PARTICULARS TO APPEAR ON THE OUTER PACKAGING
OUTER CARTON TEXT
Silgard, suspension for injection – pre-filled syringe with 2 needles, pack of 1, 10, 20

1. NAME OF THE MEDICINAL PRODUCT

Silgard, suspension for injection in a pre-filled syringe.
Human Papillomavirus Vaccine [Types 6, 11, 16, 18] (Recombinant, adsorbed).

2. STATEMENT OF ACTIVE SUBSTANCE(S)

1 dose (0.5 ml) contains:
HPV Type 6 L1 protein 20 µg
HPV Type 11 L1 protein 40 µg
HPV Type 16 L1 protein 40 µg
HPV Type 18 L1 protein 20 µg

adsorbed on amorphous aluminium hydroxyphosphate sulphate (0.225 mg Al).

3. LIST OF EXCIPIENTS

Sodium chloride, L-histidine, polysorbate 80, sodium borate, water for injections.

4. PHARMACEUTICAL FORM AND CONTENTS

Suspension for injection in a pre-filled syringe.
1 dose, 0.5 ml pre-filled syringe with 2 needles.
10 single doses, 0.5 ml pre-filled syringes with 2 needles each.
20 single doses, 0.5 ml pre-filled syringes with 2 needles each.

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular (IM) use.
Shake well before use.
Read the package leaflet before use.

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

Keep out of the sight and reach of children.

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP MM/YYYY

9. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.
Do not freeze.
Keep the syringe in the outer carton in order to protect from light.

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

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Merck Sharp & Dohme Ltd
Hertford Road, Hoddesdon
Hertfordshire EN11 9BU
United Kingdom

12. MARKETING AUTHORISATION NUMBER(S)

EU/1/06/358/007 – pack of 1
EU/1/06/358/008 – pack of 10
EU/1/06/358/021 – pack of 20

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

17. UNIQUE IDENTIFIER – 2D BARCODE

2D barcode carrying the unique identifier included.

18. UNIQUE IDENTIFIER - HUMAN READABLE DATA

PC:
SN:
NN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
Pre-filled syringe label text

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

Silgard, suspension for injection in a pre-filled syringe.

IM use.

2. METHOD OF ADMINISTRATION

3. EXPIRY DATE

EXP MM/YYYY

4. BATCH NUMBER

Lot

5. CONTENTS BY WEIGHT, BY VOLUME OR BY UNIT

1 dose, 0.5 ml.

6. OTHER

Merck Sharp & Dohme Ltd

B. PACKAGE LEAFLET
(VIAL)

Package leaflet: Information for the user

Silgard, suspension for injection
Human Papillomavirus Vaccine [Types 6, 11, 16, 18] (Recombinant, adsorbed)

Read all of this leaflet carefully before you or your child are vaccinated.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- 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. See section 4.

What is in this leaflet

1. What Silgard is and what it is used for

Silgard is a vaccine. Vaccination with Silgard is intended to protect against diseases caused by Human Papillomavirus (HPV) types 6, 11, 16, and 18.

These diseases include pre-cancerous lesions of the female genitals (cervix, vulva, and vagina); pre-cancerous lesions of the anus and genital warts in males and females; cervical and anal cancers. HPV types 16 and 18 are responsible for approximately 70% of cervical cancer cases, 75-80% of anal cancer cases; 70% of HPV-related pre-cancerous lesions of the vulva and vagina; 75% of HPV related pre-cancerous lesions of the anus. HPV types 6 and 11 are responsible for approximately 90% of genital wart cases.

Silgard is intended to prevent these diseases. The vaccine is not used to treat HPV related diseases. Silgard does not have any effect in individuals who already have a persistent infection or disease associated with any of the HPV types in the vaccine. However, in individuals who are already infected with one or more of the vaccine HPV types, Silgard can still protect against diseases associated with the other HPV types in the vaccine.

Silgard cannot cause the diseases it protects against.

Silgard produces type-specific antibodies and has been shown in clinical trials to prevent HPV 6-, 11-, 16-, and 18-related diseases in women 16-45 years of age and in men 16-26 years of age. The vaccine also produces type-specific antibodies in 9- to 15-year-old children and adolescents.

Silgard should be used in accordance with official guidelines.

