported during post-marketing surveillance. Adverse events, when reported, are not specific but similar to adverse events reported with normal vaccine administration.

Administration

INFANRIX[®] *IPV* is administered by deep intramuscular injection. For infants, the preferred site of injection is the anterolateral aspect of the thigh because of the small size of their deltoid muscle. In older children, the booster vaccination should be administered in the deltoid region of the arm. The recommended dose (0.5mL) of vaccine must be administered. Each dose of *INFANRIX*[®] *IPV* is for single use only. Any residual vaccine must be discarded.

INFANRIX[®] *IPV* VACCINE SHOULD NEVER BE ADMINISTERED INTRAVENOUSLY.

Immunisation Schedule

Primary

The primary vaccination course consists of three doses of *INFANRIX*[®] *IPV*. *INFANRIX*[®] *IPV* is recommended for administration at 2, 4 and 6 months of age. An interval of at least 1 month should be maintained between subsequent doses.

Booster

A single booster dose of *INFANRIX*[®] *IPV* can be given up to and including 6 years of age.

Storage

INFANRIX[®] *IPV* should be stored between +2°C and +8°C. DO NOT FREEZE. Discard if vaccine has been frozen. Protect from light.

The expiry date of the vaccine is indicated on the label and packaging.

PRESENTATIONS

INFANRIX[®] *IPV* is presented as a turbid white suspension in a prefilled syringe or vial*. Upon storage, a white deposit and clear supernatant can be observed.

The syringes and vials are made of neutral glass type I, which conforms to European Pharmacopoeia Requirements.

MANUFACTURER

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DISTRIBUTED IN AUSTRALIA BY

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* The vial presentation is not currently marketed in Australia.

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