PRODUCT INFORMATION

TYPHIM VI, solution for injection in prefilled syringe
POLYSACCHARIDE TYPHOID VACCINE

ENGLISH TRANSLATION

French MA updates	Sections of Annex I modified
18 June 2014	Full text

CAUTION – The French MA amendment received on 18 June 2014 contains errors.

A request was sent to Ansm on 22 July 2014 to correct the errors.
Among these errors, some of them have already been corrected, as indicated in the table below.

	Comments / corrections	ANSM text	Corrections in the PI
Annex IIB	Section 2: *Effects on the ability to drive or to use machines* Title is missing	The effects on the ability to drive and use machines have not been studied.	Driving and using machines The effects on the ability to drive and use machines have not been studied
	Section 4. Adverse reactions: bullet point is incorrect.	- severe allergic reactions (anaphylactic, anaphylactoid reactions, including shock) which can include one or several of the following symptoms: o (...) - when these signs or symptoms appear, it is usually very soon after the injection, while the person affected is still at the clinic or at the doctor's surgery. If one of these symptoms occurs after you have left the place where the injection was administered, you must consult a doctor IMMEDIATELY. - serum sickness disease: (...)	- severe allergic reactions (anaphylactic, anaphylactoid reactions, including shock) which can include one or several of the following symptoms: o (...) When these signs or symptoms appear, it is usually very soon after the injection, while the person affected is still at the clinic or at the doctor's surgery. If one of these symptoms occurs after you have left the place where the injection was administered, you must consult a doctor IMMEDIATELY. - serum sickness disease: (...)

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

TYPHIM Vi, solution for injection in prefilled syringe

Polysaccharide typhoid vaccine

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose of 0.5 ml of vaccine contains:

Polysaccharides of *Salmonella typhi* (Ty2 strain) ..... 25 micrograms

For the full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection in prefilled syringe.

Clear, colourless solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Prevention of typhoid fever in adults and in children over 2 years of age, and especially: travellers to endemic areas, migrants, health care professionals and military personnel.

4.2 Posology and method of administration

Posology

RESTRICTED TO ADULTS AND CHILDREN OVER 2 YEARS OF AGE.

A single injection ensures protection. If exposure to risk continues, revaccination will be performed every 3 years.

The vaccination schedule is the same for children and for adults.

Method of administration

Intramuscular or subcutaneous route.

4.3 Contraindications

Hypersensitivity to the active substance, to any of the excipients or to formaldehyde (which may be present as traces in each dose, owing to its use during the manufacturing process).

Vaccination should be postponed in case of acute febrile disease.

4.4 Special warnings and precautions for use

Do not inject by the intravascular route.

This vaccine protects against the risks of infection by *Salmonella typhi* but not against *Salmonella paratyphi* A or B or non-typhoidal salmonella.

This vaccine is not indicated in children under 2 years of age because of the risk of insufficient antibody response.

The immunogenicity of TYPHIM Vi may be reduced by immunosuppressive treatment or immunodeficiency. It is then recommended to wait until the end of the treatment or disease before vaccinating. Nevertheless, vaccination of subjects with chronic immunodeficiency such as HIV infection is recommended even if the immune response may be limited.

Injection must be performed via the subcutaneous route in subjects with thrombocytopenia or bleeding disorders.

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

4.5 Interaction with other medicinal products and other forms of interaction

This vaccine can be associated with other common vaccines (hepatitis A, yellow fever, diphtheria, tetanus, poliomyelitis, rabies, meningitis A + C and hepatitis B) during the same vaccination session, using separate injection sites.

4.6 Pregnancy and lactation

Pregnancy

No reliable animal teratogenic data are available.

Currently, no sufficiently relevant clinical data are available to assess a potential teratogenic or foetotoxic effect of this vaccine when administered during pregnancy.

Because of the seriousness of the disease, and in case of high risk of exposure to typhoid fever, pregnancy is not an obstacle to the vaccination protocol.

Lactation

This vaccine can be used during lactation.

4.7 Effects on ability to drive and use machines

The effects on the ability to drive and use machines have not been studied.

4.8 Undesirable effects

The adverse events come from clinical studies and worldwide post-marketing experience.

In each System Organ Class, the adverse events are ranked under headings of frequency, the most common reactions coming first, using the following convention:

Very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1000, <1/100), rare (≥1/10 000, <1/1000), very rare (<1/10 000) including isolated cases.

