Package leaflet: Information for the user

Oxycodone Hydrochloride 10mg/ml Solution for Injection or Infusion

(referred to as Oxycodone Injection in this leaflet)

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

What is in this leaflet:
1. What Oxycodone Injection is and what it is used for
2. What you need to know before you use Oxycodone Injection
3. How to use Oxycodone Injection
4. Possible side effects
5. How to store Oxycodone Injection
6. Contents of the pack and other information

1. What Oxycodone Injection is and what it is used for

This injection has been prescribed for you by your doctor to relieve moderate to severe pain. It contains the active ingredient oxycodone which is a strong analgesic ('painkiller') which belongs to a group of medicines called opioids.

2. What you need to know before you use Oxycodone Injection

Do not use Oxycodone injection if you:
• are allergic (hypersensitive) to oxycodone, or any of the other ingredients of the injection (listed in section 6) or have previously had an allergic reaction when taking other strong analgesics or painkillers (such as morphine or other opioids;
• have breathing problems, such as severe chronic obstructive lung disease, severe bronchial asthma or severe respiratory depression. Symptoms may include breathlessness, coughing or breathing more slowly or weakly than expected;
• have a condition where the small bowel does not work properly (paralytic ileus) or you have severe pain in your abdomen (acute abdomen);
• have a heart problem after long-term lung disease (cor pulmonale).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before treatment with Oxycodone injection if you:
• are elderly or weakened;
• have an under-active thyroid gland (hypothyroidism);
• have myxoedema (a thyroid disorder with dryness, coldness and swelling ('puffiness') of the skin affecting the face and limbs);
• have a head injury, severe headache or feel sick as this may indicate that the pressure in your skull is increased;
• have low blood pressure (hypotension);
• have low blood volume (hypovolaemia);
• have inflammation of the pancreas (which may cause severe pain in the abdomen and back) or problems with your gall bladder or bile duct;
• have a blockage of the gut or an inflammatory bowel disorder;
• have colicky abdominal pain or discomfort;
• have an enlarged prostate gland which causes difficulty in passing urine (in men);
• have poor adrenal gland function (your adrenal gland is not working properly) for example Addison's disease;
• have breathing problems such as severely impaired respiratory function, chronic obstructive airways disease, severe lung disease or reduced respiratory reserve. Symptoms may include breathlessness and coughing;
• have kidney or liver problems;

• you or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs (“addiction”);
• are a smoker;
• have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses;
• have withdrawal symptoms such as agitation, anxiety, palpitations, shaking or sweating upon stopping taking alcohol or drugs;
• suffer from seizures, fits or convulsions;
• are feeling light-headed or faint;
• need to take increasingly higher doses of Oxycodone to gain the same level of pain relief (tolerance);
• have an increased sensitivity to pain;
• are taking a type of medicine known as a monoamine oxidase inhibitor (examples include tranylcypromine, phenelzine, isocarboxazid, moclobemide and linezolid), or you have taken this type of medicine in the last two weeks;
• suffer from constipation.

Contact your doctor if you experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system.

Sleep-related breathing disorders
Oxycodone Injection can cause sleep-related breathing disorders such as sleep apnoea (breathing pauses during sleep) and sleep related hypoxemia (low oxygen level in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day. If you or another person observe these symptoms, contact your doctor. A dose reduction may be considered by your doctor.

If you are going to have an operation, please tell the doctor at the hospital that you are using this medicine.

You may experience hormonal changes while taking this medicine. Your doctor may want to monitor these changes.

Opioids are not the first choice of treatment for pain not related to cancer and are not recommended as the only treatment. Other medicines should be used in the treatment of chronic pain along with opioids. Your doctor should monitor you closely and make necessary adjustments to your dose while you are taking Oxycodone Injection to prevent addiction and abuse.

Tolerance, dependence and addiction

This medicine contains oxycodone which is an opioid medicine. Repeated use of opioid painkillers can result in the drug being less effective (you become accustomed to it, known as tolerance). Repeated use of Oxycodone Injection may lead to dependence, abuse, and addiction, which may result in life-threatening overdose. The risk of these side effects can increase with a higher dose and longer duration of use.

Dependence or addiction can make you feel that you are no longer in control of how much medicine you need to take or how often you need to take it. You might feel that you need to carry on taking your medicine, even when it doesn’t help to relieve your pain.

