

# Zutectra® 500 IU

## solution for injection in pre-filled syringe

### Human hepatitis B immunoglobulin

**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.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet:

1. What Zutectra is and what it is used for
2. What you need to know before you use Zutectra
3. How to use Zutectra
4. Possible side effects
5. How to store Zutectra
6. Contents of the pack and other information
7. How to inject Zutectra by yourself or by caregiver

#### 1. What Zutectra is and what it is used for

##### What Zutectra is

Zutectra contains antibodies against the hepatitis B virus which are the body's own defensive substances to protect you from hepatitis B. Hepatitis B is an inflammation of the liver caused by the hepatitis B virus.

##### What Zutectra is used for

Zutectra is used to prevent re-infection of hepatitis B in adults who have had a liver transplant at least 1 week ago because they had liver failure caused by hepatitis B.

#### 2. What you need to know before you use Zutectra

##### Do not use Zutectra

- if you are allergic to human immunoglobulin or any of the other ingredients of this medicine (listed in section 6). In particular, in very rare cases of insufficient amount of immunoglobulin A (IgA), when you have antibodies against IgA in your blood. This might lead to severe allergic reaction (anaphylaxis). An allergic reaction may include sudden wheeziness, difficulty in breathing, fast pulse, swelling of the eyelids, face, lips, throat or tongue, rash or itching.

Zutectra is for subcutaneous (under the skin) injection only. Injection into a vein or a blood vessel may result in allergic shock.

##### Warnings and precautions

##### Please tell your doctor or healthcare professional prior to treatment

- if you have been told that you have antibodies against immunoglobulins of the type IgA in your blood. This is very rare and may result in allergic reactions.

**You may be allergic to immunoglobulins** (antibodies) without knowing it, even if you have tolerated previous treatments with human immunoglobulins. Particularly if you do not have enough immunoglobulins of the type IgA in your blood, allergic reactions such as a sudden fall in blood pressure or shock may occur.

##### You will be carefully observed during and shortly after the 1<sup>st</sup> injection with Zutectra

to make sure that you do not suffer from a reaction. If you have an allergic reaction to Zutectra, the injection will be stopped immediately. Please tell your doctor or healthcare professional immediately if you notice any reactions during your injection with Zutectra.

**If you are HBs antigen positive** you will not receive Zutectra since there is no benefit in administering this medicine to you. Your doctor will be able to explain this to you.

**For your own safety** you will be monitored for antibody levels regularly.

##### Possible interference with blood tests

Zutectra might affect the results of certain blood tests (serological tests). Please tell your doctor about your treatment with Zutectra prior to any blood test.



#### **Information on the starting material of Zutectra and the possibility of transmission of infectious agents:**

The starting material or what Zutectra is made from is human blood plasma (this is the liquid part of the blood). When medicines are made from human blood or plasma, certain measures are put in place to prevent infections being passed on to patients. These include

- careful selection of blood and plasma donors to make sure those at risk of carrying infections are excluded, *and*
- the testing of each donation and pools of plasma for signs of virus/infections. Manufacturers of these medicines also include steps in the processing of the blood or plasma that can inactivate or remove viruses. Despite these measures, when medicines prepared from human blood or plasma are administered, the possibility of passing on infection cannot be totally excluded. This also applies to any unknown or emerging viruses or other types of infections.

The measures taken are considered effective for enveloped viruses such as human immunodeficiency virus (HIV), hepatitis B virus and hepatitis C virus, and for the non-enveloped hepatitis A virus. The measures taken may be of limited value against non-enveloped viruses such as parvovirus B19 virus (causative agent of Ringel rubella).

Immunoglobulins like Zutectra have not been associated with hepatitis A or parvovirus B19 infections possibly because the antibodies against these infections, which are contained in the product, are protective.

It is important to keep a record of the batch number of your Zutectra. So, every time you get a new package of Zutectra, **note down the date and the batch number** (which is on the packaging after "Lot") and keep this information in a safe place, for example your treatment diary (see section 3).

#### **Other medicines and Zutectra**

Tell your doctor or healthcare professional if you are taking, have recently taken or might take any other medicines.

#### Vaccinations

Zutectra can reduce the effectiveness of some vaccines (measles, rubella, mumps, chicken pox) for a period of up to 3 months.

You may have to wait at least 3 months after the last injection of Zutectra before you can have live attenuated vaccines.

Please tell your doctor about your treatment with Zutectra prior to any vaccination.

#### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or healthcare professional for advice before taking this medicine.

#### **Driving and using machines**

Zutectra has no or negligible effects on your ability to drive or use machines.

#### 3. How to use Zutectra

Zutectra is intended for **subcutaneous (under the skin) injection**. The content of one pre-filled syringe is intended for use once only. Do not inject into a blood vessel.

