Package leaflet: Information for the patient

Negaban 1 g powder for solution for injection/infusion
Negaban 2 g powder for solution for injection/infusion
Temocillin

Read all of this leaflet carefully before you start taking 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.
- 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 in adults and in children, where susceptible gram-negative bacilli are highly suspected or confirmed:
- complicated urinary tract infections and kidney infections,
- infections of the lung,
- infections of the skin and tissues below the skin,
- infections of the blood which is or is suspected to be associated with a type of infection mentioned above.

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 especially if:
- you have ever had kidney problems because your treatment may need to be adjusted.
- you have ever had any allergic reactions to antibiotics belonging to beta-lactam family.
- you suffered from diarrhoea whilst taking antibiotics in the past.
- you have been told that your potassium levels are low.

Tell your doctor if any of the following occurs during treatment:
- Severe, sudden allergic reaction (such as swelling of the face, tongue or throat, difficulty in breathing or swallowing, skin rash). If this happens, tell your doctor immediately since the administration of this drug will have to be stopped.

- Diarrhoea. If it becomes severe and persistent, caution should be taken and tell your doctor. Negaban treatment will have to be stopped and an appropriate therapy initiated. Do not take medicines that stop or slow down bowel movements.

This medicinal product contains 4.8 mmol (111 mg) of sodium per each gram which should be taken into consideration by patients on a controlled sodium diet.

Other medicines and Negaban
Tell your doctor, pharmacist or nurse 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 do 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 this medicine.
- You should tell your doctor or nurse if you are pregnant or think you may be pregnant before you receive Negaban because it is preferable to avoid the use of Negaban during pregnancy. Your doctor will decide whether you should use Negaban.
-You should tell your doctor or nurse if you are breastfeeding before you receive Negaban. Small quantities of this medicine may pass into the breast milk and it may affect the baby. Therefore, your doctor should decide whether you should use Negaban while breast-feeding.

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, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.
Negaban is usually given by a doctor or another healthcare professional.

Recommended dose:
The dose depends on the type and the severity of the infection, on how the kidneys work, and in children on the body weight.
Your doctor will decide the dose that you need each day and how often the injections/infusions should be administered per day.

Adults:
The standard dose for adults is 4 g per day. You will receive this dose in two administrations per day. 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.
You may receive a lower dose of Negaban if your kidneys do not work very well because Negaban is removed from your body by the kidneys.

Paediatric population:
The dose for children is usually between 25 and 50 mg for each kg of the child's body weight per day. Patients will receive the dose in two administrations per day. In case of severe infections, the highest dose is recommended (50 mg/kg per day).
The maximum daily dose is not to be more than 4 g per day.

How to use Negaban
Negaban can be given as an infusion (drip or electrical syringe pump) or as an injection directly into a vein or into a muscle.
Into a vein: Negaban may be administered by slow injection over 3 to 4 minutes, by intravenous infusion over a period of 30-40 minutes or by continuous infusion over 24 h.
Into a muscle: Negaban must be given into a muscle after reconstitution. In case of pain at the injection site, a solution of lidocaine may be used.
For instructions on reconstitution and/or dilution of the medicinal product before administration, see information intended for healthcare professionals.

If you use more Negaban than you should
If you accidentally use more than your prescribed dose, contact your doctor, pharmacist or nurse.

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

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
- Raised itchy rash (hives),
- Red or purple discolorations on the skin,
- Fever,
- High concentration of eosinophils (a type of white blood cells),
- Rash,
- Angioedema and anaphylactic shock (including rapid swelling of the face, tongue or throat, difficulty in breathing or swallowing, skin rash and low blood pressure) - See section 2 -

Some of these reactions, such as fever, pain in your joints and in muscles, can occur sometimes more than 48 hours after the beginning of the treatment.

In these cases, discontinuance of treatment and appropriate measures are needed: contact your doctor or nurse immediately.

Inflammation of a vein with or without formation of a clot.

Troubles associated with the nervous system with convulsions in patients suffering from severe malfunction of the kidneys.

Occasionally pain at the injection site following intramuscular administration.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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
HPRA Pharmacovigilance
Website: www.hpra.ie
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.

Unopened vials: Store and transport refrigerated (2°C - 8°C).
Reconstituted and diluted solutions: See further under section “Special precautions for disposal and other handling”.

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
Negaban 1 g:
Each vial contains 1 g of the active ingredient temocillin.
Each vial contains 1,11 g of disodium temocillin, equivalent to 1 g of temocillin.
Each vial contains 4.8 mmol (111 mg) of sodium.
Negaban 1 g is supplied in packs that contain 1 vial.