The risk of becoming dependent or addicted varies from person to person. You may have a greater risk of becoming dependent or addicted on Oxycodone Injection if:
- You or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs (“addiction”).
- You are a smoker.
- You have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

If you notice any of the following signs whilst taking {product name}, it could be a sign that you have become dependent or addicted.
- You need to take the medicine for longer than advised by your doctor
- You need to take more than the recommended dose
- You are using the medicine for reasons other than prescribed, for instance, ‘to stay calm’ or ‘help you sleep’
- You have made repeated, unsuccessful attempts to quit or control the use of the medicine
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again (‘withdrawal effects’)

If you notice any of these signs, speak to your doctor to discuss the best treatment pathway for you, including when it is appropriate to stop and how to stop safely (See section 3, If you stop using Oxycodone Injection).

Children and adolescents

Do not give this medicine to children under 18 years the potential benefits are not greater than the risks.

Other medicines and Oxycodone injection
Concomitant use of opioids, including oxycodone and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. However, if your doctor does prescribe Oxycodone Injection together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

The risk of side effects increases if you use antidepressants (such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine). These medicines may interact with oxycodone and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.

Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. If you use this injection with some other medicines, the effect of this injection or the other medicines may be changed.

Tell your doctor or pharmacist if you are taking:
• a type of medicine known as a monoamine oxidase inhibitor or you have taken this type of medicine in the last two weeks (see 'Warnings and precautions');
• medicines to help you sleep or stay calm (for example hypnotics or sedatives, including benzodiazepines);
• medicines to treat depression (such as paroxetine or fluoxetine);
• a herbal remedy called St. John's Wort (also known as *Hypericum perforatum*);
• medicines to treat psychiatric or mental disorders (such as phenothiazines or neuroleptics);
• medicines to treat epilepsy, pain and anxiety such as gabapentin and pregabalin;
• other strong analgesics ('painkillers');
• muscle relaxants;
• medicines to treat high blood pressure.
• quinidine (a medicine to treat a fast heartbeat);
• cimetidine (a medicine for stomach ulcers, indigestion or heartburn);
• medicines to treat fungal infections (such as ketoconazole, voriconazole, itraconazole and posaconazole);
• medicines used to treat bacterial infections (such as clarithromycin, erythromycin or telithromycin);
• a specific type of medicine known as a 'protease inhibitor' to treat HIV (e.g. boceprevir, ritonavir, indinavir, nelfinavir or saquinavir);
• rifampicin (a medicine to treat tuberculosis);
• carbamazepine (a medicine to treat seizures, fits or convulsions and certain pain conditions);
• phenytoin (a medicine to treat seizures, fits or convulsions);
• antihistamines;
• medicines to treat Parkinson's disease;

Also, tell your doctor if you have recently been given an anaesthetic.

Oxycodone Injection with food, drink and alcohol
Drinking alcohol during your treatment with this injection may make you sleepy or increase the risk of serious side effects such as shallow breathing with a risk of stopping breathing, and loss of consciousness. It is recommended not to drink alcohol while you're using Oxycodone injection.

You should avoid drinking grapefruit juice during your treatment with this medicine.

Pregnancy and breast-feeding
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

Pregnancy
You should not use this injection during pregnancy and labour unless you have been specifically told by your doctor. Depending on the dose and duration of therapy with oxycodone, slow and shallow breathing (respiratory depression) or withdrawal symptoms may occur in the newborn infant.

Breast-feeding
This injection should not be used while breast-feeding because the active ingredient may pass into breast milk.

Driving and using machinery
This injection may cause a number of side effects such as drowsiness or dizziness which could affect your ability to drive or use machinery (see section 4 for a full list of side effects).
These are usually most noticeable when you first start using the injection, or when increasing to a higher dose. If you are affected you should not drive or use machinery.

Oxycodone Injection contains sodium
This medicinal product contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'.

3. How to use Oxycodone Injection

A doctor or nurse will usually prepare and administer the injection for you. The injection should be used immediately after opening. The dose and how often the injection is given may be adjusted according to the severity of your pain.

Before starting treatment and regularly during treatment, your doctor will discuss with you what you may expect from using Oxycodone Injection, when and how long you need to take it, when to contact your doctor, and when you need to stop it (see also if you stop using Oxycodone Injection).

Adults (over 18 years of age)
The usual starting dose is dependent upon how the injection is administered.
The usual starting doses are as follows:
• As a single injection into a vein, the usual dose is 1 to 10 mg given slowly over 1 to 2 minutes. This can be repeated every 4 hours.
• As an infusion into a vein, the usual starting dose is 2 mg/hour.
• As a single injection through a fine needle into the tissue under the skin, the usual starting dose is 5 mg repeated at 4-hourly intervals if needed.
• As an infusion through a fine needle into the tissue under the skin, the usual starting dose is 7.5 mg/day.
• If given by patient controlled analgesia (PCA), the dose is worked out according to your weight (0.03 mg per kg of body weight). Your doctor or nurse will set a suitable frequency.

