Proposed Patient Information Leaflet

SCHEDULING STATUS: S4

Tetagam IM, 250 IU /2 ml, solution for injection

Tetagam IM, 500 IU /ml, solution for injection

Human tetanus immunoglobulin

Sugar free

Read all of this leaflet carefully before you are given Tetagam IM

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- Tetagam IM has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What Tetagam IM is and what it is used for
2. What you need to know before you are given Tetagam IM
3. How to receive Tetagam IM
4. Possible side effects
5. How to store Tetagam IM
6. Contents of the pack and other information

1. What Tetagam IM is and what it is used for

What Tetagam IM is

Tetagam IM is a solution for injection that contains proteins isolated from human plasma.

These proteins belong to the biological class of medicines called immunoglobulins, also known as antibodies.

Tetagam IM contains the active ingredient human tetanus immunoglobulin, which is a specific antibody that works against the tetanus toxin.

It is prepared from human plasma from healthy donors that have a high quantity of these antibodies.

What Tetagam IM is used for

Tetagam IM is used to protect against tetanus and is usually given together with the tetanus vaccine. It is usually given if:

- you have recently been exposed to tetanus because you have been wounded e.g. by a cut, bite or pierced by a foreign body:
    - and you have not had previous vaccination to tetanus, or
    - have not been properly vaccinated, or
    - do not know whether you have been vaccinated to tetanus.
- You are suffering from tetanus.

Tetagam IM will be given in addition to wound care.

Your doctor or other healthcare professional will tell you if it is advisable for you to have this medicine.

2. What you need to know before you are given Tetagam IM

Tetagam IM should not be administered to you:

- If you are hypersensitive (allergic) to human tetanus immunoglobulin or any of the other ingredients in Tetagam IM (listed in section 6).
- If you are hypersensitive to human immunoglobulins.

Your doctor will decide if you should be given this medicine in this case.

Warnings and precautions

Tetagam IM must not be administered into a vein.

Tell your doctor or health care provider before being given the injection:

- If you have had a severe allergic reaction to plasma products.
- If you are suffering from any bleeding disorders which interfere with clotting.
- If you have specifically low levels of immunoglobulin A (IgA) as the small amounts of IgA in this preparation may cause an allergic reaction the next time you are given this medicine.

Your doctor will decide if you should be given this medicine in these cases.

Special care should be taken with Tetagam IM*:*

- True hypersensitivity reactions are rare but allergic type reactions may occur. Tell your doctor or health care provider immediately in case of suspected allergy or serious allergic (anaphylactic) reactions. Your doctor will monitor you closely and will have medication available to treat you if there are any signs of an allergic reaction to Tetagam IM.
- If you are going for a blood test, soon after receiving this medicine as it may lead to misleading results. Tell your health care provider if this is the case.

Virus safety

Human tetanus immunoglobulin is prepared from human plasma.

When medicines are made from human blood or plasma, certain measures are put in place to prevent infections being passed on to patients. These include:

- Careful selection of blood and plasma donors to make sure those at risk of carrying infections are excluded,
- The testing of each donation and pools of plasma for signs of virus/infections,
- The inclusion of steps in the processing of the blood or plasma that can inactivate or remove viruses.

Despite these measures, when medicines prepared from human blood or plasma are administered, the possibility of passing on infection cannot be totally excluded. This also applies to any unknown or emerging viruses or other types of infections.

The measures taken are considered effective for enveloped viruses such as human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV).

The measures taken may be of limited value against non-enveloped viruses such as hepatitis A virus and parvovirus B19.

Immunoglobulins have not been associated with hepatitis A or parvovirus B19 infections possibly because the antibodies against these infections, which are contained in the product, are protective.

Traceability

It is strongly recommended that when you receive a dose of Tetagam IM, the name and batch number of the product are recorded in order to maintain a record of the batch used.

Please speak to your health care provider should you require additional information in this regard.

