IMOGAM RABIES pasteurized®

Human rabies immunoglobulin

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about IMOGAM RABIES pasteurized (IMOGAM). It does not contain all the available information.

It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking IMOGAM against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor.

Keep this leaflet.
You may need to read it again.

What IMOGAM is used for

IMOGAM is used to help prevent rabies infection in people who have been bitten, licked or scratched by a rabies-infected animal.

Rabies is an infection caused by a virus which affects the brain and is fatal if not treated early.

IMOGAM is prepared from blood obtained from voluntary donors. It contains protein substances called antibodies, which can provide protection against rabies.

Before IMOGAM is used

SPECIAL WARNING

This product is made from human plasma obtained from voluntary donors immunized against rabies. 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, HIV (human immunodeficiency virus), or parvovirus B19. 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 to the selection of blood donors and donations. The product is specially treated to remove and kill certain viruses. This special treatment is considered effective against viruses known as enveloped viruses such as HIV and hepatitis B and C viruses, and the non-enveloped virus, hepatitis A. The effect against the non-enveloped virus, human parvovirus B19 is limited. However, the product contains specific antibodies which can provide some protection against parvovirus B19.

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.

Tell your doctor if:

- **you have an allergy to any of the ingredients listed at the end of this leaflet.**
- **you have already had injections of IMOGAM or more than one injection of rabies vaccine.**
- **you have already been given measles, rubella, or mumps vaccine in the last two weeks.**
- **you are pregnant or intend to become pregnant.**
- **you are breast feeding or intend to breast feed.**
- **If you are not sure about anything, ask your doctor.**

When IMOGAM must not be used

As IMOGAM can be a lifesaving product, it should not be withheld from anyone who needs it.

How IMOGAM is given

The doctor will usually inject some IMOGAM into the place where the animal bit, scratched or licked. The remaining vaccine may be injected into the buttocks.

Your doctor will also give you a rabies vaccine product to help prevent rabies.

How much is injected

Your doctor will decide how much IMOGAM you need. The amount you need is calculated on how much you weigh.

Follow all directions given to you by your doctor carefully.

Overdose

Overdose is unlikely as your doctor is giving you the injections.

If you have any concerns, ask your doctor.

After you have been given IMOGAM

If you need to see a doctor, dentist or pharmacist tell them that you have been given a dose of IMOGAM.
Some vaccines such as measles, rubella and mumps may not work if given too soon after IMOGAM.

Side effects

As with most medicines, IMOGAM can have side effects in some people.

Tell your doctor if any of these symptoms occur any time up to two weeks after an injection of IMOGAM.

These may sometimes include:

- pain and discomfort where the injection was given
- skin reactions
- fever or shivering
- nausea and vomiting
- fast heart beat
- dizziness and light-headedness (low blood pressure)
- allergic reactions such as itching, rash, hives and swelling with fluid.

If the following happens, tell your doctor or pharmacist immediately or go to Accident and Emergency at your nearest hospital.

Very rare reactions include:

- severe allergic reactions
- Examples of allergic reactions include:
- rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body.
- pinkish, itchy swellings on the skin, also called hives or nettle rash.
- shortness of breath, wheezing or trouble breathing.

Tell your doctor as soon as possible if you do not feel well after you have been given IMOGAM.

After using IMOGAM

Storage

IMOGAM is usually stored in the doctors surgery or clinic, or at the pharmacy. However, if you need to store IMOGAM:

- **Keep it where children cannot reach it.**
- **Keep IMOGAM in the original pack until it is time for it to be given.**

Keep IMOGAM in the fridge protected from light. Do not put it in the freezer.
If IMOGAM is left out of the fridge or put in the freezer, it may not work. It should not be used after the expiry date on the package.

Product description

What it looks like

Each pack of IMOGAM contains one vial of clear pale yellow to light brown liquid.

Ingredients

Each vial contains the active ingredient, human rabies immunoglobulin. There are at least 300 International Units of human rabies immunoglobulin in each 2mL vial, and 1500 International Units in each 10mL vial.

Each vial also contains ingredients which are not active.

These are glycine, sodium chloride and water.

IMOGAM does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Further information

This medicine is available only with a doctor's prescription.

If you are unsure about anything or want more information about IMOGAM please ask your doctor.

Manufacturer

Sanofi Pasteur SA
Lyon, France

Distributor

Sanofi Pasteur Pty Ltd.
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Aust R number

- 2 mL vial - Aust R 72931
- 10 mL - vial Aust R 72931

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