Children
Children and adolescents under 18 years of age should not be given this injection.

Patients with kidney or liver problems
Please tell your doctor if you suffer from kidney or liver problems as they may prescribe you an alternative medicine or a lower dose depending on your condition.

If you use more Oxycodone injection than you should, or if someone else uses your injection
Call your doctor or hospital straight away. An overdose may result in:
• A reduction in size of pupils in the eye
• Breathing more slowly or weakly than expected (respiratory depression)
• Drowsiness or loss of consciousness
• Low muscle tone (hypotonia)
• Reduced pulse rate
• A fall in blood pressure
• Difficulty in breathing due to fluid on the lungs (pulmonary oedema)
• A brain disorder (known as toxic leukoencephalopathy).

In severe cases an overdose may lead to unconsciousness or even death. When seeking medical attention make sure that you take this leaflet and any remaining injection with you to show to the doctor.

If you have been given too much or too high a dose of the injection under no circumstances should you put yourself in a situation that requires you to be alert e.g. driving a car.

If you stop using Oxycodone Injection

You should not suddenly stop using this injection unless your doctor tells you to. If you want to stop using your injection, discuss this with your doctor first. They will tell you how to do this, usually by reducing the dose gradually so you do not experience unpleasant effects. Withdrawal symptoms such as yawning, abnormal dilation of the pupil of the eye, tear disorder, runny nose, agitation, anxiety, convulsions, difficulty in sleeping, palpitations, shaking or sweating may occur if you suddenly stop using this injection.

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

4. Possible side effects

Like all medicines, Oxycodone Injection can cause side effects, although not everybody gets them.
This medicine can cause allergic reactions, although serious allergic reactions are reported in rare cases. **Tell your doctor immediately** if you get any sudden wheeziness, difficulties in breathing, swelling of the eyelids, face or lips, rash or itching especially those covering your whole body.

The most serious side effect is a condition where you breathe more slowly or weakly than expected (respiratory depression – a typical hazard of an opioid overdose).

As with all strong analgesics or painkillers, there is a risk that you may become addicted or reliant on this injection.

Other possible side effects

Very common (May affect more than 1 in 10 people)
• Constipation (your doctor can prescribe a laxative to overcome this problem).
• Feeling or being sick (this should normally wear off after a few days, however your doctor can prescribe an anti-sickness medicine if it continues to be a problem).
• Drowsiness (this is most likely when you start using your medicine or when your dose is increased, but it should wear off after a few days).
• Dizziness.
• Headache.
• Itchy skin.

Common (May affect up to 1 in 10 people)
• Dry mouth, loss of appetite, indigestion, abdominal pain or discomfort, diarrhoea.
• Confusion, depression, a feeling of unusual weakness, shaking, lack of energy, tiredness, anxiety, nervousness, difficulty in sleeping, abnormal thoughts or dreams.
• Difficulty in breathing or wheezing, shortness of breath.
• Difficulty in passing urine.
• Rash.
• Sweating, high temperature.

Uncommon (May affect up to 1 in 100 people)
• A condition where you breathe more slowly or weakly than expected (respiratory depression).
• Difficulty in swallowing, belching, hiccups, wind, a condition where the bowel does not work properly (ileus), inflammation of the stomach, changes in taste, mouth ulcers, sore mouth.
• A condition which causes abnormal production of antidiuretic hormone (syndrome of inappropriate antidiuretic hormone secretion).
• A feeling of dizziness or ‘spinning’ (vertigo), hallucinations, mood swings, a feeling of extreme happiness, agitation, generally feeling unwell, loss of memory, difficulty in speaking, reduced sensitivity to pain or touch, tingling or numbness, seizures, fits or convulsions, abnormal manner or style of walking, feeling detached from oneself, being unusually overactive, fainting, reduced consciousness, unusual muscle stiffness or slackness, involuntary muscle contractions.
• Impotence, decreased sexual drive, low levels of sex hormones in the blood (‘hypogonadism’, seen in a blood test).
• Flushing of the skin.
• Dehydration, weight change, thirst, chills, swelling of the hands, ankles or feet.
• Dry skin.
• Tear disorder, blurred vision, reduction in size of the pupils in the eye.
• A need to take increasingly higher doses of the injection to gain the same level of pain relief (tolerance).
• A ringing or buzzing sound in the ears.
• Swelling and irritation inside the nose, nose bleeds, voice alteration.
• Chills.
• Chest pain.
• Inability to fully empty the bladder.