2. What you need to know before you receive Silgard

Do not receive Silgard if:
- you or your child is allergic (hypersensitive) to any of the active substances or any of the other ingredients of Silgard (listed under "other ingredients"– see section 6).
- you or your child developed an allergic reaction after receiving a dose of Silgard.
- you or your child suffer from an illness with high fever. However, a mild fever or upper respiratory infection (for example cold) itself is not a reason to delay vaccination.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before vaccination if you or your child
- has a bleeding disorder (a disease that makes you bleed more than normal), for example haemophilia
- has a weakened immune system, for example due to a genetic defect, HIV infection or medicines that affect the immune system.

Fainting, sometimes accompanied by falling, can occur (mostly in adolescents) following any needle injection. Therefore tell the doctor or nurse if you fainted with a previous injection.

As with any vaccine, Silgard may not fully protect 100% of those who get the vaccine.

Silgard will not protect against every type of Human Papillomavirus. Therefore appropriate precautions against sexually transmitted disease should continue to be used.

Silgard will not protect against other diseases that are not caused by Human Papillomavirus.

Vaccination is not a substitute for routine cervical screening**.** You should continue to follow your doctor's advice on cervical smear/Pap tests and preventative and protective measures.

What other important information should you or your child know about Silgard

The duration of protection is currently unknown. Longer term follow-up studies are ongoing to determine whether a booster dose is needed.

Other medicines or vaccines and Silgard
Silgard can be given with a Hepatitis B vaccine or with a combined booster vaccine containing diphtheria (d) and tetanus (T) with either pertussis [acellular, component] (ap) and/or poliomyelitis [inactivated] (IPV) (dTap, dT-IPV, dTap-IPV vaccines) at a separate injection site (another part of your body, e.g. the other arm or leg) during the same visit.

Silgard may not have an optimal effect if:
- used with medicines that suppress the immune system.

In clinical trials, oral or other contraceptives (e.g. the pill) did not reduce the protection obtained by Silgard.

Please tell your doctor or pharmacist if you or your child are taking or have taken recently any other medicines, including medicines obtained without a prescription.

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 for advice before taking this medicine.
Silgard may be given to women who are breast-feeding or intend to breast-feed.

Driving and using machines
No studies on the effects on the ability to drive and use machines have been performed.

3. How Silgard is given

Silgard is given as an injection by your doctor. Silgard is intended for adolescents and adults from 9 years of age onwards.

If you are from 9 to and including 13 years of age
Silgard can be administered according to a 2-dose schedule:
- First injection: at chosen date
- Second injection: 6 months after first injection

If the second vaccine dose is administered earlier than 6 months after the first dose, a third dose should always be administered.

Alternatively, Silgard can be administered according to a 3-dose schedule:
- First injection: at chosen date
- Second injection: 2 months after first injection
- Third injection: 6 months after first injection

The second dose should be administered at least one month after the first dose and the third dose should be administered at least 3 months after the second dose. All three doses should be given within a 1-year period. Please speak to your doctor for more information.

If you are from 14 years of age
Silgard should be administered according to a 3-dose schedule:
- First injection: at chosen date
- Second injection: 2 months after first injection
- Third injection: 6 months after first injection

The second dose should be administered at least one month after the first dose and the third dose should be administered at least 3 months after the second dose. All three doses should be given within a 1-year period. Please speak to your doctor for more information.

It is recommended that individuals who receive a first dose of Silgard complete the vaccination course with Silgard.

Silgard will be given as an injection through the skin into the muscle (preferably the muscle of the upper arm or thigh).

The vaccine should not be mixed in the same syringe with any other vaccines and solutions.

If you forget one dose of Silgard:

If you miss a scheduled injection, your doctor will decide when to give the missed dose.
It is important that you follow the instructions of your doctor or nurse regarding return visits for the follow-up doses. If you forget or are not able to go back to your doctor at the scheduled time, ask your doctor for advice. When Silgard is given as your first dose, the completion of the vaccination course should be done with Silgard, and not with another HPV vaccine.

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

4. Possible side effects

Like all vaccines and medicines, Silgard can cause side effects, although not everybody gets them.

The following side effects can be seen after the use of Silgard:

Very commonly (more than 1 in 10 patients), side effects found at the injection site include: pain, swelling and redness. Headache was also seen.

Commonly (more than 1 in 100 patients), side effects found at the injection site include: bruising, itching, pain in extremity. Fever and nausea have also been reported.

