

Diluted solution:
It is recommended that Cerezyme is used immediately after it has been mixed with sterile water. The mixed solution in the vial cannot be stored and should be promptly diluted in an infusion bag; only the diluted solution can be held for up to 24 hours if it is kept cool (2°C – 8°C) and in the dark.

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 protect the environment.

6 Contents of the pack and other information

What Cerezyme contains

- The active substance is imiglucerase. Imiglucerase is a modified form of the human enzyme acid β-glucosidase produced by recombinant DNA technology. One vial contains 400 units of imiglucerase. After reconstitution, the solution contains 40 units of imiglucerase per ml.
- The other ingredients are: mannitol, sodium citrate, citric acid monohydrate and polysorbate 80.

What Cerezyme looks like and contents of the pack

Cerezyme, 400 Units, is presented as a powder for concentrate for solution for infusion (in a vial, pack size of 1, 5 or 25). Not all pack sizes may be marketed.

Cerezyme is supplied as a white to off-white powder. After reconstitution it is a clear, colourless liquid, free from foreign matter. The reconstituted solution must be further diluted.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Sanofi B.V.,
Paasheuvelweg 25, 1105 BP, Amsterdam, The Netherlands

Manufacturer

Genzyme Ireland Limited, IDA Industrial Park,
Old Kilmeaden Road, Waterford, Ireland

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

Ireland

sanofi-aventis Ireland Ltd. T/A SANOFI
Tel: +353 (0) 1 403 56 00

Malta

Sanofi S.r.l
Tel: +39 02 39394275

United Kingdom (Northern Ireland)

sanofi-aventis Ireland Ltd. T/A SANOFI
Tel: +44 (0) 800 035 2525

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Detailed information on this medicine is available on the European Medicines Agency web site: <http://www.ema.europa.eu/>. There are also links to other websites about rare diseases and treatments.