Other medicines and Tetagam IM:

Tetagam IM should not be mixed with other medicines for injection when being given to you.

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines)

Vaccinations

Human tetanus immunoglobulin (antibodies) may interfere with the response to some live virus vaccines, especially, mumps, rubella and varicella (chickenpox) vaccines. These vaccines should not be given for 3 months after you were last given Tetagam IM, as the effectiveness of such vaccinations may be reduced.

Tetagam IM with food and drink:

Tetagam IM is injected directly into the muscle and is not affected by food or drink.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before receiving this medicine.

Driving and using machines

You may experience dizziness and other side effects when you receive Tetagam IM.

It is not always possible to predict to what extent Tetagam IM may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which Tetagam IM affects you.

3. How to receive Tetagam IM

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself Tetagam IM. It will be given to you by a person who is qualified to do so.

Tetagam IM is for intramuscular use only must never be injected into a vein due to the risk of going into shock.

It must be injected slowly into a large muscle (like the arm or thigh) different from the one in which you were given the vaccine.

Doses:

As a precaution, 250 IU will be given to you. This may be increased to 500 IU if your wound is more serious.

As treatment for tetanus, you will be given a large single dose of 3000 to 6000 IU, administered into several different muscles.

If you receive more Tetagam IM than you should:

Your dose is calculated by your doctor but if you feel unwell after being given this medicine, you should tell your doctor.

Since a health care provider will administer Tetagam IM he/she will control the dosage. However, in the event of overdosage, your doctor will manage the overdosage.

If you missed a dose of Tetagam IM

Since a health care provider will administer Tetagam IM, it is unlikely that the dose will be missed.

4. Possible side effects

Tetagam IM can have side effects.

Not all side effects reported for Tetagam IM are included in this leaflet. Should your general health worsen or if you experience any untoward effects after receiving Tetagam IM, please consult your health care provider for advice.

If any of the following happens, tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- Allergic reaction
- Faintness

These are all very serious side effects. If you have them, you may have had a serious reaction to Tetagam IM. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following side effects with unknown frequency:

- Headache
- Flushing
- Nausea
- Skin reactions
- Back pain
- Administration site reaction or injection site pain
- Fever
- Chills

If you notice any side effects not mentioned in this leaflet, please inform your healthcare provider.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (https://primaryreporting.who-umc.org/ZA) found on SAHPRA website or to National Bioproducts Institute NPC via the email address Pharmacovigilance@nbisa.org.za. By reporting side effects, you can help provide more information on the safety of Tetagam IM.

5. How to store Tetagam IM

Store all medicines out of reach of children.

- Store between 2 °C and 8 °C (in a refrigerator).

- Do not freeze.
- Protect from light.
- Keep the ampoule in the outer carton until required for use.
- Do not use after the expiry date stated on the label.

Disposal:

After injection of the correct dose, your doctor or nurse will dispose of any solution that remains, along with used syringes, needles and containers, according to correct procedures. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Tetagam IM contains

- The active substance is a sterile solution of human tetanus immunoglobulin (antibodies).
- Each ampoule of Tetagam IM 250 IU contains 250 IU of tetanus antibodies.
- Each ampoule of Tetagam IM 500 IU contains 500 IU of tetanus antibodies.
- The other ingredients are glycine, sodium chloride, sodium hydroxide, hydrochloric acid, human hepatitis B immunoglobulin, human albumin, human normal immunoglobulin and water for injections.
- Tetagam IM does not contain any preservatives.

What Tetagam IM looks like and contents of the pack

Tetagam IM is a solution for injection.

The sterile solution is a clear liquid, with a slightly turbid/cloudy appearance, which is almost colourless or pale yellow to light brown.

Tetagam IM 250 IU: 2 ml solution in a sterile, clear, colourless, 2 ml glass ampoule marked with a green ring.

Tetagam IM 500 IU: 1 ml solution in a sterile, clear, colourless, 2 ml glass ampoule marked with a black ring.

Holder of Certificate of Registration

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