

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Polysorbate 80
Sodium hydroxide (for pH adjustment)
Glacial acetic acid
Water for injections

6.2 Incompatibilities

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

6.3 Shelf life

3 years

6.4 Special precautions for storage

Pre-filled syringe

Store in a refrigerator (2°C - 8°C). Do not freeze.
Keep the pre-filled syringe in the outer carton in order to protect from light.
After removal from the refrigerator, Aimovig must be used within 7 days when stored at room temperature (up to 25°C), or discarded. If it is stored at a higher temperature or for a longer period it must be discarded.

Pre-filled pen

Store in a refrigerator (2°C - 8°C). Do not freeze.
Keep the pre-filled pen in the outer carton in order to protect from light.
After removal from the refrigerator, Aimovig must be used within 7 days when stored at room temperature (up to 25°C), or discarded. If it is stored at a higher temperature or for a longer period it must be discarded.

6.5 Nature and contents of container

Pre-filled syringe

Aimovig is supplied in a pre-filled syringe (1 ml, Type 1 glass) with a stainless steel needle and a needle cover (rubber containing latex).

Aimovig is available in packs containing 1 pre-filled syringe.

Pre-filled pen

Aimovig is supplied in a pre-filled pen (1 ml, Type 1 glass) with a stainless steel needle and a needle cover (rubber containing latex).

Aimovig is available in packs containing 1 pre-filled pen and in multipacks containing 3 (3x1) pre-filled pens.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Before administration, the solution should be inspected visually. The solution should not be injected if it is cloudy, distinctly yellow or contains flakes or particles.

Pre-filled syringe

To avoid discomfort at the site of injection, the pre-filled syringe(s) should be left to stand at room temperature (up to 25°C) for at least 30 minutes before injecting. It should also be protected from direct sunlight. The entire contents of the pre-filled syringe(s) must be injected. The syringe(s) must not be warmed by using a heat source such as hot water or microwave and must not be shaken.

Pre-filled pen

To avoid discomfort at the site of injection, the pre-filled pen(s) should be left to stand at room temperature (up to 25°C) for at least 30 minutes before injecting. It should also be protected from direct sunlight. The entire contents of the pre-filled pen(s) must be injected. The pen(s) must not be warmed by using a heat source such as hot water or microwave and must not be shaken.

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