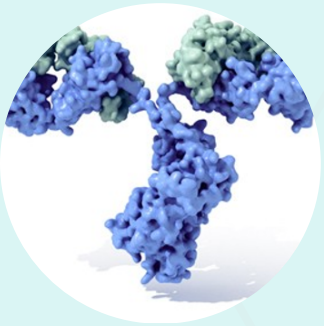
How to handle biological drugs

This folder describes how you should handle your biological drugs. The information given here is general and you also have to obtain information on the specific drug you are handling.

More information:

www.realhope.se



What are biological medicines?

A biological drug is derived from living organisms.
They include therapeutic proteins, monoclonal antibodies, blood components, DNA and RNA-based drugs, vaccines, and stem cells.

Why is it important to handle biological drus properly?

Most biologics are complex and sensitive mixtures. These need careful handling to avoid damaging the product which has consequences on their activity and safety.

How should biological drugs be transported?

DO:

- Transport the drug at the same temperature indicated in the product datasheet
- Pack your drug carefully in order to minimise shaking during transport

DO NOT:

- Drop on the floor
- Expose to light or temperatures outside the range given in the product datasheet
- Transport through pneumatic tube systems

PACKAGE LEAFLET: INFORMATION FOR THE USER

Herceptin 150 mg powder for concentrate for solution for infusion
trastuzumab

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

In this leaflet:

1. What Herceptin is and what it is used for

How should I store biological drugs?

Most biologic drugs need to be stored refrigerated (2-8°C)
DO:

- Store the drugs in the original packaging (including cardboard box)
- Check on a regular basis the range of temperature of your refrigerator

DO NOT:

- Freeze the drug if not stated that it should be frozen
- Store near the freezing wall of the refrigerator
- Store in humid refrigerators

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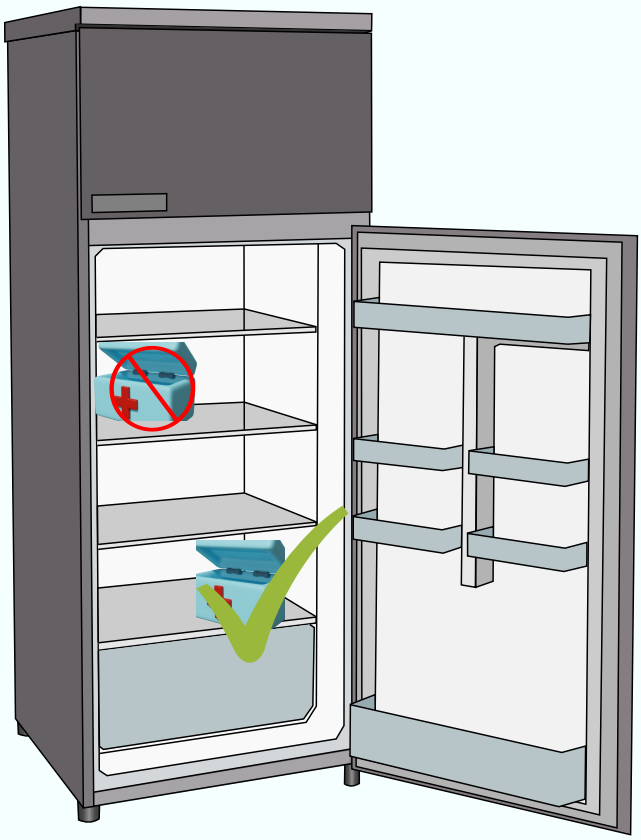

How should you prepare biological drugs?

DO:

- Use aseptic technique
- Follow the instructions provided by the manufacturer – it will vary from drug to drug
- Check compatibility with the solutions and medical devices used for compounding (e.g. syringes, plastic bags, Closed System Drug- Transfer Devices
- Check for the occurrence of turbidity and particles in the solution

DO NOT:

- Flick the syringe
- Drop the preparation on the floor
- Shake the preparation
- Avoid the formation of foam and bubbles
- Mix different drugs in one IV bag or use the same syringe to prepare several products