In most cases you will be given the injection by your doctor or nurse. However, if your antibody levels are sufficient and you have a fixed dose regimen, you or your caregiver may be trained to carry out the injection at home (see below).

For the documentation of your injections of Zutectra it is strongly recommended to use the treatment diary. Your doctor will explain you how to use it.

The dose can be individually established and adapted from 500 IU up to 1,000 IU (in exceptional cases up to 1,500 IU) weekly or fortnightly. The dose will depend on your condition. Your doctor will regularly check your condition and tell you how much and how often you need to use Zutectra.

#### **Injecting by yourself or by caregiver**

You can inject Zutectra yourself without the help of your doctor, if they have trained you to do this. **If you are administering Zutectra yourself, please read instructions in the section "How to inject Zutectra by yourself or by caregiver" carefully.**

Zutectra must be brought to room temperature (approx. 23°C–27°C) before use.

#### **If you use more Zutectra than you should**

Consequences of an overdose are not known. However, if you have used more than the prescribed dose of Zutectra, contact your doctor, healthcare professional or pharmacist straight away for advice.

#### **If you forget to use Zutectra**

Do not take a double dose to make up for a forgotten injection. Talk to your doctor about managing the dose. Your doctor will tell you how much and how often you need to use Zutectra.

**Make sure you use Zutectra as prescribed and as instructed by your doctor to avoid the risk of a hepatitis B re-infection.**

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Most side effects observed with Zutectra were mild to moderate in nature. In very rare cases human normal immunoglobulins may cause a serious allergic reaction.

#### **If you notice any of the following effects stop the injection and tell your doctor immediately:**

- rash,
- itching,
- wheezing,
- difficulty in breathing,
- swelling of the eyelids, face, lips, throat or tongue,
- low blood pressure, fast pulse

**This can be an allergic reaction or a serious allergic reaction (anaphylactic shock).**

**In case of any adverse event after the injection speak to your doctor immediately.**

#### **The following side effects have been reported with Zutectra:**

**Common** (may affect up to 1 in 10 people):

- injection site reactions: pain, hives (urticaria) at injection site, haematoma (a collection of blood in tissue under the skin), reddening of the skin (erythema).

**Uncommon** (may affect up to 1 in 100 people):

- headache
- upper abdominal pain (from your chest to the belly button)

#### **Furthermore, the following reactions have been reported once only:**

- tiredness (fatigue)
- high blood pressure (hypertension)
- inflammation of the nose and throat (nasopharyngitis)
- muscle spasm
- allergic reactions (hypersensitivity)
- abnormal heartbeat (palpitations), cardiac discomfort
- itching (pruritus), rash
- pain in the mouth and throat

#### **With other human immunoglobulin preparations, the following additional symptoms have been reported:**

- chills
- headache
- dizziness
- fever
- vomiting
- mild allergic reactions
- nausea (urge to vomit)
- joint pain
- low blood pressure
- moderate low back pain
- injection site reactions: swelling, soreness, redness, hardening of the skin, local heat, itching, bruising and rash.

#### **Reporting of side effects**

If you get any side effects, talk to your doctor, healthcare professional or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://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 Zutectra

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 outer carton, the blister and the pre-filled syringe label after EXP. The expiry date refers to the last day of that month.

Store and transport refrigerated (2°C–8°C). Do not freeze. Keep the pre-filled syringe in the outer carton in order to protect from light.

Once the protective cap has been removed from the pre-filled syringe, the solution should be administered immediately.

Do not use Zutectra if you notice that the solution is cloudy or contains particles.

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. Once the injection has been completed, dispose of all needles, syringes and empty glass containers without delay in a container intended for sharp objects you were provided with.

#### 6. Contents of the pack and other information

##### What Zutectra contains

- The **active substance** is human hepatitis B immunoglobulin 500 IU/mL.
- Zutectra contains 150 mg/mL of human plasma protein of which at least 96 % is immunoglobulin G (IgG). The maximum immunoglobulin A (IgA) content is 6,000 micrograms/mL.
- The **other ingredients** are glycine and water for injections.

##### What Zutectra looks like and the contents of the pack

Zutectra is presented as a solution for injection provided in pre-filled syringes (500 IU/mL – pack size of 5 in a blister). The colour of the solution can vary from clear to opalescent and colourless to pale yellow.

One pre-filled syringe of 1 mL Zutectra contains 500 IU. Zutectra is supplied in a pack size containing 5 pre-filled syringes each in a blister pack.

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#### 7. How to inject Zutectra by yourself or by caregiver

The following instructions are intended to explain how to inject Zutectra. Please read the instructions carefully and follow them step by step. The doctor or his/her assistant will teach you the process of administration.

Do not attempt to inject Zutectra until you are sure that you understand how to prepare the injection solution and give the injection.