Rarely (less than 1 in 1000 patients): hives (urticaria).

Very rarely (less than 1 in 10,000 patients), difficulty breathing (bronchospasm) has been reported.

When Silgard was given with a combined diphtheria, tetanus, pertussis [acellular, component] and poliomyelitis [inactivated] booster vaccine during the same visit, there was more headache and injection-site swelling.

Side effects that have been reported during marketed use include:

Fainting, sometimes accompanied by shaking or stiffening, has been reported. Although fainting episodes are uncommon, patients should be observed for 15 minutes after they receive HPV vaccine.

Allergic reactions that may include difficulty breathing, wheezing (bronchospasm), hives and rash have been reported. Some of these reactions have been severe.

As with other vaccines, side effects that have been reported during general use include: swollen glands (neck, armpit, or groin); muscle weakness, abnormal sensations, tingling in the arms, legs and upper body, or confusion (Guillain-Barré Syndrome, acute disseminated encephalomyelitis); dizziness, vomiting, joint pain, aching muscles, unusual tiredness or weakness, chills, generally feeling unwell, bleeding or bruising more easily than normal, and skin infection at the injection site.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Silgard

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 vial label and the outer carton (after EXP). The expiry date refers to the last day of that month.
Store in a refrigerator (2ºC - 8ºC).
Do not freeze.
Keep the vial in the outer carton in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Silgard contains
The active substances are: highly purified non-infectious protein for each of the Human Papillomavirus types (6, 11, 16, and 18).

1 dose (0.5 ml) contains approximately:

Human Papillomavirus[1] Type 6 L1 protein[2,3]	20 micrograms
Human Papillomavirus[1] Type 11 L1 protein[2,3]	40 micrograms
Human Papillomavirus[1] Type 16 L1 protein[2,3]	40 micrograms
Human Papillomavirus[1] Type 18 L1 protein[2,3]	20 micrograms

[1]Human Papillomavirus = HPV
[2]L1 protein in the form of virus like particles produced in yeast cells (*Saccharomyces cerevisiae* CANADE 3C-5 (Strain 1895)) by recombinant DNA technology.

[3]adsorbed on amorphous aluminium hydroxyphosphate sulphate adjuvant (0.225 milligrams Al).

The other ingredients in the vaccine suspension are:

Sodium chloride, L-histidine, polysorbate 80, sodium borate and water for injections.

What Silgard looks like and contents of the pack
1 dose of Silgard suspension for injection contains 0.5 ml.

Prior to agitation, Silgard may appear as a clear liquid with a white precipitate. After thorough agitation, it is a white, cloudy liquid.

Silgard is available in packs of 1, 10 or 20 vials.

Not all pack sizes are marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
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Manufacturer
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For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

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This leaflet was last revised in {MM/YYYY}.

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

The following information is intended for medical or healthcare professionals only:

The vaccine should be used as supplied; no dilution or reconstitution is necessary. The full recommended dose of the vaccine should be used. Any unused product or waste material should be disposed of in accordance with local requirements.

Shake well before use. Thorough agitation immediately before administration is necessary to maintain suspension of the vaccine.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Discard the product if particulates are present or if it appears discolored.

B. PACKAGE LEAFLET
(PREFILLED SYRINGE)

PACKAGE LEAFLET: INFORMATION FOR THE USER

Silgard, suspension for injection in a pre-filled syringe
Human Papillomavirus Vaccine [Types 6, 11, 16, 18] (Recombinant, adsorbed)

Read all of this leaflet carefully before you or your child are vaccinated.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or pharmacist.
- 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. See section 4.

What is in this leaflet

1. What Silgard is and what it is used for

Silgard is a vaccine. Vaccination with Silgard is intended to protect against diseases caused by Human Papillomavirus (HPV) types 6, 11, 16, and 18.

These diseases include pre-cancerous lesions of the female genitals (cervix, vulva, and vagina); pre-cancerous lesions of the anus and genital warts in males and females; cervical and anal cancers. HPV types 16 and 18 are responsible for approximately 70% of cervical cancer cases, 75-80% of anal cancer cases; 70% of HPV-related pre-cancerous lesions of the vulva and vagina; 75% of HPV related pre-cancerous lesions of the anus. HPV types 6 and 11 are responsible for approximately 90% of genital wart cases.