Clinical studies

During clinical development, more than 10 000 people received TYPHIM Vi (first or second injection). The most common adverse events were mild injection site reactions. They generally occurred within 48 hours of vaccination and disappeared within two days.

General disorders and administration site conditions
Very common: injection site pain, injection site induration, injection site erythema.
Common: fever.

Post-marketing experience

Based on spontaneous reporting, the following adverse events have also been reported during the commercial use of TYPHIM Vi. These events were very rarely reported. However, the exact incidence is not known (cannot be estimated based on the available data).

Immune system disorders
Anaphylactic, anaphylactoid reactions, including shock; serum sickness disease.

Nervous system disorders
Cephalalgia.

Respiratory, thoracic and mediastinal disorders
Asthma.

Gastrointestinal disorders
Nausea, vomiting, diarrhoea, abdominal pain.

Skin and subcutaneous tissue disorders
Allergic-like reactions such as pruritus, skin rash, urticaria.

Musculoskeletal and connective tissue disorders
Arthralgia, myalgia.

General disorders and administration site conditions
Fatigue, malaise.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system: « Agence nationale de sécurité du médicament et des produits de santé (Ansm) et réseau des Centres Régionaux de Pharmacovigilance » - Site internet: www.ansm.sante.fr.

4.9 Overdose

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ANTI-TYPHOID VACCINE

Pharmacotherapeutic group: bacterial vaccines: ATC code: J07AP03.

Vaccine prepared from purified Vi capsular polysaccharides of *Salmonella typhi*. Immunity appears about 15 days to 3 weeks after the injection. Protection lasts around 3 years.

During studies carried out in highly endemic areas, a seroprotection rate (for typhoid fever) of 77% in Nepal and 55% in South Africa has been observed after one vaccine injection. In industrialized countries, seroconversion is observed in more than 90% of subjects after a single injection.

5.2 Pharmacokinetic properties

Not applicable.

5.3 Preclinical safety data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phenol and a buffer solution containing sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate and water for injections.

6.2 Incompatibilities

In the absence of compatibility studies, this vaccine must not be mixed with other medicinal products.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store in a refrigerator (2°C - 8°C).

Do not freeze.

6.5 Nature and contents of container

0.5 ml of solution in prefilled syringe (type I glass) with a plunger stopper (chlorobromobutyl or chlorobutyl or bromobutyl). Box of 1 and 20.

0.5 ml of solution in prefilled syringe (type I glass) with a plunger stopper (chlorobromobutyl or chlorobutyl or bromobutyl), a tip-cap (chlorobromobutyl), without needle. Box of 1.

0.5 ml of solution in prefilled syringe (type I glass) with a plunger stopper (chlorobromobutyl or chlorobutyl or bromobutyl), a tip-cap (chlorobromobutyl), with 1 to 2 separate needles. Box of 1.

Not all pack sizes may be marketed.

6.6 Instructions for use, handling and disposal

The vaccine should be kept at room temperature for a few minutes before use.

For syringes without attached needles, the separate needle must be fitted firmly to the syringe, rotating it by a one quarter turn.

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

7. MARKETING AUTHORISATION HOLDER

SANOFI PASTEUR
2, AVENUE PONT PASTEUR
69007 LYON
FRANCE

8. MARKETING AUTHORISATION NUMBER(S)

- 339 841-1 or 34009 339 841 1 3: 0.5 ml of solution in prefilled syringe (type I glass) with a plunger stopper (chlorobromobutyl or chlorobutyl or bromobutyl). Box of 1.
- 331 507-5 or 34009 331 507 5 4: 0.5 ml of solution in prefilled syringe (type I glass) with a plunger stopper (chlorobromobutyl or chlorobutyl or bromobutyl). Box of 20.
- 369 928-8 or 34009 369 928 8 7: 0.5 ml of solution in prefilled syringe (type I glass) with a plunger stopper (chlorobromobutyl or chlorobutyl or bromobutyl), a tip-cap (chlorobromobutyl), without needle. Box of 1.
- 369 929-4 or 34009 369 929 4 8: 0.5 ml of solution in prefilled syringe (type I glass) with a plunger stopper (chlorobromobutyl or chlorobutyl or bromobutyl), a tip-cap (chlorobromobutyl), with one separate needle. Box of 1.
- 369 930-2 or 34009 369 930 2 0: 0.5 ml of solution in prefilled syringe (type I glass) with a plunger stopper (chlorobromobutyl or chlorobutyl or bromobutyl), a tip-cap (chlorobromobutyl), with two separate needles. Box of 1.

