ANNEX III

PACKAGE LEAFLET

Package leaflet: Information for the patient

NEGABAN 1g, powder for solution for injection/infusion
Temocillin

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Negaban is and what it is used for

Negaban is an antibiotic that contains the active substance temocillin. It belongs to a group of antibiotics called penicillins (beta-lactam family).. It works by killing some types of bacteria that may cause infections.
Negaban is used to treat the following infections:
• bacterial infections of the chest and lungs,
• bacterial infections of the kidneys and bladder,
• other types of infections when there are bacteria in the bloodstream.

2. What you need to know before you use Negaban

Do not use Negaban
- if you are allergic to temocillin.
- if you ever had an allergic reaction to other antibiotics of the beta-lactam family such as penicillins, cephalosporins, carbapenems or monobactams.

If you are not sure, you should talk to your doctor, pharmacist or nurse before you receive Negaban. This is especially important if you have ever had an allergic reaction to any antibiotic but you are not sure what type of antibiotic it was.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using Negaban.
- if you have been told that your kidneys do not work normally.
- if you have been told that your potassium levels are low.

If any of the above applies to you, your doctor may still decide to give you Negaban but may choose a lower dose than is usually given.

This medicine contains approximately 5 mmol (115 mg) of sodium per each vial which should be taken into consideration by patients on a controlled sodium diet.

Other medicines and Negaban
You should continue to take all other medicines that you may be taking on a regular basis on the advice of your doctor while you are receiving Negaban.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Negaban with food and drink
Food and drink does not affect your treatment with Negaban.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine.
• You should tell your doctor or nurse if you are pregnant or think you may be pregnant before you receive Negaban because it should not usually be given to pregnant women.
• You should tell your doctor or nurse if you are breastfeeding before you receive Negaban. Small quantities of this medicine appear in breast milk and can be passed on to your baby. Your doctor may decide that you should not have Negaban or may advise you to have Negaban but stop breast-feeding while you are being treated.

Driving and using machines
Negaban should not interfere with your ability to drive or operate machinery.

Negaban does not contain any excipient.

3. How to use Negaban

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Recommended dose
Your doctor will decide how much of this medicine you need each day and how often the injections should be given. The usual doses used are:

Adults of all ages
The usual dose for adults is 4 g per day. You will receive this dose in two administrations per day or as continuous infusion.
In case of severe infections, a higher dose is recommended (6 g per day). You will receive this higher dose in three administrations per day or as continuous infusion. Before start of the continuous infusion you will receive an additional dose of 2 g.

Adults with kidneys that do not work normally
People whose kidneys do not work normally may need a lower daily dose of Negaban. The dose may be reduced to no more than 1 gram per day or even 1 gram every other day.
Because some temocillin is removed from the body during haemodialysis treatments for very poor kidneys, a dose of Negaban is usually given after completing a haemodialysis session.
Your doctor will tell you how much you should have if your kidneys do not work normally.

Use in children
Insufficient data are available to recommend an appropriate dosage regime.
Your doctor will decide how long your treatment with Negaban will last.

Method of administration
Negaban will first be dissolved by your doctor, nurse or pharmacist. This solution will then be given to you either by injection into a vein or by injection into a muscle.

When Negaban is injected into a vein:
- It may be given in 3-4 minutes, be put into an infusion (drip) and given over about 30 minutes or more, or by continuous infusion using an electrical syringe.

- Your doctor or nurse will make sure that Negaban is not given into a drip that also contains blood or blood products, other fluids that contain proteins or fats, or antibiotics called aminoglycosides.

When Negaban is injected into a muscle:
- It may be dissolved in a weak solution of lidocaine so as to lessen the local pain that is sometimes felt when it is given in this way.
- If your doctor decides to give Negaban with lidocaine,
  - he/she will check with you that you are not allergic to lidocaine or to any similar local anaesthetics,
  - and your doctor or nurse will ensure that the injection is not accidentally given into a blood vessel.

If you use more Negaban than you should
Since Negaban is given by a doctor or nurse, it is very unlikely that you will receive too much temocillin. If you think that you may have been given too much, or an extra dose, tell your doctor or nurse.

If you forget to use Negaban
If you think that an injection has been missed, speak to your nurse, doctor or pharmacist.

If you stop using Negaban
Not applicable.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

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

Allergic reactions such as a rash, itching, breathing problems, swelling of the tongue, lips, face and neck can occur occasionally. Some of these reactions can be very severe, can occur very soon after having a dose of Negaban or up to 48 hours later, and can happen after the first dose. In these cases, discontinuance of treatment and urgent medical treatment is needed: contact your doctor or nurse immediately.