Silgard is intended to prevent these diseases. The vaccine is not used to treat HPV related diseases. Silgard does not have any effect in individuals who already have a persistent infection or disease associated with any of the HPV types in the vaccine. However, in individuals who are already infected with one or more of the vaccine HPV types, Silgard can still protect against diseases associated with the other HPV types in the vaccine.

Silgard cannot cause the diseases it protects against.

Silgard produces type-specific antibodies and has been shown in clinical trials to prevent HPV 6-, 11-, 16-, and 18-related diseases in women 16-45 years of age and in men 16-26 years of age. The vaccine also produces type-specific antibodies in 9- to 15-year-old children and adolescents.

Silgard should be used in accordance with official guidelines.

2. What you need to know before you receive Silgard

Do not receive Silgard if:
- you or your child is allergic (hypersensitive) to any of the active substances or any of the other ingredients of Silgard (listed under "other ingredients"– see section 6).
- you or your child developed an allergic reaction after receiving a dose of Silgard.
- you or your child suffer from an illness with high fever. However, a mild fever or upper respiratory infection (for example cold) itself is not a reason to delay vaccination.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before vaccination if you or your child
- has a bleeding disorder (a disease that makes you bleed more than normal), for example haemophilia
- has a weakened immune system, for example due to a genetic defect, HIV infection or medicines that affect the immune system.

Fainting, sometimes accompanied by falling, can occur (mostly in adolescents) following any needle injection. Therefore tell the doctor or nurse if you fainted with a previous injection.

As with any vaccine, Silgard may not fully protect 100% of those who get the vaccine.

Silgard will not protect against every type of Human Papillomavirus. Therefore appropriate precautions against sexually transmitted disease should continue to be used.

Silgard will not protect against other diseases that are not caused by Human Papillomavirus.

Vaccination is not a substitute for routine cervical screening**.** You should continue to follow your doctor's advice on cervical smear/Pap tests and preventative and protective measures.

What other important information should you or your child know about Silgard

The duration of protection is currently unknown. Longer term follow-up studies are ongoing to determine whether a booster dose is needed.

Other medicines or vaccines and Silgard
Silgard can be given with a Hepatitis B vaccine or with a combined booster vaccine containing diphtheria (d) and tetanus (T) with either pertussis [acellular, component] (ap) and/or poliomyelitis [inactivated] (IPV) (dTap, dT-IPV, dTap-IPV vaccines) at a separate injection site (another part of your body, e.g. the other arm or leg) during the same visit.

Silgard may not have an optimal effect if:
- used with medicines that suppress the immune system.

In clinical trials, oral or other contraceptives (e.g. the pill) did not reduce the protection obtained by Silgard.

Please tell your doctor or pharmacist if you or your child are taking or have taken recently any other medicines, including medicines obtained without a prescription.

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 for advice before taking this medicine.
Silgard may be given to women who are breast-feeding or intend to breast-feed.

Driving and using machines
No studies on the effects on the ability to drive and use machines have been performed.

3. How Silgard is given

Silgard is given as an injection by your doctor. Silgard is intended for adolescents and adults from 9 years of age onwards.

If you are from 9 to and including 13 years of age
Silgard can be administered according to a 2-dose schedule:
- First injection: at chosen date
- Second injection: 6 months after first injection

If the second vaccine dose is administered earlier than 6 months after the first dose, a third dose should always be administered.

Alternatively, Silgard can be administered according to a 3-dose schedule:
- First injection: at chosen date
- Second injection: 2 months after first injection
- Third injection: 6 months after first injection

The second dose should be administered at least one month after the first dose and the third dose should be administered at least 3 months after the second dose. All three doses should be given within a 1-year period. Please speak to your doctor for more information.

If you are from 14 years of age
Silgard should be administered according to a 3-dose schedule:
- First injection: at chosen date
- Second injection: 2 months after first injection
- Third injection: 6 months after first injection

The second dose should be administered at least one month after the first dose and the third dose should be administered at least 3 months after the second dose. All three doses should be given within a 1-year period. Please speak to your doctor for more information.

It is recommended that individuals who receive a first dose of Silgard complete the vaccination course with Silgard.

Silgard will be given as an injection through the skin into the muscle (preferably the muscle of the upper arm or thigh).

The vaccine should not be mixed in the same syringe with any other vaccines and solutions.