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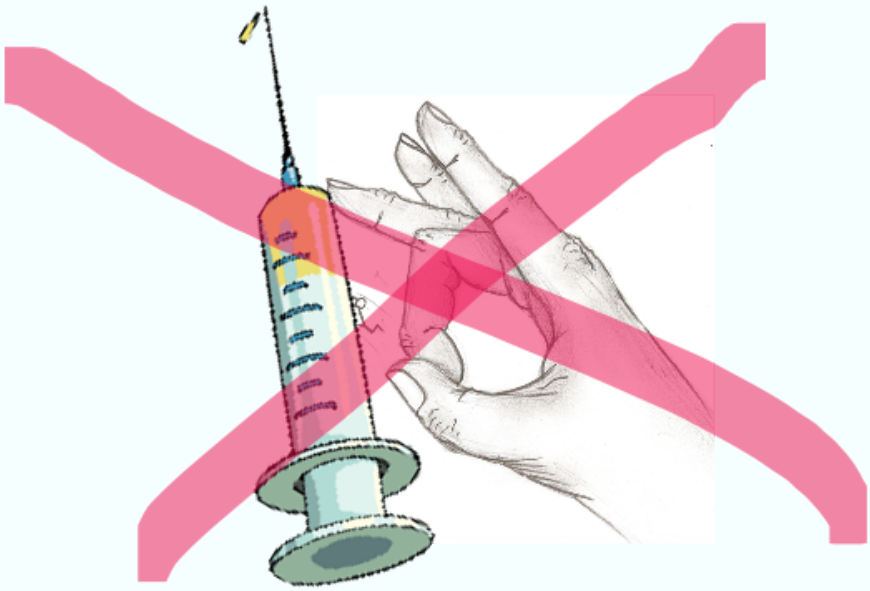

How should you administrate biological drugs?

DO:

- Follow the instructions provided by the manufacturer – it will vary from drug to drug
- Check compatibility with medical devices used for administration
- Check for the occurrence of turbidity (particulates) in the solution
- Chilled medicines need to be warmed to room temperature
- Check for possible reactions or allergies to the drug for each patient
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DO NOT:

- Administer two drugs at the same time without checking the Y-site compatibility
- Use the drug after dropping the drug on the floor
- Shake the drug- avoid foam and bubbles

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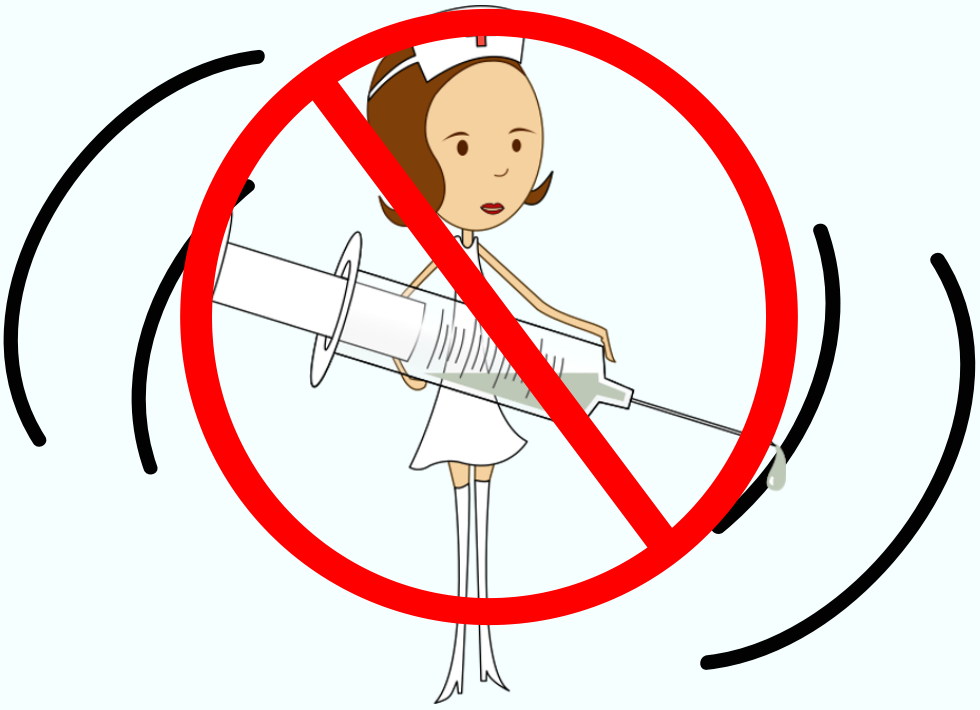

Where do I find more information on biological drugs?

Use your local medical agency or go to EMAs home page
1.Input in your browser: «[drug name] epar»
2.Click on the webpage redirecting to **EMA website**
3.Search for “product information”
4.Download product information in your language
5.Paragraphs 6.2/6.4/6.6 will provide extensive information on handling issues

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This information was created as a part of the RealHOPE project

RealHOPE is a 4 year research project that aims to measure real-life events during drug handling to develop methods for simulating these events. We hope that the results of the RealHOPE project will aid the development of more robust protein drugs with increased safety for patients. The project has received funding from IMI, EU Horizon2020 and EFPIA companies.

You can find more information at www.realhope.se

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