• A worsening of liver function tests (seen in a blood test)
• Withdrawal symptoms (see section 3 'If you stop using Oxycodone Injection').

Rare (May affect up to 1 in 1,000 people)
• Low blood pressure.
• A feeling of 'faintness' especially on standing up.
• Hives.

Not known (Frequency cannot be estimated from the available data)
• An increased sensitivity to pain.
• Aggression.
• Sudden wheeziness, difficulties in breathing, swelling of the eyelids, face or lips, rash or itching especially those covering your whole body.
• Tooth decay.
• Colicky abdominal pain or discomfort.
• Absence of menstrual periods.
• A blockage in the flow of bile from the liver. This can cause itchy skin, yellow skin, very dark urine and very pale stools.
• Long term use of Oxycodone injection during pregnancy may cause life-threatening withdrawal symptoms in the newborn. Symptoms to look for in the baby include irritability, hyperactivity and abnormal sleep pattern, high pitched cry, shaking, being sick, diarrhoea and not putting on weight.
• Sleep apnoea (breathing pauses during sleep).
• A problem affecting a valve in the intestines that may cause severe upper abdominal pain (sphincter of Oddi dysfunction).

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 systems listed below.

Ireland
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 Oxycodone Injection

Keep this medicine out of the sight and reach of children. Accidental overdose by a child is dangerous and may be fatal. Store this medicine in a locked safe and secure storage space, where other people cannot access it. It can cause serious harm and be fatal to people when it has not been prescribed for them.
- This medicinal product does not require any special temperature storage conditions.
- Keep the ampoules in the outer carton in order to protect from light.
- Do not use after the expiry date (shown as Exp. on the packaging). The expiry date refers to the last day of the month, your doctor or nurse will check for this.
- This medicine should be used immediately after opening.

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 Oxycodone Injection contains
The active ingredient is oxycodone hydrochloride.

Each 1 ml ampoule contains oxycodone hydrochloride 10 mg (equivalent to 9 mg of oxycodone base). Each 2 ml contains oxycodone hydrochloride 20 mg (equivalent to 18mg of oxycodone base).

The other ingredients are: citric acid monohydrate, sodium citrate, sodium chloride, hydrochloric acid, sodium hydroxide and water for injections.

What Oxycodone Injection looks like and the contents of the pack
Oxycodone Injection is a clear colourless solution and is supplied in packs of 5 containing either 1ml or 2ml clear glass ampoules.

Marketing Authorisation Holder: Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland

Manufacturer: CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

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

Ireland: Oxycodone Hydrochloride 10mg/ml Solution for Injection or Infusion

This leaflet was last revised in 01/2024.

Information for Healthcare Professionals

Oxycodone Hydrochloride 10 mg/ml Solution for Injection or Infusion.
Please refer to the Summary of Product Characteristics (SmPC) for further details on this product.

Qualitative and Quantitative Composition
Each 1 ml ampoule contains oxycodone hydrochloride 10 mg (equivalent to 9 mg of oxycodone base).
Each 2 ml contains oxycodone hydrochloride 20 mg (equivalent to 18mg of oxycodone base).

Pharmaceutical Form
Solution for injection or infusion. A clear, colourless solution practically free of particles.

Therapeutic indications
For the treatment of moderate to severe pain in patients with cancer and post-operative pain. For the treatment of severe pain requiring the use of a strong opioid.

Posology and method of administration
Route of administration:
Subcutaneous injection or infusion. Intravenous injection or infusion.

Posology:
Prescribers should consider concomitant treatment with antiemetics and laxatives for the prevention of nausea, vomiting and constipation.

The dose should be adjusted according to the severity of pain, the total condition of the patient and previous or concurrent medication.

Adults over 18 years:
The following starting doses are recommended. A gradual increase in dose may be required if analgesia is inadequate or if pain severity increases.

i.v. (Bolus): Dilute to 1 mg/ml in 0.9% saline, 5% dextrose or water for injections. Administer a bolus dose of 1 to 10 mg slowly over one to two minutes. Doses should not be administered more frequently than every four hours.

i.v. (Infusion): Dilute to 1 mg/ml in 0.9% saline, 5% dextrose or water for injections. A starting dose of 2 mg/hour is recommended.

i.v. (PCA): Dilute to 1 mg/ml in 0.9% saline, 5% dextrose or water for injections. Bolus doses of 0.03 mg/kg should be administered with a minimum lock-out time of five minutes.

s.c. (Bolus): Use as 10 mg/ml concentration. A starting dose of 5 mg is recommended, repeated at four-hourly intervals as required.

s.c. (Infusion): Dilute to 1 mg/ml in 0.9% saline, 5% dextrose or water for injections if required. A starting dose of 7.5 mg/day is recommended in opioid naïve patients, titrating gradually according to symptom control.

