Package leaflet: Information for the user
Vaxneuvance® suspension for injection in pre-filled syringe
Pneumococcal polysaccharide conjugate vaccine (15-valent, adsorbed)

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you or your child may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you or your child is vaccinated because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, or nurse.
- This vaccine has been prescribed for you or your child only. Do not pass it on to others.
- If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Vaxneuvance is and what it is used for

Vaxneuvance is a pneumococcal vaccine given to:
- **children from 6 weeks to less than 18 years of age** to help protect against diseases such as lung infection (pneumonia), inflammation of the coverings of the brain and spinal cord (meningitis), a severe infection in the blood (bacteraemia) and ear infections (acute otitis media),
- **individuals 18 years of age and older** to help protect against diseases such as lung infection (pneumonia), inflammation of the coverings of the brain and spinal cord (meningitis) and a severe infection in the blood (bacteraemia), caused by 15 types of bacteria called *Streptococcus pneumoniae* or pneumococcus.

2. What you need to know before you or your child receives Vaxneuvance

Do not receive Vaxneuvance if:
- you or your child is allergic to the active substances or to any of the ingredients of this vaccine (listed in section 6), or to any vaccine that contains diphtheria toxoid.

Warnings and precautions
Talk to your doctor, pharmacist, or nurse before you or your child receives Vaxneuvance if:
- the immune system is weak (which means the body is less able to fight off infections) or if you or your child is taking certain medicines that may make the immune system weak (for example, immunosuppressants or steroids).
- you or your child has a high fever or severe infection. In these cases, the vaccination may have to be postponed until you or your child has recovered. However, a mild fever or infection (for example having a cold) itself is not a reason to delay vaccination.
- you or your child has any bleeding problems, bruises easily, or is taking medicines to prevent blood clots.

If your child is an infant, also tell your doctor if your child was born prematurely (too early).

As with any vaccine, Vaxneuvance may not fully protect all persons who are vaccinated.

Other medicines/vaccines and Vaxneuvance
Your child can be given Vaxneuvance at the same time as other routine childhood vaccines.

In adults, Vaxneuvance can be given at the same time as the flu (inactivated influenza) vaccine.

Tell your doctor, pharmacist, or nurse if:
- you or your child is taking, has recently taken, or might take any prescription medicines (for example, immunosuppressants or steroids which may make the immune system weak) or any medicines obtained without a prescription.
- you or your child has recently received or plan to receive any other vaccine.

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 you receive this vaccine.

Driving and using machines
Vaxneuvance has no or negligible influence on the ability to drive and use machines. However, some of the effects mentioned under section 4 “Possible side effects” may temporarily affect the ability to drive or use machines.

Vaxneuvance contains sodium
This medicine contains less than 1 mmol sodium (23 milligrams) per dose, that is to say essentially ‘sodium-free’.

3. How Vaxneuvance is given

Tell your doctor, pharmacist, or nurse if you or your child has been given a pneumococcal vaccine before.
Your doctor or nurse will give the vaccine into your arm muscle or into your child's arm or leg muscle.

Infants and children aged 6 weeks to less than 2 years
Your child should receive an initial course of 2 injections of the vaccine followed by a booster dose.
- The first injection may be given as early as 6 weeks of age.
- A second injection is administered 2 months later.
- A third injection (booster) will be given between 11 through 15 months of age.

You will be told when your child should come back for each injection.

According to official recommendations in your country, an alternative schedule of 3 injections followed by a booster dose may be used by your healthcare provider. Please speak to your doctor, pharmacist, or nurse for more information.

Premature infants (born earlier than 37 weeks of pregnancy)
Your child should receive an initial course of 3 injections of the vaccine followed by a booster dose.
- The first injection may be given as early as 6 weeks of age.
- The second and third injections are given thereafter with an interval of 4 to 8 weeks between doses.
- A fourth injection (booster) will be given between 11 through 15 months of age.

Infants, children and adolescents starting the vaccination at 7 months of age or older
Infants 7 to less than 12 months of age should receive a total of 3 injections. The first two injections will be given at least 1 month apart. The third injection (booster) will be given after 12 months of age and at least 2 months after the second injection.

Children 12 months to less than 2 years of age should receive a total of 2 injections. The two injections will be given at least 2 months apart.
Children and adolescents 2 to less than 18 years of age should receive 1 injection.

Adults
Adults should receive 1 injection.

Special populations
One or more injections of Vaxneuvance may be given to individuals who have one or more underlying conditions that increase their risk for pneumococcal disease (such as individuals with sickle cell disease or living with human immunodeficiency virus [HIV] or recipients of a stem cell transplant).

If you have any further questions on the use of Vaxneuvance, ask your doctor, pharmacist, or nurse.

4. Possible side effects

Like all vaccines, Vaxneuvance can cause side effects, although not everybody gets them.

