**Package leaflet: Information for the patient**

**Hydrocortison Medochemie 100 mg poeder voor oplossing voor injectie/infusie**
hydrocortison

**Read all of this leaflet carefully before you are given 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 Hydrocortisone Medochemie is and what it is used for

The active ingredient in Hydrocortisone Medochemie, hydrocortisone, is a glucocorticoid (a natural hormone) that is produced in humans, in the adrenal cortex. The main effect of hydrocortisone is the suppression of inflammatory and immune reactions (reactions of the immune system against foreign substances). In addition, it has an effect on the sugar and protein metabolism.

When your adrenal cortex does not work properly, for example in Addison's disease or adrenogenital syndrome, hydrocortisone can be used in combination with other adrenal cortex hormones. In addition, it can be used if the adrenal cortex does not function due to another condition.

Hydrocortisone is indicated for any condition in which rapid and intense corticosteroid effect is required such as:
- in case of severe exacerbations of asthma, chronic bronchitis or emphysema (long-term condition that causes shortness of breath);
- in status asthmaticus (a persistent asthma attack);
- in combination with other agents for severe allergic reactions.

## 2. What you need to know before you are given Hydrocortisone Medochemie

**Hydrocortisone Medochemie must not be given**
- if you are allergic to hydrocortisone or any of the other ingredients of this medicine (listed in section 6).
- if you suffer from any acute viral, fungal, tropical worm infections. Bacterial infections must first be treated before starting treatment with hydrocortisone.
- if you have a gastric (stomach) or duodenal (small intestine) ulcer.
- if you received or need to receive vaccines with live or attenuated virus, do not use hydrocortisone at a dose that weakens your immune system.
- by the epidural route.

The general conditions for not using adrenal cortex hormones (glucocorticosteroids) and the precautions that apply when using systemic glucocorticosteroid therapy are also applicable to hydrocortisone.

**Warnings and precautions**
This medicine is not recommended for use by the intrathecal route of administration, except as part of certain chemotherapy regimens.

Because the risk of side effects with the use of glucocorticosteroids increases as the dose increases and the treatment duration becomes longer, the advantages and disadvantages of the treatment in the determination of the dose and duration of treatment will be carefully weighed against each other.

The use of hydrocortisone should not be stopped suddenly, but gradually withdrawn.

Talk to your doctor, pharmacist or nurse before you are given Hydrocortisone Medochemie.
- Glucocorticoids can suppress the symptoms of an infection and new infections can occur during their use, because your resistance may decrease. In case of a bacterial infections your doctor will first determine the type of bacteria and he will treat the infection before you are treated with glucocorticoids.
- If you use medicines that suppress the immune system, you may be more susceptible to infections than healthy individuals.
- If you have septic shock. This is a condition caused by an infection that is characterized by a sharp drop in blood pressure, paleness, restlessness, weak rapid pulse, clammy skin and reduced consciousness. Routine use of hydrocortisone is not recommended in that case.
- You should not be vaccinated with a live virus vaccine during treatment with a high dose of hydrocortisone.
- If you have active tuberculosis or you are being treated for tuberculosis, your doctor will monitor you closely during the treatment with hydrocortisone.
- If you have had an allergic reaction to a medicine previously, your doctor will take the necessary precautions before starting treatment.
- Patients who undergo surgery, suffer an accident or get an infection during or after the treatment with hydrocortisone sometimes need be treated with fast-acting glucocorticoids.
- If you have Cushing's disease (disease caused by excess levels of the hormone cortisol in the blood).
- If you have reduced thyroid function (hypothyroidism).
- If you have an over-active thyroid gland (hyperthyroidism)
- If you have diabetes.
- During treatment, psychiatric changes can occur, for example light-heartedness, insomnia, irritability, personality changes and depression.
- If you have a disease associated with fits/seizures (such as epilepsy).
- There have been reports of accumulation of fat in the spinal canal with long-term use of corticosteroids in high doses.
- If you have a herpes eye infection, you should be checked regularly by the ophthalmologist during treatment.
- Treatment with corticosteroids may cause loosening of the retina of the eye and cataracts. Contact your doctor if you experience blurred vision or other visual disturbances.
- Corticosteroid therapy may lead to retinal detachment and to cataracts.
- If you have a pre-existing risk factor for cardiovascular (heart) disease, you may be at an increased risk for additional cardiovascular disease with high doses and long-term use of hydrocortisone. Examples include increased blood pressure and an increase and/or decrease of one or more of the blood fats (lipids, cholesterol, triglycerides).
- If you suffer from inflammation in the stomach or intestines, increased blood pressure, active or latent stomach ulcer, impaired kidney function, tumour in the adrenal medulla, Kaposi sarcoma (a certain form of skin cancer), osteoporosis (disease that weakens your bones), myasthenia gravis (a certain muscle disease), or if you suffer from or are at increased risk of thrombosis (formation of blood clots), your doctor will be extra careful when prescribing hydrocortisone.
- If you have liver disease, your doctor may prescribe a lower dose, as hydrocortisone may have an enhanced effect on you.
- If you use certain painkillers with inflammation-preventing and fever-reducing effect (NSAIDs).
- If you have an inflammation of the pancreas with strong pain in the upper stomach radiating towards the back, and nausea and vomiting.