Cancer patients transferring from oral oxycodone may require higher doses.

Elderly:
The lowest dose should be administered with careful titration to pain control. Controlled pharmacokinetic studies in elderly patients (ages 65 years) have shown that compared with younger adults the clearance of oxycodone is only slightly reduced. No untoward adverse drug reactions were seen based on age, therefore adult doses and dosage intervals are appropriate.

Patients with renal or hepatic impairment:
The dose initiation should follow a conservative approach in these patients. The recommended adult starting dose should be reduced by 50% (for example a total daily dose of 10 mg orally in opioid naïve patients), and each patient should be titrated to adequate pain control according to their clinical situation.

Unlike morphine preparations, the administration of oxycodone does not result in significant levels of active metabolites. However, the plasma concentration of oxycodone in this patient population may be increased

compared with patients having normal renal or hepatic function. Therefore, dose initiation should follow a conservative approach in these patients.

A reduced dosage may be appropriate in these patients but each patient should be titrated to adequate pain control according to their clinical response.

Children under 18 years:
There are no data on the use of Oxycodone injection in patients under 18 years of age.

Duration of treatment
Oxycodone should not be used for longer than necessary.

Discontinuation of treatment:
When a patient no longer requires therapy with oxycodone, it may be advisable to taper the dose gradually to prevent symptoms of withdrawal.

Overdose
Acute overdose with oxycodone can be manifested by respiratory depression, somnolence, progressing to stupor or coma, hypotonia, miosistic pupils, bradycardia, hypotension, pulmonary oedema and death.

Treatment of overdose
A patent airway must be maintained. The pure opioid antagonists such as naloxone are specific antidotes against symptoms from opioid overdose. Other supportive measures should be employed as needed.

Incompatibilities
This medicinal product must not be mixed with other medicinal products except those mentioned under “Special precautions for disposal and other handling”.

Cyclizine at concentrations of 3 mg/ml or less, when mixed with Oxycodone injection, either undiluted or diluted with water for injections, shows no sign of precipitation over a period of 24 hours storage at room temperature. Precipitation has been shown to occur in mixtures with Oxycodone injection at cyclizine concentrations greater than 3 mg/ml or when diluted with 0.9% saline. It is recommended that water for injections be used as a diluent when cyclizine and oxycodone hydrochloride are co-administered either intravenously or subcutaneously as an infusion. Prochlorperazine is chemically incompatible with Oxycodone injection.

Shelf life
Unopened: 2 years.
The injection should be given immediately after opening the ampoule. Once opened, any unused portion should be discarded. Chemical and physical in-use stability has been demonstrated for 24 hours at room temperature.

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 would normally not be longer than 24 hours at 2 to 8°C, unless reconstitution, dilution, etc has taken place in controlled and validated aseptic conditions.

Special precautions for storage
This medicinal product does not require any special temperature storage conditions.
Keep the ampoules in the outer carton in order to protect from light.

Nature and contents of container
Type I clear glass ampoules: 1 ml and 2 ml.
Pack size: 5 ampoules.

Special precautions for disposal and other handling
Oxycodone injection has been shown to be compatible with the following drugs:
• Hyoscine butylbromide • Hyoscine hydrobromide • Dexamethasone sodium phosphate • Haloperidol • Midazolam hydrochloride • Metoclopramide hydrochloride • Levomepromazine hydrochloride

Oxycodone injection, undiluted or diluted to 1 mg/ml with 0.9% w/v saline, 5% w/v dextrose or water for injections, is physically and chemically stable when in contact with representative brands of polypropylene or polycarbonate syringes, polyethylene or PVC tubing, and PVC or EVA infusion bags, over a 24 hour period at room temperature.

The injection, whether undiluted or diluted to 1 mg/ml in the infusion fluids used in these studies and contained in the various assemblies, does not need to be protected from light.

Inappropriate handling of the undiluted solution after opening of the original ampoule, or of the diluted solutions may compromise the sterility of the product.

Date of Revision of the Text 01/2024