

- acute narrowing of the airways
- abnormally low oxygen levels in the blood
- difficulty in breathing when lying flat
- liver damage/failure
- swelling of the face, lips and throat
- kidney failure
- abnormally low levels of fluid around baby in womb
- failure of the lungs of the baby to develop in the womb
- abnormal development of the kidneys of the baby in the womb

Some of the side effects you experience may be due to your underlying cancer. If you receive Herzuma in combination with chemotherapy, some of them may also be due to the chemotherapy.

If you get any side effects, talk to your doctor, pharmacist or nurse.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via UK: Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Herzuma

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the on the outer carton and on the vial label after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C).

Infusion solutions should be used immediately after dilution. Do not use Herzuma if you notice any particulate matter or discoloration prior to administration.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Contents of the pack and other information

What Herzuma contains

- The active substance is trastuzumab. Each vial contains 420 mg trastuzumab that has to be dissolved in 20 mL of water for injection. The resulting solution contains approximately 21 mg/mL trastuzumab.
- The other ingredients are L-histidine hydrochloride, L-histidine, α,α -trehalose dihydrate, polysorbate 20.

What Herzuma looks like and contents of the pack

Herzuma is a powder for concentrate for solution for intravenous infusion, which is supplied in a glass vial with a rubber stopper containing 420 mg of trastuzumab. The powder is a white to pale yellow pellet. Each carton contains 1 vial of powder.

Marketing Authorisation Holder

Celltrion Healthcare Hungary Kft.
1062 Budapest, Váci út 1-3.
WestEnd Office Building B torony.
Hungary

Manufacturer

Biotec Services International Ltd.
Biotec House
Central Park
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

United Kingdom

NAPP Pharmaceuticals Ltd.
Tel: +44-(0)-1223-424444

This leaflet was last revised in March 2019.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: <http://www.ema.europa.eu>

This leaflet is available in all EU/EEA languages on the European Medicines Agency website.

This leaflet is also available in large print, Braille or as an audio CD. To request a copy, please call the RNIB Medicine Information line on:

United Kingdom 0800 198 5000

You will need to give details of the product name and reference number.

These are as follows:

Product name: **Hermuza**

Reference number: EU/1/17/1257/002