- If you have muscle problems (pain or weakness) have happened while taking steroid medicines in the past.
- If you have kidney disease.
- If you suffer from reduced pumping power of the heart (congestive heart failure).
- Hydrocortisone can cause elevation of blood pressure, salt and water retention and increased excretion of potassium. Your doctor can prescribe a low-salt diet and potassium supplementation for this. Dietary salt restriction and potassium supplementation may be necessary. All corticosteroids increase calcium excretion.
- If you are suffering from a traumatic brain injury.
- If you are suffering from pheochromocytoma (a rare tumour of adrenal gland tissue. The adrenal glands are located above the kidneys).
- If you are suffering from tumour lysis syndrome (a life-threatening emergency that occurs because of the rapid breakdown of multiplying cancer cells causing high levels of calcium, uric acid, potassium and phosphate) in patients with cancer.

Contact your doctor promptly if you experience muscle weakness, muscle aches, cramps and stiffness while using hydrocortisone. These can be symptoms of a condition called Thyrotoxic Periodic Paralysis, which may occur in patients with an over-active thyroid gland (hyperthyroidism) who are treated with hydrocortisone. You may need additional treatment to alleviate this condition.

**Children and adolescents**
Long-term treatment with glucocorticoids can lead to growth retardation in children and adolescents.
The doctor will therefore usually treat children with alternate doses.
Babies and children treated with long-term corticosteroids are at an increased risk of elevated pressure within the skull.
High doses of corticosteroids can cause pancreatitis (swelling of the pancreas) in children.
If hydrocortisone is administered to a premature newborn, the function and structure of the heart may need to be monitored.

**Other medicines and Hydrocortisone Medochemie**
Tell your doctor if you are using, have recently used or might use any other medicines.
You must inform your doctor about any other medicines, such as:
- Isoniazid: used to treat bacterial infections.
- Rifampicin: antibiotic used to treat tuberculosis.
- Substances that counteract blood coagulation (oral anticoagulants).
- Barbiturates, carbamazepine and phenytoin used to treat epilepsy.
- Substances used to treat certain nervous system diseases (anticholinergics).
- Substances used for the muscle disease myasthenia gravis (anticholinesterases).
- Substances used to treat diabetes (antidiabetics).
- Aprepitant and fosaprepitant: used to prevent nausea and vomiting.
- Itraconazole and ketoconazole: used to treat fungal infections.
- Some medicines may increase the effects of hydrocortisone and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: indinavir, ritonavir, cobicistat).
- Aminoglutethimide and cyclophosphamide: used to treat cancer.
- Diltiazem: used to treat heart problems or high blood pressure.
- Digoxin: medicine for the heart which belongs to a group of medicines called cardiac glycosides.
- Oestrogens (including oral contraceptives that contain oestrogens).
- Ciclosporin: used to treat conditions such as severe joint inflammation (rheumatoid arthritis), severe skin conditions associated with scaly, dry skin rashes (psoriasis) and to prevent rejection of a transplanted organ.
- Cyclophosphamide or tacrolimus: medicines used following an organ transplant to prevent rejection of the organ.
- Clarithromycin, erythromycin and/or troleandomycin: medicines used to prevent/fight certain infections.
- Aspirin (acetylsalicylic acid) and a certain group of painkillers that also have inflammation preventing and fever-reducing action (NSAIDs).