Get medical care right away if you or your child has symptoms of an allergic reaction, which may include:
- Wheezing or trouble breathing
- Swelling of the face, lips, or tongue
- Hives
- Rash

The following side effects can be seen after the use of Vaxneuvance in infants, children and adolescents:

Very common (may affect more than 1 in 10 people):
- Fever (temperature of 38 °C or higher in those 6 weeks to less than 2 years of age)
- Irritability (in those 6 weeks to less than 2 years of age)
- Drowsiness (in those 6 weeks to less than 2 years of age)
- Pain, redness or swelling at the injection site
- Decreased appetite (in those 6 weeks to less than 2 years of age)
- Hardness at the injection site (in those 6 weeks to less than 2 years of age)
- Muscle aches (in those 2 to less than 18 years of age)
- Feeling tired (in those 2 to less than 18 years of age)
- Headache (in those 2 to less than 18 years of age)

Common (may affect up to 1 in 10 people):
- Hardness at the injection site (in those 2 to less than 18 years of age)
- Hives
- Fever (temperature of 38 °C or higher in those 2 to less than 18 years of age)
- Vomiting (in those 6 weeks to less than 2 years of age)
- Rash (in those 6 weeks to less than 2 years of age)
- Irritability (in those 2 to less than 18 years of age)
- Drowsiness (in those 2 to less than 18 years of age)
- Decreased appetite (in those 2 to less than 18 years of age)
- Bruising at the injection site
- Nausea (in those 2 to less than 18 years of age)

Uncommon (may affect up to 1 in 100 people):
- Vomiting (in those 2 to less than 18 years of age)

Not known (cannot be estimated from the available data):
- Rash (in those 2 to less than 18 years of age)

The following side effects can be seen after the use of Vaxneuvance in adults:

Very common (may affect more than 1 in 10 people):
- Pain, swelling, or redness at the injection site
- Feeling tired
- Muscle aches
- Headaches
- Joint pain (in those 18 to 49 years of age)

Common (may affect up to 1 in 10 people):
- Joint pain (in those 50 years of age and older)
- Nausea (in those 18 to 49 years of age)
- Fever (in those 18 to 49 years of age)
- Itchiness at the injection site
- Dizziness (in those 18 to 49 years of age)
- Chills (in those 18 to 49 years of age)

Uncommon (may affect up to 1 in 100 people):
- Fever (in those 50 years of age and older)
- Warmth at the injection site
- Bruising at the injection site
- Dizziness (in those 50 years of age and older)
- Nausea (in those 50 years of age and older)
- Vomiting
- Chills (in those 50 years of age and older)
- Rash

Rare (may affect up to 1 in 1,000 people):
- Allergic reaction such as hives, tongue swelling, flushing, and throat tightness

These side effects are generally mild and last a short time.

Reporting of side effects
If you or your child gets any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vaxneuvance

Keep this vaccine out of the sight and reach of children.

Do not use this vaccine after the expiry date which is stated on the carton and syringe label after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C – 8 °C). Do not freeze. Keep the pre-filled syringe in the outer carton in order to protect from light.

Vaxneuvance should be administered as soon as possible after being removed from the refrigerator. However, in circumstances where Vaxneuvance is temporarily held outside of refrigeration, the vaccine is stable at temperatures up to 25 °C for 48 hours.

6. Contents of the pack and other information

What Vaxneuvance contains
The active substances are:
- bacterial sugars from pneumococcus types 1, 3, 4, 5, 6A, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F, and 33F (2.0 micrograms of each type);
- bacterial sugar from pneumococcus type 6B (4.0 micrograms).

Each bacterial sugar is linked to a carrier protein (CRM_{197}). The bacterial sugars and the carrier protein are not alive and do not cause disease.

One dose (0.5 mL) contains approximately 30 micrograms carrier protein, adsorbed on aluminium phosphate (125 micrograms aluminium [Al^{3+}]). Aluminium phosphate is included in the vaccine as an adjuvant. Adjuvants are included to improve the immune responses of vaccines.

The other ingredients are sodium chloride (NaCl), L-histidine, polysorbate 20, and water for injections.

What Vaxneuvance looks like and contents of the pack
Vaxneuvance is an opalescent suspension for injection, provided in a single-dose, pre-filled syringe (0.5 mL). Vaxneuvance is available in pack sizes of 1 or 10, either without needles, with 1 separate needle, or with 2 separate needles.
Vaxneuvance is also available in multipacks comprising 5 cartons, each containing 10 pre-filled syringes without needles.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder:
Merck Sharp & Dohme (UK) Limited
120 Moorgate
London EC2M 6UR
United Kingdom

Manufacturer:
Merck Sharp & Dohme B.V.
Waarderweg 39
2031 BN Haarlem
The Netherlands

For any information about this medicine, please contact:
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The following information is intended for healthcare professionals only:

Vaxneuvance must not be injected intravascularly.

- Immediately prior to use, hold the pre-filled syringe horizontally and shake vigorously to obtain an opalescent suspension. Do not use the vaccine if it cannot be resuspended.
- Inspect the suspension visually for particulate matter and discolouration prior to administration. Discard the vaccine if particulates are present and/or if it appears discoloured.
- Attach a needle with Luer lock connection by twisting in a clockwise direction until the needle fits securely on the syringe.
- Inject immediately using the intramuscular (IM) route, preferably in the anterolateral aspect of the thigh in infants or in the deltoid area of the upper arm in children and adults.
- Exercise care to avoid harm from an accidental needle stick.

No data are available for administration via the intradermal route.

Vaxneuvance must not be mixed with any other vaccines in the same syringe.

Vaxneuvance can be given concomitantly with other routine childhood vaccines.
Vaxneuvance can be administered concomitantly with seasonal quadrivalent influenza vaccine (split virion, inactivated) in adults.
Different injectable vaccines should always be administered at different injection sites.

Store in a refrigerator (2 ℃– 8 ℃). Do not freeze.

Keep the pre-filled syringe in the outer carton in order to protect from light.

Vaxneuvance should be administered as soon as possible after being removed from the refrigerator.

In the event of temporary temperature excursions, stability data indicate that Vaxneuvance is stable at temperatures up to 25 ℃ for 48 hours.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

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