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

- Date of first authorisation: 28 November 1998
- Date of renewal of authorisation: 27 July 2007

10. DATE OF REVISION OF THE TEXT

18 June 2014

11. DOSIMETRY

Not applicable.

12. INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS

Not applicable.

GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product not subject to medical prescription.

ANNEX II

A. MANUFACTURER(S) OF THE BIOLOGICAL ACTIVE SUBSTANCE(S) AND MANUFACTURING AUTHORISATION HOLDER(S) RESPONSIBLE FOR BATCH RELEASE

A.1. Name and address of the manufacturer(s) of the biological active substance(s)

SANOFI PASTEUR
1541, AVENUE MARCEL MÉRIEUX
69280 MARCY L'ETOILE
FRANCE

A.2. Name and address of the manufacturer(s) responsible for batch release

SANOFI PASTEUR
2, AVENUE PONT PASTEUR
69007 LYON
FRANCE

B. CONDITIONS OF THE MARKETING AUTHORISATION

B.1. Conditions or restrictions regarding supply and use imposed on the marketing authorisation holder

Medicinal product not subject to medical prescription.

B.2. Conditions or restrictions with regard to the safe and effective use of the medicinal product

Not applicable.

B.3. Other conditions

Not applicable.

C. SPECIFIC OBLIGATIONS TO BE FULFILLED BY THE MARKETING AUTHORISATION HOLDER

Not applicable.

D. QUALITATIVE AND QUANTITATIVE COMPOSITION IN EXCIPIENTS

One dose (0.5 ml) of vaccine contains:

Phenol ..... ≤1.250 mg

Buffer solution containing:

- sodium chloride ..... 4.150 mg
- sodium dihydrogen phosphate dihydrate ..... 0.023 mg
- disodium phosphate dihydrate ..... 0.065 mg

Water for injections ..... qs 0.5 ml

The vaccine contains traces of formaldehyde.

ANNEX IIIA

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

NATURE/TYPE Outer packaging or immediate packaging

Outer packaging

1. NAME OF THE MEDICINAL PRODUCT

TYPHIM Vi, solution for injection in prefilled syringe.

Polysaccharide typhoid vaccine

2. STATEMENT OF ACTIVE SUBSTANCES

One dose of 0.5 ml of vaccine contains:

Polysaccharides of *Salmonella typhi* (Ty2 strain) ..... 25 micrograms

3. LIST OF EXCIPIENTS

Phenol and a buffer solution containing sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate and water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

Solution for injection (0.5 ml) in prefilled syringe <without needle> <with> <one> <two> <separate needles>.
Box of 1 and/or 20.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular (IM) or subcutaneous (SC) route.

Read the package leaflet before use.

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

Not applicable.

8. EXPIRY DATE

EXP {MM/YYYY}.

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2°C - 8°C).

Do not freeze.

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

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

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Holder

SANOFI PASTEUR
2, AVENUE PONT PASTEUR
69007 LYON
FRANCE

Distributor

SANOFI PASTEUR MSD SNC
8, RUE JONAS SALK
69007 LYON
FRANCE

Manufacturer

Not applicable.

12. MARKETING AUTHORISATION NUMBER(S)

Authorised Medicinal product N°:

13. BATCH NUMBER

Batch {number}.

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product not subject to medical prescription.

15. INSTRUCTIONS ON USE

Prevention of typhoid fever in adults and in children over 2 years of age.

16. INFORMATION IN BRAILLE

According to official recommendations.

PICTOGRAM TO APPEAR ON THE OUTER PACKAGING OR, WHERE THERE IS NO OUTER PACKAGING, ON THE IMMEDIATE PACKAGING

Not applicable.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

NATURE/TYPE Blisters/strips

Not applicable.

1. NAME OF THE MEDICINAL PRODUCT

Not applicable.

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Holder

Not applicable.

Distributor

Not applicable.

3. EXPIRY DATE

Not applicable.

4. BATCH NUMBER

Not applicable.

