



ADACEL – A summary of the product information for providers

What does ADACEL protect against?

Diphtheria-tetanus-pertussis = dTpa

ADACEL is a:

Pertussis Vaccine –Acellular combined with Diphtheria and Tetanus Toxoids (Adsorbed)

Description

ADACEL is a sterile, uniform, cloudy, white suspension for injection.

Dosage and Administration

- **ADACEL is supplied as a single dose (0.5ml) in a 2 ml glass vial**
- The same dosage, a single 0.5ml dose, applies to all age groups
- The vaccines normal appearance is a uniform cloudy, white suspension which may sediment during storage
- Shake the vial well to uniformly distribute the suspension before withdrawing the dose
- Inspect for any discolouration or ‘particles’ prior to administration – do not administer if these conditions exist
- ADACEL should be administered intramuscularly
- The preferred site is into the deltoid muscle
- The intravascular or subcutaneous routes should not be used
- ADACEL must not be mixed in the same syringe with other vaccines

Storage

- Store at 2-8°C
- Refrigerate. DO NOT FREEZE

Contraindications

- **ADACEL should not be administered to individuals who have :**
 - had previous hypersensitivity reaction to any vaccine containing diphtheria or tetanus toxoids, or Pertussis (acellular or whole cell)
 - known hypersensitivity to any component of the vaccine or residues carried over from the manufacture (such as formaldehyde and glutaraldehyde).
- **ADACEL should not be administered to subjects** who experienced encephalopathy of unknown origin within 7 days of previous immunisations with a pertussis –containing vaccine, or
 - to subjects who have experienced other neurological complications following previous immunisation with any of the antigens in ADACEL

Precautions

- The vaccine must be given intramuscularly, as subcutaneous administration increases the chances of a local reaction
- Do not administer by intravascular injection





Delivering a Healthy WA

- A persistent nodule at the site of injection may occur with all adsorbed vaccines particularly if administered into the superficial layers of the subcutaneous tissue
- Intramuscular injections should be given with care in patients suffering from coagulation disorders because of the risk of haemorrhage
- In these situations administration of ADACEL by deep subcutaneous injection may be considered, although there is a risk of increased local reactions
- The immunogenicity of the vaccine could be reduced by immunosuppressive treatment or immunodeficiency
- It is recommended to postpone the vaccination until the end of such disease or treatment if practical

Be prepared for some minor adverse reactions which are usually short lasting

Very Common

- pain at the site of injection
 - swelling and redness at the injection site
 - headache
 - decreased energy
 - generalised body ache
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- All adverse reactions reported to the TGA were generally mild and transient in duration
 - Fever was reported in <3% of vaccinees
 - There were no reports of fever over 39.9 degrees

Post Marketing Experience

- The following events have been reported during the commercial use of ADACEL – in addition to clinical studies
- injection site bruising
- sterile abscess
- pruritus
- urticaria

Variation of product information

- The product information for Adacel states that the vaccine is recommended for use in those aged >10 years
- NHMRC (Australian Immunisation Handbook) recommends that they may be used in people aged ≥8 years.
- The product information also states that dTpa should not be given within 5 years of a tetanus toxoid-containing vaccine.
- NHMRC recommends that a single dose of dTpa vaccine can be administered at any time following receipt of a diphtheria and tetanus toxoid-containing vaccine (this is a booster dose so the antigen is lower than that found in primary course vaccines)

