

State of California—Health and Human Services Agency California Department of Public Health



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TO: California Vaccines for Children (VFC) Program Providers

FROM: Sarah Royce, M.D., M.P.H, Chief

Center for Infectious Diseases

Division of Communicable Disease Control, Immunization Branch

SUBJECT: TENIVAC® SUPPLY ISSUES AND NEW Td (TETANUS AND

DIPHTHERIA TOXOIDS-ADSORBED), GRIFOLS, OPTION

The California Vaccines for Children (VFC) program was recently notified that Tenivac[®] (Tetanus and Diphtheria Toxoids Adsorbed) Td vaccine will be unavailable during the first half of 2017. As a substitute during this temporary shortage, Td vaccine from Grifols is now available for VFC orders.

Grifols Td vaccine is manufactured by Mass Biologics and was first licensed by the U.S. Food and Drug Administration (FDA) in 1970. It is indicated for the prevention of tetanus and diphtheria in persons 7 years of age and older. This vaccine contains ≤0.3 mcg mercury/dose, trace levels below the threshold level in California's thimerosal law. For further details, please review the <u>FDA Product Information</u>.

Td Vaccine Use

Td vaccine use is limited in children and adolescents; Tdap vaccine is indicated in most instances. <u>ACIP recommends</u> giving 1 dose of Tdap to any person 7 through 18 years of age who has not previously received any doses of pediatric DTP, DTaP, DT or Td vaccine, followed by a dose of Td four weeks after the first dose and a second dose of Td 6-12 months later. After a severe or contaminated wound or burn, Td is recommended 5 years after the most recent dose of Tdap or Td.

Reminder: <u>Each pregnant teen should receive Tdap vaccine</u>, rather than Td, at the earliest opportunity during the recommended 27-36 week gestation period with EACH pregnancy to protect her baby against whooping cough (pertussis), regardless of history of prior Tdap.

Administration of Td (Grifols)

Shake the vial well to resuspend the vaccine before withdrawing the dose. After shaking, the vaccine is a homogenous milky white suspension. Inspect the vaccine visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If there are any particulates or discoloration, do not administer the vaccine. Administer vial contents via intramuscular injection, preferably in the deltoid muscle.

How Supplied

Package of 10 single dose vials (0.5 mL). The stopper of the vial is latex-free.

Storage

Store at 2°C–8°C (36°F–46°F). Do NOT freeze. Discard if exposed to freezing.

Please review the references in this letter for further information on ACIP recommendations and other details.

ORDERING INSTRUCTIONS

The Td (Grifols) vaccine is now available for VFC Providers to order through their MyVFCvaccines account. Once VFC supplies of Tenivac[®] are depleted, the product will be temporarily removed from the online VFC order form until supply becomes available again later in 2017.

REFERENCES

FDA Product Information:

 $\frac{http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm164123}{.htm}$

<u>ACIP Recommendations</u>: https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/tdap-td.html

<u>Td Vaccine Information Statement (VIS):</u> https://www.cdc.gov/vaccines/hcp/vis/vis-statements/td.html

VFC Resolution:

https://www.cdc.gov/vaccines/programs/vfc/downloads/resolutions/1012-1-dtap.pdf

Medi-Cal Provider Manual: http://files.medi-cal.ca.gov/pubsdoco/Manuals menu.asp

CHDP Provider Manual: http://files.medi-cal.ca.gov/pubsdoco/chdp_manual.asp