Tetanus Immunoglobulin-VF (For Intravenous Use)

Human Tetanus Immunoglobulin, solution for intravenous injection.

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Tetanus Immunoglobulin-VF (For Intravenous Use). It does not contain complete information about Tetanus Immunoglobulin-VF (For Intravenous Use). It does not take the place of talking to your doctor.

If you have any concerns about using this medicine, ask your doctor. Follow your doctor's advice even if it is different from what this leaflet says.

Please read this leaflet carefully and keep it for future reference.

The information in this leaflet is subject to change. Please check with your doctor whether there is any new information about this medicine that you should know since you were last treated.

What Tetanus Immunoglobulin-VF (For Intravenous Use) is used for

Tetanus Immunoglobulin-VF (For Intravenous Use) is manufactured from human plasma (the liquid component of blood) collected by the Australian Red Cross Blood Service. Donations are selected on the basis that they contain high levels of antibodies against the poison produced by bacteria which cause tetanus. This medicine is used for the treatment of tetanus infection.

Ask your doctor if you have any questions about why Tetanus Immunoglobulin-VF (For Intravenous Use) has been prescribed for you. Your doctor will have assessed the risks and benefits for you associated with the use of this product.

Before you are given Tetanus Immunoglobulin-VF (For Intravenous Use)

Tetanus Immunoglobulin-VF (For Intravenous Use) must not be used if you have a history of allergy to human immunoglobulin products.

Tell your doctor if you have allergies to any other medicines or if you have ever had an allergic reaction to an injection.

Tell your doctor also if you:

- have previously been advised that you have Immunoglobulin A (IgA) deficiency
- have previously been advised that you have kidney disease
- have previously been advised that you have diabetes
- are taking or using any other medicines. These include medicines bought from pharmacies, supermarkets and health food stores.

- have any other medical conditions
- are pregnant or breast-feeding
- intend to receive any vaccinations in the next three months.

If you want any further information, consult your doctor.

About blood products

When products are made from human blood and injected into you, it is possible that viruses or other substances could be present in the product and cause an illness. These could be viruses such as hepatitis, human immunodeficiency virus (HIV), or human parvovirus B19 and theoretically the Creutzfeldt-Jakob Disease (CJD) agent. There could also be other infectious agents some of which may not yet have been discovered.

To reduce the risk of this happening, extra steps are taken when manufacturing this product. Strict controls are applied when selecting blood donors and donations. The product is specially treated to remove and kill certain viruses. These special treatments are considered effective against viruses known as enveloped viruses such as HIV, hepatitis B virus and hepatitis C virus and non-enveloped viruses, such as hepatitis A virus and human parvovirus B19. Despite these measures, the risk of viral and other agent's infectivity cannot be totally eliminated.

Vaccines are available against some of these viruses and your doctor will be able to help you decide whether it is worthwhile having any of those vaccines.

Please discuss the risks and benefits of this product with your doctor.

How to use Tetanus Immunoglobulin-VF (For Intravenous Use)

Your doctor will determine the dose(s) of Tetanus Immunoglobulin-VF (For Intravenous Use) that you are to receive. Your doctor will give you Tetanus Immunoglobulin-VF (For Intravenous Use) as an infusion, that is, an injection given slowly into the vein.

Side effects

Along with their intended effects, medicines occasionally cause some unwanted effects, some of which are serious. Individuals may react differently to similar doses of the same product. This applies to Tetanus Immunoglobulin-VF (For Intravenous Use).

Severe allergic reactions to immunoglobulins are rare. Should a hypersensitivity reaction occur, the doctor will stop the infusion.

Unwanted effects which may occur include: stomach pain, headache, chest-tightness, flushed or pale face, feeling hot, shortness of breath, non-itchy skin rash, itching, faintness, nausea or vomiting, or a hot feeling or redness at the site of the injection. Should any of these effects develop during infusion, the doctor will take appropriate action.

Some patients may develop delayed unwanted effects such as nausea, vomiting, chest pain, chills or shivering, dizziness or aching legs. These effects may occur after the infusion has stopped but usually within 24 hours.

A condition called Aseptic Meningitis Syndrome (AMS) has been reported to occur infrequently in association with infusions similar to Tetanus Immunoglobulin-VF (For Intravenous Use). It usually begins within several hours to two days following treatment. The signs include severe headache, neck stiffness, drowsiness, fever, inability to stand bright light, painful eye movements, and nausea and vomiting. The condition reverses without ill effects when treatment is stopped.

There have been reports that the kidneys may be affected with infusions similar to Tetanus Immunoglobulin-VF (For Intravenous Use). These occurrences are extremely rare.

If you experience any of the mentioned effects or any other abnormal signs after treatment, contact your doctor immediately.

Contact your doctor immediately if you experience any of these symptoms at any time: fever, loss of appetite, extreme tiredness, stomach pain, jaundice (yellow skin and eyes), dark urine, joint pains and skin rashes.

Tetanus Immunoglobulin-VF (For Intravenous Use) can interfere with some live vaccines (e.g. measles and polio), even up to three months later. Advise your doctor if you are to receive other vaccines within three months of receiving Tetanus Immunoglobulin-VF (For Intravenous Use).

Interference with glucose estimations

The maltose present in Tetanus Immunoglobulin-VF (For Intravenous Use) may interfere with some blood glucose measurements, resulting in the overestimation of blood glucose results. If this glucose measurement is used to guide treatment, hypoglycaemia may occur. Only certain glucose tests have been implicated, so when monitoring glucose levels consult your doctor to ensure that maltose does not interfere with the blood glucose reading of the test you are using.

If you want further information, or if you are worried about any other symptoms after the infusion, consult your doctor.

Overdose

No cases of overdose have ever been reported.

Storing Tetanus Immunoglobulin-VF (For Intravenous Use)

Store at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light.

Do not use after the expiry date shown on the label.

Further information

Tetanus Immunoglobulin-VF (For Intravenous Use) can only be obtained on a doctor's prescription. This leaflet does not contain the complete information about Tetanus Immunoglobulin-VF (For Intravenous Use). If you require further information about Tetanus Immunoglobulin-VF (For Intravenous Use) and your treatment generally, or if you have any questions or are not sure about something in this leaflet, consult your doctor.

Product description

What it looks like

Tetanus Immunoglobulin-VF (For Intravenous Use) is a clear, colourless, non-viscous (not thick) solution. It is available in glass bottles.

Ingredients

In each vial of Tetanus Immunoglobulin-VF (For Intravenous Use) is a sterile solution containing 6% blood proteins of which at least 98% is immunoglobulins with a tetanus antitoxin activity of 4000 IU per vial. It also contains 10% maltose (a sugar).

Manufacturer

Tetanus Immunoglobulin-VF (For Intravenous Use) is manufactured in Australia by:

CSL Behring (Australia) Pty Ltd
ABN 48 160 734 761
189–209 Camp Road
Broadmeadows VIC 3047
Australia

Distributor

Australian Red Cross Blood Service

Date of most recent amendment

August 2014

Australian Register Number
AUST R 31829