Negaban 2 g:
Each vial contains 2 g of the active ingredient temocillin.
Each vial contains 2,21 g of disodium temocillin, equivalent to 2 g of temocillin.
Each vial contains 9.6 mmol (222 mg) of sodium.
Negaban 2 g is supplied in packs that contain 1 vial.

Marketing Authorisation Holder and Manufacturer

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This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium, France	Negaban
Germany	Temopen

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The following information is intended for healthcare professionals.

Incompatibilities

Negaban may not be dissolved in solutions of sodium bicarbonate, proteins or proteins hydrolysates and lipids, or in blood or plasma.

Should Negaban be simultaneously administered with an aminoglycoside, both antibiotics may not be mixed in the syringe or in the recipient containing the infusion solution because there is a risk of loss of activity.

This medicinal product must not be mixed with other medicinal products except those mentioned thereafter.

Special precautions for disposal and other handling

At recommended concentrations, chemical and physical in-use stability of the reconstituted and diluted solutions has been demonstrated for 24 hours at 25°C and at 2-8°C for the solvents recommended for intravenous administration (see section “Preparation of solution and administration of Negaban”).

From a microbiological point of view, unless the method of reconstitution and dilution precludes the risk of microbial contamination, the product should be used immediately.
If not used immediately, in-use storage times and conditions are the responsibility of user.

For single use only. Discard any unused solution.

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

Preparation of solution and administration of Negaban

Standard aseptic techniques should be used for solution preparation and administration.
The solution should be visually inspected prior to use. Only clear solutions practically free from particles should be used.

From a microbiological point of view, the product should always be used immediately after reconstitution and dilution.

Dose	Suitable solvents	Preparation of solution and administration
Intramuscular injection		
1 g	Water for injection Physiological saline 0.5 or 1% lidocaine solution. Lidocaine solution should not be administered intravenously.	To prepare the 1 g dose, introduce a syringe needle through the vial closure and inject 3 mL of solvent in 1 vial of Negaban 1 g. Withdraw the needle and shake the vial to obtain a clear solution. Administer immediately after preparation.
Intravenous injection		
1 g or 2 g	Water for injection Physiological saline	To prepare a 1 g dose, introduce a syringe needle through the vial closure and inject 10 mL of solvent in 1 vial of Negaban 1 g. To prepare a 2 g dose, introduce a syringe needle through the vial closure and inject 20 mL of solvent in 1 vial of Negaban 2 g. Withdraw the needle and shake the vial to obtain a clear solution. Administer in 3 to 4 minutes.
Intermittent intravenous infusion		
1 g or 2 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)	To prepare the 1 g dose, introduce a syringe needle through the vial closure and inject 10 mL of solvent in 1 vial of Negaban 1 g. To prepare the 2 g dose, introduce a syringe needle through the vial closure and inject 20 mL of solvent in 1 vial of Negaban 2 g. Withdraw the needle and shake the vial to obtain a clear solution. Dilute into a 50-, 100- or 150-mL solution for infusion. Administer in 30 to 40 minutes.

Continuous infusion		
6 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)	Negaban 1 g: introduce a syringe needle through the vial closure and inject 5 mL of solvent in each of 6 vials. Negaban 2 g: introduce a syringe needle through the vial closure and inject 10 mL of solvent in each of 3 vials. Withdraw the needle and shake the vial to obtain a clear solution. Using a syringe of 50 mL, collect all solutions from the vials and bring the volume to 48 mL with the same solvent. Administer the solution over 24 h (2 mL/h). Note: A loading dose of 2 g temocillin is required before starting the continuous infusion.

ADVICE/MEDICAL EDUCATION

Antibiotics are used to cure bacterial infections. They are ineffective against viral infections.
If your doctor has prescribed antibiotics, you need them precisely for your current illness.
Despite antibiotics, some bacteria may survive or grow. This phenomenon is called resistance: some antibiotic treatments become ineffective.
Misuse of antibiotics increases resistance. You may even help bacteria become resistant and therefore delay your cure or decrease antibiotic efficacy if you do not respect appropriate:

- dosage
- schedules
- duration of treatment.

Consequently, to preserve the efficacy of this drug:

1. Use antibiotics only when prescribed.
2. Strictly follow the prescription.
3. Do not re-use an antibiotic without medical prescription, even if you want to treat a similar illness.
4. Never give your antibiotic to another person; maybe it is not adapted to her/his illness.
5. After completion of treatment, return all unused drugs to your chemist's shop to ensure they will be disposed of correctly.