

TQ-PCV VAX

13-valent Pneumococcal Polysaccharide Conjugate Vaccine

pre-filled syringe or vial injection, 0.5 mL/syringe or vial

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What TQ-PCV VAX is and what it is used for.
2. Before you take TQ-PCV VAX.
3. How to take TQ-PCV VAX.
4. Possible side effects.
5. How to store TQ-PCV VAX.
6. Further information.

1. What TQ-PCV VAX is and what it is used for:

TQ-PCV VAX is a pneumococcal vaccine given to:

TQ-PCV VAX is a vaccine which helps protect against infectious diseases caused by bacteria (germs) called Streptococcus pneumoniae types 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F.

TQ-PCV VAX may be given to infants and children aged 6 weeks through 5 years of age (before their 6th birthday).

TQ-PCV VAX works by helping the body to produce its own protection (antibodies) against the bacteria. TQ-PCV VAX provides protection against 13 types of Streptococcus pneumoniae bacteria. It does not protect against infections caused by other types of Streptococcus pneumoniae and diseases caused by other bacteria or viruses.

2. Before you take TQ-PCV VAX:

TQ-PCV VAX should not be given if you or your child:

- 1) are allergic to any of the active substance or any of the other ingredients in this vaccine (listed in section 6) or have experienced a previous allergic reaction to this vaccine.

Signs of an allergic reaction may include itchy skin rash, shortness of breath and swelling of the face or tongue. See your doctor immediately if you notice any of these.

b. Take special care with TQ-PCV VAX:

Talk to your doctor, pharmacist, or nurse before the vaccination if you or your child:

- 1) have any bleeding problems or bruises easily.
- 2) have a weakened immune system (such as due to HIV infection), you/she/he may not get the full benefit from TQ-PCV VAX.
- 3) have acute infectious disease and fever. If this applies, the vaccination will be given after the infection is under control.

Talk to your doctor, pharmacist, or

nurse before the vaccination if your child was born very prematurely (at or before 30 weeks of gestation). See also section 4.

As with any vaccine, TQ-PCV VAX will not fully protect all people who are vaccinated. Some people who have had a pneumococcal vaccine may still get pneumococcal diseases, but they tend to be less severe than if they did not get the shot.

TQ-PCV VAX will only protect against infectious disease caused by the types of Streptococcus pneumoniae for which the vaccine has been developed. It will not protect against other disease that are caused by bacteria types that are not in the vaccine.

Other medicines / vaccines and TQ-PCV VAX

Tell your doctor, pharmacist, or nurse if you or your child are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

The safety and immunogenicity of TQ-PCV VAX given concomitantly with other vaccines remain unknown.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor, pharmacist, or nurse for advice before receiving TQ-PCV VAX.

Driving and using machines

TQ-PCV VAX is not likely to affect your ability to drive, cycle, or use machines. However, do not drive, circle, or use any machines if you are not feeling well.

TQ-PCV VAX contains sodium

This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e., essentially 'sodium-free'

3. How to take TQ-PCV VAX:

The doctor, pharmacist, or nurse will inject the recommended dose (0.5 mL) of the vaccine into your arm or your child's arm or leg muscle.

Infants aged 2 months (≥ 6 weeks) to 6 months:

Typically, your child should receive an initial course of three injections of the vaccine followed by a booster dose.

Infants aged 2 months (≥ 6 weeks):

- The first injection may be given as early as 6 weeks of age.

- Each injection will be given 2 months apart.

- A fourth injection (booster) will be given between 12 and 15 months of age.

Your child will receive an initial course of three injections. The first injection may be given as early as six weeks of age with 2 months between doses. Between 12 and 15 months of age, your child will receive a fourth injection (booster).

Infants aged 3 months without previous PCV dosing:

- The first injection may be given at the age of 3 months.

- Each injection will be given 1 month apart.

- A fourth injection (booster) will be given between 12 and 15 months of

age.

Your child will receive an initial course of three injections. The first injection may be given at 3 months of age with 1 month between doses. Between 12 and 15 months of age, your child will receive a fourth injection (booster).

Infants and Children 7 months of age (prior to the 6th birthday) and above:

Infants aged 7 to 11 months without previous PCV dosing should receive 3 injections. Each injection will be given at least 2 months apart. A third injection will be given in the second year of life.

Children aged 12 to 23 months without previous PCV dosing should receive 2 injections. Each injection will be given at least 2 months apart.

Children aged 2 to 5 years without previous PCV dosing should receive one injection.

It is important to follow the instructions from the doctor, pharmacist, or nurse so that your child completes the course of injections.

If you forget to go back at the scheduled time, ask the doctor, pharmacist, or nurse for advice.

4. Possible side effects

Like all vaccines, TQ-PCV VAX can cause side effects, although not everybody gets them.

The following side effects may happen with TQ-PCV VAX in infants and children (6 weeks to 5 years of age):

Very common (these may occur with more than 1 in 10 people):

- Fever.
- Diarrhea.
- Redness where the injection is given.
- Common (these may occur with up to 1 in 10 people):
- Crying.
- Cough.
- Nausea/vomiting.
- Feeling tired (fatigue)/ feeling drowsy.
- Allergic reaction.
- Reactions where the injection is given such as swelling, pain, or hard lump.

Uncommon (these may occur with up to 1 in 100 people):

- Muscle pain.
- Itching where the injection is given.
- Rare (these may occur with up to 1 in 1,000 people):
- Rash where the injection is given.

Reporting of suspected adverse reactions

Website: jpc@jfda.jo

The link to the electronic reporting on JFDA website (www.jfda.com):

<https://primaryreporting.who-umc.org/10>

Tel: +962-6-5632000

rapid response number QR Code:



5. How to store TQ-PCV VAX

- Keep out of the reach and sight of children.

- Do not use TQ-PCV VAX after the expiry date, which is stated on the carton and the blister after EXP., The expiry date refers to the last day of that month.

- Store and transport at 2-8 °C, protect from light, do not freeze, Discard if the vaccine is frozen.

- Use immediately after shaking well.

6. Further information

a. What TQ-PCV VAX contains:

The active substance: contains 2.6 µg/dose of each of serotype 1 and 19A, 2.5 µg/dose of each of serotype 3, 5, 6A, and 9V, 3.0 µg/dose of each of serotype 4 and 23F, 6 µg/dose of serotype 6B, 2.85 µg/dose of serotype 7F, 2.75 µg/dose of each of serotype 14 and 19F, 3.25 µg/dose of serotype 18C.

b. what TQ-PCV VAX look like and contents of the pack:

TQ-PCV VAX: Each 1 mL syringe or vial contains a single 0.5 mL dose of vaccine for intramuscular administration, with no preservative.

The other ingredient: Sodium chloride, sodium dihydrogen phosphate monohydrate, disodium hydrogen phosphate dodecahydrate, aluminum phosphate and water for injection.

- Physical Description:

The vaccine is a homogeneous milky suspension. During storage, a white deposit and clear supernatant might be observed due to adjuvant precipitation.

- Pharmaceutical form:

Pre-filled syringe or vial injection, 0.5 mL/syringe or vial, 0.5 mL for each human dose.

c. Marketing Authorization Holder Al-Taqaddom Pharmaceutical Industries

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Vaccine Manufacturer: Yuxi Walvax Biotechnology Co., Ltd.

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Fax: 0877-2076918

d. This leaflet was last revised in 04/2024;

I-TQPCVVAX-TPMV-L0-R0/AE

This is a medicament

- A medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep medicament out of the reach of children.

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