If you forget one dose of Silgard:

If you miss a scheduled injection, your doctor will decide when to give the missed dose.
It is important that you follow the instructions of your doctor or nurse regarding return visits for the follow-up doses. If you forget or are not able to go back to your doctor at the scheduled time, ask your doctor for advice. When Silgard is given as your first dose, the completion of the vaccination course should be done with Silgard, and not with another HPV vaccine.

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

4. Possible side effects

Like all vaccines and medicines, Silgard can cause side effects, although not everybody gets them.

The following side effects can be seen after the use of Silgard:

Very commonly (more than 1 in 10 patients), side effects found at the injection site include: pain, swelling and redness. Headache was also seen.

Commonly (more than 1 in 100 patients), side effects found at the injection site include: bruising, itching, pain in extremity. Fever and nausea have also been reported.

Rarely (less than 1 in 1000 patients): hives (urticaria).

Very rarely (less than 1 in 10,000 patients), difficulty breathing (bronchospasm) has been reported.

When Silgard was given with a combined diphtheria, tetanus, pertussis [acellular, component] and poliomyelitis [inactivated] booster vaccine during the same visit, there was more headache and injection-site swelling.

Side effects that have been reported during marketed use include:

Fainting, sometimes accompanied by shaking or stiffening, has been reported. Although fainting episodes are uncommon, patients should be observed for 15 minutes after they receive HPV vaccine.

Allergic reactions that may include difficulty breathing, wheezing (bronchospasm), hives and rash have been reported. Some of these reactions have been severe.

As with other vaccines, side effects that have been reported during general use include: swollen glands (neck, armpit, or groin); muscle weakness, abnormal sensations, tingling in the arms, legs and upper body, or confusion (Guillain-Barré Syndrome, acute disseminated encephalomyelitis); dizziness, vomiting, joint pain, aching muscles, unusual tiredness or weakness, chills, generally feeling unwell, bleeding or bruising more easily than normal, and skin infection at the injection site.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Silgard

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 syringe label and the outer carton (after EXP). The expiry date refers to the last day of that month.
Store in a refrigerator (2ºC - 8ºC).
Do not freeze.
Keep the syringe in the outer carton in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Silgard contains
The active substances are: highly purified non-infectious protein for each of the Human Papillomavirus types (6, 11, 16, and 18).

1 dose (0.5 ml) contains approximately:

Human Papillomavirus[1] Type 6 L1 protein[2,3]	20 micrograms
Human Papillomavirus[1] Type 11 L1 protein[2,3]	40 micrograms
Human Papillomavirus[1] Type 16 L1 protein[2,3]	40 micrograms
Human Papillomavirus[1] Type 18 L1 protein[2,3]	20 micrograms

[1]Human Papillomavirus = HPV
[2]L1 protein in the form of virus like particles produced in yeast cells (*Saccharomyces cerevisiae* CANADE 3C-5 (Strain 1895)) by recombinant DNA technology.

[3]adsorbed on amorphous aluminium hydroxyphosphate sulphate adjuvant (0.225 milligrams Al).

The other ingredients in the vaccine suspension are:

Sodium chloride, L-histidine, polysorbate 80, sodium borate and water for injections.

What Silgard looks like and contents of the pack
1 dose of Silgard suspension for injection contains 0.5 ml.

Prior to agitation, Silgard may appear as a clear liquid with a white precipitate. After thorough agitation, it is a white, cloudy liquid.

Silgard is available in packs of 1, 10 or 20 pre-filled syringes.

Not all pack sizes are marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Merck Sharp and Dohme Ltd
Hertford Road, Hoddesdon
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United Kingdom

Manufacturer
Merck Sharp & Dohme BV
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The Netherlands

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

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Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu.

The following information is intended for medical or healthcare professionals only:

- Silgard is available in a pre-filled syringe ready to use for intramuscular injection (IM), preferably in the deltoid area of the upper arm.
- If 2 needles of different lengths are provided in the pack, choose the appropriate needle to ensure an IM administration depending on your patient's size and weight.
- Parenteral drug products should be inspected visually for particulate matter and discolouration prior to administration. Discard the product if particulates are present or if it appears discoloured. Any unused product or waste material should be disposed of in accordance with local requirements.

Shake well before use. Attach the needle by twisting in a clockwise direction until the needle fits securely on the syringe. Administer the entire dose as per standard protocol.