- Potassium-lowering substances, such as diuretics.

**Hydrocortisone Medochemie with food, drink and alcohol**
Grapefruit juice can change the effects of hydrocortisone. Always consult your doctor or pharmacist about drinking grapefruit juice together with this medicine.

**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 for advice before you are given this medicine.

**Pregnancy**
Hydrocortisone can be used in accordance with approved indications. Chronic use of higher doses should be avoided as much as possible.

**Breast-feeding**
Corticosteroids pass into breast milk. Therefore, breast-feeding during treatment with corticosteroids is not recommended, unless this happens in consultation with your doctor.

**Fertility**
There is no evidence that corticosteroids interfere with fertility.

**Driving and using machines**
A number of possible side effects with hydrocortisone such as blurred vision, mood changes, muscle weakness and involuntary muscle contractions may negatively affect the ability to drive and use machines.

**Hydrocortisone Medochemie contains sodium**
This medicine contains less than 1 mmol sodium (23 mg) per vial, that is to say essentially 'sodium-free'.

## 3. How Hydrocortisone Medochemie is given

Hydrocortisone is injected by your doctor or a nurse. It can be given into a vein (with a syringe or an infusion) or into a muscle (with a syringe).

Your doctor will determine the right dose for you depending on your illness and situation.

**If you are given more Hydrocortisone Medochemie than you should**
No data on acute overdose of hydrocortisone are known. Hydrocortisone is dialysable. This means that in the event of an overdose, excess hydrocortisone can be removed from the blood with the aid of an artificial kidney. With long-term repeated use (daily or several times a week), Cushing's syndrome (including a full-moon face) may occur.

**If you miss a dose of Hydrocortisone Medochemie**
Your doctor will normally ensure that you receive the next dose on time. You should not be given a double dose to make up for a forgotten dose.

**If you stop receiving Hydrocortisone Medochemie**
If treatment with hydrocortisone is stopped suddenly or if you have to undergo surgery during the treatment, an accident or a severe infection, your adrenal cortex may not work as well. This would allow the symptoms of the disease for which you are treated to come back. Epileptic seizures (fits), dizziness and headache may occur, especially in children, if the treatment is stopped too soon.
Therefore, your doctor will usually gradually reduce treatment with hydrocortisone.

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.

The following side effects have been reported at unknown frequencies, which means that the frequency cannot be determined based on available data:

- Hydrocortisone suppresses the symptoms of an inflammatory response, as a result of which infections can be hardly recognized, dormant infections can be activated and new infections can occur.
- Infections that are normally rare may occur (opportunistic infection).
- A form of skin cancer (Kaposi sarcoma).
- Strong increase in blood pressure due to a swelling of the adrenal medulla (pheochromocytoma).
- More white blood cells in the blood than normal (leucocytosis).
- Severe allergic reaction to certain substances, involving a sharp drop in blood pressure, paleness, restlessness, weak rapid pulse, clammy skin and reduced consciousness following a sudden, important vasodilation (anaphylactic reaction).
- Sharp drop in blood pressure, paleness, restlessness, weak rapid pulse, clammy skin and reduced consciousness due to sudden, important vasodilation without an already existing allergy (anaphylactoid reaction).
- Hypersensitivity (allergic reaction) to medicines.
- The development of obesity (head, trunk), full moon face and high blood pressure (Cushing syndrome).
- Shortage of one or more hormones secreted by the pituitary gland (hypothalamic-pituitary-adrenal axis suppression).
- Syndrome associated with withdrawal symptoms that may occur after stopping treatment with corticosteroids (steroid withdrawal syndrome).
- Acidification of the blood (metabolic acidosis).
- Retention of sodium salt by the kidney (sodium retention).
- Retention of excess fluid in the body (fluid retention).
- Disruption of fat metabolism (dyslipidaemia).
- Disturbed acid-base balance of the blood due to excessive potassium loss (hypokalemic alkalosis).
- Reduced ability to tolerate glucose (reduced glucose tolerance).
- Blood sugar dysregulation that allows dormant diabetes to be detected or increases need for insulin or other blood sugar lowering medication.
- Increased appetite.
- Accumulation of adipose tissue in different parts of the body (lipomatosis).
- Psychotic disorders, such as excess light-heartedness associated with having a great deal of energy (mania), delusions, observations of things that are not there (hallucinations) and a serious mental illness (schizophrenia) characterized by a gradually change of personality.
- Mood disorders such as depressed mood, extreme feeling of joy (euphoria), emotional lability, drug dependence, suicidal thoughts.
- Mental disorder.
- Confusion.
- Fear.
- Personality change.
- Mood swings.
- Abnormal behaviour.
- Insomnia.
- Irritability.
- Worsening of already existing psychotic behaviour.
- Accumulation of fat in the spinal canal (epidural lipomatosis).
- Increased skull pressure.
- Increased pressure in the brain with swollen mucous membranes (benign intracranial hypertension).
- Attack of unconsciousness with muscle twitching (convulsion).
- Memory loss (amnesia).

- Disruption in cognitive functions such as perception, attention, concentration, memory, orientation, language use and skills (cognitive impairment).
- Dizziness.
- Headache.
- Retinal and choroidal disease (chorioretinopathy).
- Blurred vision.
- Cloudy lens (cataract).
- Increased eye pressure (glaucoma).
- Abnormal bulging of the eye (exophthalmia).
- Vertigo (feeling of spinning, even when you are not moving).
- The pumping power of the heart could be reduced in at-risk patients (congestive heart failure).
- Increased blood clotting (thrombosis).
- Reduced blood pressure (hypotension).
- Increased blood pressure (hypertension).
- Pulmonary embolism (blood clots in your lung that creates a blockage).
- Persistent hiccups.
- Gastric/duodenal ulcers with possible perforation and bleeding.
- Bleeding and injury of the intestinal wall (intestinal perforation).
- Gastric bleeding.
- Inflammation of the pancreas with severe pain in the upper abdomen radiating to the back, nausea and vomiting (pancreatitis).
- Inflammation of the oesophagus with or without ulcers (esophagitis).
- Pain in the abdomen (abdominal pain).
- Swollen stomach (abdominal distension).
- Diarrhoea.
- Disturbed digestion with a full feeling in the upper stomach, pain in the stomach, burping, nausea, vomiting and heart burn (dyspepsia).
- Nausea.
- Sudden fluid accumulation in the skin and mucous membranes (such as throat or tongue), breathing difficulties and/or itching and skin rash, often as an allergic reaction (angioedema).
- Excessive hair growth in women (hirsutism).
- Small spots of bruising under the skin (petechiae).
- Small spots of bruising in a mucous membrane (ecchymosis).
- Thin, fragile, wrinkled skin (skin atrophy).
- Redness of the skin (erythema).
- Excessive sweating (hyperhidrosis).
- Streaks on the skin (striae).
- Skin rash.
- Itching (pruritus).
- Skin rash with severe itching and formation of bumps (urticaria).
- (Youth) Pimples (acne).
- Muscle weakness.
- Muscle pain (myalgia).
- Muscle disease (myopathy).
- Reduction of muscle tissue because a muscle is not used or can no longer be used due to a nervous system disease (muscle atrophy).
- Bone breakdown (osteonecrosis).
- Bone decalcification (osteoporosis).
- Bone fracture (pathological fracture).
- Joint disease due to a nervous disorder (neuropathic arthropathy).
- Joint pain (arthralgia).
- Growth retardation.
- Collapsed vertebrae (spinal compression fracture).
- Torn tendons.
- Irregular menstruation.
- Impaired wound healing.
- Fluid accumulation in the arms and legs (peripheral oedema).