5. OTHER

Not applicable.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

NATURE/TYPE Small immediate packaging units

Prefilled syringe

1. NAME OF THE MEDICINAL PRODUCT AND ROUTE(S) OF ADMINISTRATION

TYPHIM Vi, solution for injection in prefilled syringe
Polysaccharide typhoid vaccine

IM or SC route.

2. METHOD OF ADMINISTRATION

Not applicable.

3. EXPIRY DATE

EXP {MM/YYYY}

4. BATCH NUMBER

Batch {number}

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

1 dose = 0.5 ml.

6. OTHER

Not applicable.

ANNEX IIIB

PACKAGE LEAFLET: INFORMATION FOR THE USER

Name of the medicinal product

TYPHIM Vi, solution for injection in prefilled syringe

Polysaccharide typhoid vaccine

Boxed text

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See Section 4.

Package leaflet summary

In this leaflet:

1. WHAT TYPHIM Vi, solution for injection in prefilled syringe IS AND WHAT IT IS USED FOR

Pharmacotherapeutic group

This medicinal product is a vaccine.

Vaccines are used to protect against infectious diseases.

Therapeutic indications

This vaccine helps protect adults and children over 2 years of age against typhoid fever.

Typhoid fever is caused by a bacterium called *Salmonella typhi.* The main symptoms include high fever (40°C), headache, insomnia, dizziness, epistaxis (nose bleeding), anorexia (loss of appetite), nausea, diarrhoea and consciousness disorders.

When you or your child receive an injection of TYPHIM Vi, the body's natural defences elaborate a protection against the infection caused by this bacterium.

TYPHIM Vi is intended for travellers to endemic areas (areas where the disease is present and affects a large part of the population), migrants, health care professionals and military personnel.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE TYPHIM Vi, solution for injection in prefilled syringe

List of information necessary before taking the medicinal product

Not applicable.

Contraindications

Do not use TYPHIM Vi:

- if you or your child are allergic (hypersensitive) to the active substance, to any of the other components of TYPHIM Vi (listed in Section 6), to formaldehyde (used during the production of the vaccine and which may be present in it in small amounts),
- if you or your child are ill with a high temperature. Vaccination must be postponed until after you have recovered.

Precautions for use; special warnings

Take special care with TYPHIM Vi:

- This vaccine protects against the typhoid fever bacterium (*Salmonella typhi*), but not against the related bacteria (*Salmonella paratyphi* A or B) or non-typhoidal salmonella.
- This vaccine is not indicated in children less than 2 years of age because it is not efficient enough.
- If you or your child have a weak immune system, due to:
  - Corticosteroid drugs, cytotoxic medicines, radiotherapy or other treatments likely to weaken your immune system. You doctor may wait until the end of treatment.
  - HIV (Human Immunodeficiency Virus) infection or any other diseases which weaken your immune system. It is recommended to administer the vaccine although it may not protect you as well as it would in a person with a normal immune system.
- If you or your child suffer from haemophilia or if you are easily prone to bruising or bleeding.

Interactions with other medicinal products

Use of other medicinal products:

TYPHIM Vi can be associated with other vaccines (hepatitis A, yellow fever, diphtheria, tetanus, poliomyelitis, rabies, meningitis A + C and hepatitis B) during the same vaccination session. However injections must be performed in separate injection sites, i.e. in another part of the body such as the other arm or the other leg, and the vaccines must not be mixed in the same syringe.

Please inform your doctor or pharmacist if you or your child take or have recently taken any other medicines, even those not prescribed.

Interactions with food and drinks

Not applicable.

Interaction with phytotherapy or alternative therapies

Not applicable.

Use during pregnancy and breast-feeding

Pregnancy and breast-feeding

Because of the seriousness of the disease, and in case of high risk of exposure to typhoid fever, pregnancy is not an obstacle to vaccination.

This vaccine will be used during pregnancy only if advised by your doctor.

This vaccine can be used during breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicines.

Athletes

Not applicable.

Effects on the ability to drive or to use machines

Driving and using machines

The effects on the ability to drive and use machines have not been studied.

List of excipients with recognised effect

Not applicable.

3. HOW TO USE TYPHIM Vi, solution for injection in prefilled syringe

Instructions for proper use

Not applicable.

Dosage, Method and/or route(s) of administration, Frequency of administration and Duration of treatment

Dosage

RESTRICTED TO ADULTS AND CHILDREN OVER 2 YEARS OF AGE.