Other side effects that have been reported with Negaban treatment include diarrhoea (several loose bowel movements a day) and pain in the muscles or in the joints at the injection site, inflammation of a vein with or without formation of a clot. In case of persistent diarrhoea, treatment must be discontinued immediately.

Bleeding manifestations and disorders of the nerves with muscular contractions have been reported in patients suffering from severe malfunction of the kidneys.

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 the Yellow Card Scheme on the website www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Negaban

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 label and carton after EXP. The expiry date refers to the last day of that month.

Since Negaban is usually given in hospitals, your doctor, nurse or pharmacist will take care that unopened vials are stored in a refrigerator (2°C - 8°C) in the original package and will check that they are not used after the expiry date.

They will also ensure that the powder is made into a solution immediately before it is given to you. Solutions prepared with certain diluents are stable for 24 hours at 25°C.

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 Negaban contains
The active substance is temocillin. There are no other ingredients.

What Negaban looks like and contents of the pack
Each vial of Negaban 1 g powder for solution for injection/infusion contains 1 gram of the active ingredient temocillin. Negaban 1 g powder for solution for injection/infusion is supplied in packs that contain 1 vial.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Eumedica S.A.
Winston Churchill Avenue 67
BE-1180 Brussels
Belgium

Manufacturer
Eumedica S.A.
Chemin de Nauwelette 1
BE-7170 Manage
Belgium

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The following information is intended for healthcare professionals only:

For single-use only.

Negaban is not intended for multi-dose use, any part-used antibiotic solution should be discarded. Solutions are normally a pale yellow colour.

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

Special precautions for disposal and other handling

The solutions should preferably be used immediately after their preparation.

Chemical and physical in-use stability has been demonstrated for 24 hours at 25°C for the following solvents: water for injection, physiological saline (0.9% sodium chloride), dextrose 5%, sodium chloride compound (Ringer's solution), Hartmann solution (sodium lactate compound + Ringer's lactate solution).

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and should normally not be longer than 24 hours at 2-8°C, unless reconstitution/dilution has taken place in controlled and validated aseptic conditions.

Intravenous administration

Intravenous injection

Dose	Suitable solvents	Recommended volume of solvent to be added for dissolution	Final volume
1 g	Water for injection Physiological saline	Dissolve in 10 mL of one suitable solvent.	10.7 ml

Inject I.V. solutions in 3-4 minutes, within one hour following their preparation.

Intermittent intravenous infusion

Solutions should be prepared as described for intravenous injection and then added to an intravenous infusion solution in a mini-bag or in-line burette and administered over a period of 30-40 minutes. Alternatively, using a suitable reconstitution device, the appropriate volume of intravenous fluid may be transferred from the infusion bag into the vial and then drawn back into the bag after dissolution.

Dose	Suitable solvents	Recommended volume of solvent to be added for dissolution
1 g	Water for injection Physiological saline (0.9% sodium chloride) Dextrose 5% Sodium chloride compound (Ringer's solution) Hartmann (Sodium lactate compound – Ringer's lactate solution) Dextrose 10% Sodium lactate M/6 Sorbitol Dextran solutions	Dissolve in 10 mL of one suitable solvent and shake it well until the contents of the vial have dissolved completely. The solution should be visually inspected prior to use. Only clear solutions practically free from particles should be used. Then dilute into a 50-, 100- or 150-mL solution for infusion.

Continuous intravenous infusion

Solutions should be prepared as described and administered over 24 h at a rate of 2 mL/hour. A loading dose of 2 g temocillin is required before starting the continuous infusion.

Daily dose	Suitable solvents	Recommended volume of solvent to be added for dissolution
4 g	Water for injection Physiological saline (0.9% sodium chloride) Dextrose 5% Sodium chloride compound (Ringer's solution) Hartmann (Sodium lactate compound – Ringer's lactate solution)	Dissolve the contents of 4 or 6 vials of Negaban 1 g in 48 mL of one suitable solvent and shake it well until the contents have dissolved completely. The solution should be visually inspected prior to use. Only clear solutions practically free from particles should be used.
6 g		

Intramuscular administration

Intramuscular injection

Dose	Suitable solvents	Recommended volume of solvent to be added for dissolution	Final volume
1 g	Water for injection Physiological saline 0.5 or 1% lidocaine solution. Lidocaine solution should not be administered intravenously.	2 ml	2.7 ml

After addition of water to the vial, shake vigorously. Inject I.M. solutions immediately after preparation.