- Tiredness.
- General feeling unwell, feeling sick (malaise).
- Skin reactions at the site of injection.
- Increase of the eyebolt pressure.
- Reduced ability to process sugars (carbohydrates), leading to a possible increased need for insulin or another substance to reduce blood sugar levels.
- Reduced potassium level in the blood, in severe form recognizable by muscle spasms or muscle weakness and fatigue (hypokalaemia).
- Increased calcium level in the urine.
- Abnormal blood test results (increased alanine aminotransaminase, aspartate aminotransaminase or blood alkaline phosphatase).
- Increased amount of waste products in the blood due to degradation of proteins (increased blood urea).
- Suppression of reactions to skin allergy tests.
- Thickening of the heart muscle (hypertrophic cardiomyopathy) in premature newborns.
- Weight gain.

**Additional side effects in children and adolescents**
- Growth inhibition may occur in children.

**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 national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Hydrocortisone Medochemie

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

This medicinal product does not require any special storage conditions. Keep the vial in the outer carton in order to protect from light.
Storage after reconstitution:
After reconstitution, the solution should be used immediately.

Storage after dilution:
Regarding the intravenous infusion, this medicinal product can be diluted with sodium chloride 9 mg/ml (0.9%) or 5% glucose.
Chemical and physical in-use stability has been demonstrated as follows:
- At 0.1 mg/mL, the diluted solution may be stored for up to 6 hours at room temperature or in a refrigerator (2–8°C).
- At 1 mg/mL, the diluted solution may be stored:
  - Up to 3 hours at room temperature in sodium chloride or glucose solution
  - Up to 6 hours in a refrigerator
  - Up to 6 hours at room temperature if diluted in a mixture of sodium chloride and glucose

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

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 Hydrocortisone Medochemie contains**
- The active substance is hydrocortisone. Each vial contains 100 mg hydrocortisone as hydrocortisone sodium succinate.
- The other ingredients are: sodium carbonate E500(i), sodium dihydrogen phosphate monohydrate E339(i) and disodium phosphate E339(ii).

**What Hydrocortisone Medochemie looks like and contents of the pack**
White or nearly white, hygroscopic amorphous powder.
7 ml glass vials type III, sealed with a 20mm Sterile rubber stopper and aluminum flip off caps suitable for parenteral preparation.
Boxes of 1 and 10 vials are available.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**
**Registratiehouder**
Medochemie Limited
1-10 Konstantinoupoleos Street
3011 Limassol Cyprus

**Fabrikant**
MEDOCHEMIE LTD
Agios Athanassios Industrial Area
Iapetou 48
4101 Limassol Cyprus

**In het register ingeschreven onder**
Hydrocortison Medochemie 100 mg poeder voor oplossing voor injectie/infusie RVG 134247
**This medicinal product is authorised in the Member States of the EEA under the following names:**

| | |
|---|---|
| Netherlands | Hydrocortison Medochemie 100 mg poeder voor oplossing voor injectie/infusie |
| Czech Republic | HYDROCORTISONE MEDOCHEMIE |
| Estonia | Hydrocortisone Medochemie |
| Spain | Hidrocortisona Medochemie 100 mg polvo para solución inyectable y para perfusión EFG |
| Croatia | Hidrokortizon Medochemie 100 mg prašak za otopinu za injekciju/infuziju |
| Latvia | Hydrocortisone Medochemie 100 mg pulveris injekciju/infūziju šķīduma pagatavošanai |
| Malta | Hydrocortisone Medochemie 100mg/vial powder for solution for injection/infusion |
| Portugal | Hidrocortisona Medochemie 100 mg pó para solução injetável ou para perfusão |
| Romania | Hidrocortizon Medochemie 100 mg pulbere pentru soluție injectabilă/perfuzabilă |
| Slovenia | Hidrokortizon Medochemie 100 mg prašek za raztopino za injiciranje/infundiranje |

**Deze bijsluiter is voor het laatst goedgekeurd in mei 2026.**

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The following information is intended for healthcare professionals only:

**Posology and method of administration:**
Hydrocortisone Medochemie may be administered by intravenous or intramuscular injection, or by intravenous infusion. The intravenous injection is the preferred method for initial emergency use.