A single dose (0.5 ml) is enough.

If exposure to risk continues, revaccination will be performed every 3 years.

The vaccination schedule is the same for children and for adults.

Method of administration

This vaccine will be administered to you in a muscle or under the skin by a healthcare professional.

This vaccine should never be administered into a blood vessel.

Symptoms and instructions in the case of overdose

If you use more TYPHIM Vi than you should:

Not applicable.

Actions to be taken when one or more doses have been missed

If you forget to use TYPHIM Vi:

Not applicable.

Risk of withdrawal syndrome

If you stop using TYPHIM Vi:

Not applicable.

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

4. POSSIBLE SIDE EFFECTS

Description of side effects

Like all medicines, TYPHIM Vi can cause side effects, although not everybody gets them.

Very common reactions (reported by more than 1 in 10 persons)

- Injection site pain, injection site hardening (induration), injection site redness (erythema).

Common reactions (reported by less than 1 in 10 persons but more than 1 in 100 persons)

- Fever.

Very rare reactions (reported by less than 1 in 10 000 persons)

- Serious allergic reactions:
  - severe allergic reactions (anaphylactic, anaphylactoid reactions, including shock) which can include one or several of the following symptoms:

- urticaria, skin rash,
- swelling of face and/or neck
- breathing difficulties, bluish discoloration of the tongue or lips,
- low blood pressure, rapid heart rate and weak pulse, skin coldness, dizziness and potentially fainting.

When these signs or symptoms appear, it is usually very soon after the injection, while the person affected is still at the clinic or at the doctor's surgery. If one of these symptoms occurs after you have left the place where the injection was administered, you must consult a doctor IMMEDIATELY.

- serum sickness disease: joint pain, skin rash, enlarged lymph nodes and generally feeling unwell. When these symptoms appear, it is generally within 2 and 4 weeks after vaccination.

- Headache (cephalalgia).
- Cough, wheezing, respiratory discomfort (asthma)
- Nausea, vomiting, diarrhoea, stomach pain (abdominal pain).
- Rash, sometimes swollen and itchy (pruritus, skin rash, urticaria).
- Joint and muscle pain.
- Fatigue, generally feeling unwell.

Reporting of side effects

If you get 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 national reporting system: « Agence nationale de sécurité du médicament et des produits de santé (Ansm) et réseau des Centres Régionaux de Pharmacovigilance » - Site internet: www.ansm.sante.fr. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE TYPHIM Vi, solution for injection in prefilled syringe

Keep out of the sight and reach of children.

Expiry date

Do not use TYPHIM Vi after the expiry date stated on the box and syringe label after EXP.

The expiry date refers to the last day of that month.

Storage conditions

Store in a refrigerator (2°C - 8°C).

Do not freeze.

Where appropriate, warning against certain visible signs of deterioration

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

Full statement of the active substances and excipients

What TYPHIM Vi contains?

The active substance is: Polysaccharides of *Salmonella typhi* (Ty2 strain) 25 micrograms for one 0.5-ml dose.

The other components are: phenol and a buffer solution containing sodium chloride, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate and water for injections.

Pharmaceutical form and contents

What TYPHIM Vi looks like and contents of the pack

TYPHIM Vi is presented in the form of a solution for injection (0.5 ml in prefilled syringe with or without needles) box of 1 or 20.

Not all pack sizes may be marketed.

The solution is clear and colourless.

Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release, if different

Holder

SANOFI PASTEUR
2, AVENUE PONT PASTEUR
69007 LYON
FRANCE

Distributor

SANOFI PASTEUR MSD SNC
8, RUE JONAS SALK
69007 LYON
FRANCE

Manufacturer

SANOFI PASTEUR
2, AVENUE PONT PASTEUR
69007 LYON
FRANCE

Names of the medicinal product in the Member States of the European Economic Area

Not applicable.

Date of approval of the package leaflet

This leaflet was last approved in: 06/2014.

Marketing authorisation under exceptional circumstances

Not applicable.

Internet information

Detailed information on this medicine is available on the website of ANSM (France).

Information intended for healthcare professionals

The following information is intended for healthcare professionals only:

This vaccine must not be mixed with other vaccines in the same syringe.

For syringes without attached needles, the needle must be fitted firmly to the syringe, rotating it by a one quarter turn.

Other

Not applicable.