##### General information:

- Keep the syringes and syringe disposal unit out of the reach of children; lock the supplies if possible.
- Try to take the injection at the same time of day. This makes it easier to remember it.
- Always double-check the dose.
- The solution must be brought to room temperature (approx. 23 °C–27 °C) before use.
- Take each pre-filled syringe only out of the pack when you are ready for an injection. Once the protective cap has been removed from the pre-filled syringe, you should administer the injection immediately.
- The colour of the solution can vary from clear to opalescent and colourless to pale yellow. Do not use solutions that are cloudy or have particles.
- This medicine must not be mixed with other medicines.

##### Before the injection:

**1.** Wash your hands. It is important to have your hands and the items you use as clean as possible.

**2.** Lay out everything you need in advance. Find a clean place where you can spread out all the items you are going to use:

- two alcohol swabs,
- one pre-filled syringe of Zutectra,
- one needle suitable for subcutaneous injection.

Please note that alcohol swabs and needles are not contained in the pack and you need to supply them yourself. Make sure to have your treatment diary and a container intended for sharp objects for waste disposal available.

**3.** Before preparing the injection, decide where you are going to inject. You should inject Zutectra into the fatty layer between the skin and muscle (about 8 to 12 mm under the skin). The best places for injections are where the skin is loose and soft for example in the abdomen, arm, thigh or buttocks, and away from joints, nerves, bones.

**Important:** Do not use on any area where you can feel lumps, bumps, firm knots, pain or on an area that is discoloured, indented, scabbed, or where the skin is broken. Talk to the doctor or healthcare professional about these or any other unusual conditions you may find. You should rotate the injection site at every injection. If some areas are too difficult for you to reach, you may need a caregiver to help you with these injections.

#### 4. Prepare the Zutectra pre-filled syringe:



- Take the pre-filled syringe out of the pack.
- Examine the solution carefully. It should be clear and contain no particles. If the solution is discoloured, cloudy or contains particles, discard it and start again with a new pre-filled syringe.
- Remove the protective cap from the syringe.



- Take the needle out of its sterile pack and fit the needle onto the syringe.

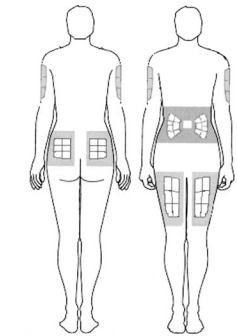
#### 5. Get rid of any air bubbles that may be in the pre-filled syringe.



- Hold the syringe with the needle pointing upwards, and tap the syringe gently with your fingers until the air has collected at the tip. Carefully push the plunger in until the air bubbles have disappeared.

#### Injection

1. Choose the area where you will make the injection and make a note of it in the diary. Further note down the date and the batch number (see "Information on the starting material of Zutectra and the possibility of transmission of infectious agents" in section 2 of this package leaflet).



**Abdomen** (stomach): Do not use the area within one inch around the navel. Avoid using the belt line area, as rubbing may irritate the injection site. Avoid surgical scars. This is likely to be the easiest place to inject if you are doing it yourself.

**Thighs:** Use middle and outer areas where you can pinch up tissue. You are likely to have more fatty tissue the closer you are to the hip and the further you are from the knee.

**Arms:** The back of the upper arm should be used. It is hard to pinch up the tissue and inject Zutectra yourself using this site. If you do choose to inject your arm yourself, try to pinch up the tissue by placing your upper arm over the back of a chair or brace it against a wall. It is much easier for someone else to use this site if you do need help.

**Buttocks:** Use any area where you can pinch up tissue. It's harder to give yourself an injection here. Try standing in front of a mirror to locate the site or you may want to ask your caregiver to give you the injection.

**It's important to change (rotate) the injection sites.** This will help the skin stay supple and help the medicine be absorbed evenly. Rotating sites means starting at one site and using all other sites before going back to the first site you used. Then start the rotation again. It may be helpful to keep a record of where you had the last injection to avoid problems.

The administration in thighs is shown as an example in the following pictures:



2. Wipe the intended area with an alcohol swab. Let the skin air-dry.



3. Gently pinch the skin together around the disinfected injection site (to raise it up a little) and push the needle into the skin with a rapid, confident movement at an angle of 45 to 90 degrees. Inject beneath the skin as you have been shown by the doctor or nurse.



4. Inject the liquid by pressing gently on the plunger. Allow yourself enough time to inject the whole of the solution until the syringe is empty.



5. Then pull the needle out immediately and let go of the pinched skin.



6. Clean the injection site by wiping it in a circular motion with the alcohol swab.

#### Dispose of all used items

Once the injection has been completed, dispose of all needles and empty glass containers without delay in a container intended for sharp objects.