Following the initial emergency period, consideration should be given to employing a longer-acting injectable preparation or an oral preparation. The duration of intravenous administration depends on the dose; it can vary from 30 seconds (for example 100 mg) to 10 minutes (for example 500 mg or more).
In general high-dose corticosteroid therapy should be continued only until the patient's condition has stabilised (usually not beyond 48 to 72 hours).
Although adverse effects associated with high dose, short-term corticoid therapy are uncommon, peptic ulceration may occur. Prophylactic antacid therapy may be indicated.
If hydrocortisone therapy must be continued beyond 48 to 72 hours hypernatremia may occur, therefore it may be preferable to replace hydrocortisone with a corticosteroid such as methylprednisolone sodium succinate as little or no sodium retention occurs.
The initial dose of hydrocortisone is 100 mg to 500 mg or more, depending on the severity of the condition. This dose may be repeated at intervals of 2, 4 or 6 hours as indicated by the patient's clinical condition. Corticosteroid therapy is an adjunct to, and not a replacement for, conventional therapy.
In patients with liver disease, there may be an increased effect and reduced dosing may be considered.

Paediatric population
The dose of hydrocortisone in paediatrics is governed more by the severity of the condition and response of the patient, than by age or body weight. Dose may be reduced for these patients but should not be less than 25 mg daily.

**Preparation of solutions**
Instructions for reconstitution
Under aseptic conditions, add 2 ml of water for injection to the vial containing sterile powder.

Intravenous or intramuscular injection
Prepare the solution as described above. No further dilution is required for intravenous or intramuscular injection.

Intravenous infusion
First prepare the solution as described above. The 100 mg solution may then be added to 100 to 1000 ml of one of the following solutions:
- aqueous 5% glucose solution
- sodium chloride 9 mg/ ml (0.9%) solution.
- sodium chloride 9 mg/ ml (0.9%) with 5% glucose solution

Stability after dilution
- 0.1 mg/mL: chemically and physically stable for 6 hours at 2–8°C or 25°C in all tested diluents.
- 1 mg/mL:
    - Stable for 3 hours at 25°C in sodium chloride 9 mg/ ml (0.9%) or 5% glucose
    - Stable for 6 hours at 2–8°C in sodium chloride 9 mg/ ml (0.9%) or 5% glucose
    - Stable for 6 hours at 2–8°C and 25°C in sodium chloride 9 mg/ ml (0.9%) with 5% glucose

From a microbiological point of view, the product should be used immediately.

The pH of the reconstituted solution prepared as described above is between 7 and 8.

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

**Shelf life**
*Vial*: 2 years

After reconstitution
After reconstitution with Water for Injections, the solution should be used immediately.

After dilution for intravenous infusion
Chemical and physical in-use stability has been demonstrated as follows:

- At a concentration of 0.1 mg/mL hydrocortisone, the diluted solution is stable for 6 hours at 2–8°C and at 25°C when diluted with:
    - sodium chloride 9 mg/ ml (0.9%) solution
    - 5% glucose solution
    - sodium chloride 9 mg/ ml (0.9%) and 5% glucose solution
- At a concentration of 1 mg/mL hydrocortisone:
    - Stable for 3 hours at 25°C when diluted with sodium chloride 9 mg/ ml (0.9%) or 5% glucose
    - Stable for 6 hours at 2–8°C when diluted with sodium chloride 9 mg/ ml (0.9%) or 5% glucose
    - Stable for 6 hours at 2–8°C and 25°C when diluted with sodium chloride 9 mg/ ml (0.9%) and 5% glucose solution

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

**For further information see the Summary of Product Characteristics.**