Read all of this leaflet carefully before you start taking this medicine
Keep this leaflet. You may need to read it again.
If you have further questions, please ask your doctor or pharmacist.
This medicine has been prescribed only for you. Do not give it to anybody else or use it for
any other illnesses.
If any of the side effects affects you severely, or if you notice any side effects not listed in this
leaflet, please tell your doctor or pharmacist.

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1 What Cataflam is and what it is used for

What Cataflam is
The active substance in Cataflam solution for injection, sugar-coated tablets, soft capsules and
suppositories is diclofenac potassium.
Cataflam belongs to a group of medicines called “non-steroidal anti-inflammatory drugs”
(NSAIDs), which are used to treat pain and inflammation.

What Cataflam is used for

Solution for injection
Injections of Cataflam into a muscle are used to treat the following conditions:
• Pain and swelling following surgery and injuries.
• Pain due to gallstones or kidney stones.

**Sugar-coated tablets and soft capsules**

Cataflam can be used for short-term treatment of the following conditions:
• Sprains, strains, or other injuries.
• Pain and swelling after surgery.
• Painful inflammatory conditions in gynecology, including painful menstrual periods.
• Back pain, frozen shoulder, tennis elbow, and other forms of soft-tissue rheumatism.
• Infections of the ear, nose, or throat.
• Migraine attacks

Cataflam may also be used to treat other conditions as determined by your doctor.

**Suppositories**

Cataflam can be used for short-term treatment of the following conditions:
• Sprains, strains, or other injuries.
• Pain and swelling after surgery.
• Painful inflammatory conditions in gynecology, including painful menstrual periods.
• Back pain, frozen shoulder, tennis elbow, and other forms of soft-tissue rheumatism.
• Infections of the ear, nose or throat.

Cataflam may also be used to treat other conditions as determined by other doctor.

**How Cataflam works**

Cataflam relieves the symptoms of inflammation, such as pain and swelling, by blocking the synthesis of the molecules (prostaglandins) responsible for inflammation, pain and fever. It has no effect on the causes of inflammation or fever.

If you have any questions about how Cataflam works or why this medicine has been prescribed to you, ask your doctor.

**Monitoring during your treatment with Cataflam**

If you have established heart disease or significant risks for heart disease, your doctor will periodically re-evaluate whether you should continue treatment with Cataflam, especially in case you are treated for more than 4 weeks.
If you have any liver impairment, kidney impairment or blood impairment, you will have blood tests during treatment. These will monitor either your liver function (level of transaminases) or your kidney function (level of creatinine) or your blood count (level of white and red blood cells and platelets). Your doctor will take these blood tests into consideration to decide if Cataflam needs to be discontinued or if the dose needs to be changed.

2 Before you take Cataflam

Follow all the doctor’s instructions carefully. They may differ from the general information contained in this leaflet.

Do not receive/take/use Cataflam

- If you are allergic (hypersensitive) to diclofenac, sodium metabisulphite (or other sulphites) *(solution for injection only)* or to any of the other ingredients of Cataflam listed at the end of this leaflet.

- If you have ever had an allergic reaction after taking medicines to treat inflammation or pain (e.g. acetylsalicylic acid, diclofenac or ibuprofen). Reactions may include asthma, runny nose, skin rash, face swelling. If you think you may be allergic, ask your doctor for advice.

- If you have a stomach or intestinal ulcer.

- If you have gastrointestinal bleeding or perforation, symptoms of which may include blood in your stools or black stools.

- If you suffer from severe kidney or liver disease.

- If you suffer from severe heart failure.

- If you are in the last three months of pregnancy.

- If your rectum is painful (sometimes with bleeding and discharge) *(suppositories only).*

If any of these apply to you, tell your doctor without taking Cataflam solution for injection, sugar-coated tablets, suppositories.

If you think you may be allergic, ask your doctor for advice.

Take special care with Cataflam

- If you have established disease of the heart or blood vessels (also called cardiovascular disease, including uncontrolled high blood pressure, congestive heart failure, established
ischemic heart disease, or peripheral arterial disease), as treatment with Cataflam is generally not recommended.

- If you have established cardiovascular disease (see above) or significant risk factors such as high blood pressure, abnormally high levels of fat (cholesterol, triglycerides) in your blood, diabetes, or if you smoke, and your doctor decides to prescribe Cataflam, you must not increase the dose above 100 mg per day if you are treated for more than 4 weeks.

- It is generally important to take the lowest dose of Cataflam that relieves your pain and/or swelling and for the shortest time possible in order to keep your risk for cardiovascular side effects as small as possible.

- If you are taking Cataflam simultaneously with other anti-inflammatory medicines including acetylsalicylic acid, corticosteroids, “blood thinners” or “SSRIs” (see “Taking other medicines”).

- If you have asthma or hay fever (seasonal allergic rhinitis).

- If you have ever had gastrointestinal problems such as stomach ulcer, bleeding or black stools, or have experienced stomach discomfort or heartburn after taking anti-inflammatory medicines in the past.

- If you have an inflammation of the colon (ulcerative colitis) or intestinal tract (Crohn’s disease).

- If you have liver or kidney problems.

- If you could be dehydrated (e.g. by sickness, diarrhea, before or after major surgery).

- If you have swollen feet.

- If you have a bleeding disorder or other blood disorders, including a rare liver condition called porphyria.

If any of these above apply to you, **tell your doctor before you receive/take/use Cataflam.**

- If, at any time while taking Cataflam you experience any signs or symptoms of problems with your heart or blood vessels such as chest pain, shortness of breath, weakness, or slurring of speech, contact your doctor immediately.

- Cataflam may reduce the symptoms of an infection (e.g. headache, high temperature) and may therefore make the infection more difficult to detect and to treat adequately. If you feel unwell and need to see a doctor, remember to mention that you are taking Cataflam.
In very rare cases, Cataflam, like other anti-inflammatory medicines, may cause severe allergic skin reactions (e.g. rash). If you get any of the above described symptoms, tell your doctor straight away.

**Taking other medicines**

It is particularly important to tell your doctor if you are taking any of the following medicines:

- Lithium or selective serotonin-reuptake inhibitors (SSRIs) (medicines used to treat some types of depression).
- Digoxin (a medicine used for heart problems).
- Diuretics (medicines used to increase the amount of urine).
- ACE inhibitors or beta-blockers (classes of medicines used to treat high blood pressure and heart failure).
- Other anti-inflammatory medicines such as acetylsalicylic acid or ibuprofen.
- Corticosteroids (medicines used to provide relief for inflamed areas of the body).
- “Blood thinners” (a medicine used to prevent blood clotting).
- Medicines used to treat diabetes, except insulin.
- Methotrexate (a medicine used to treat some kinds of cancer or arthritis).
- Ciclosporin, Tacrolimus (medicines primarily used in patients who have received organ transplants).
- Trimethoprim (a medicine used to prevent or treat urinary tract infections)
- Quinolone antibacterials (medicines used against infections).
- Voriconazole (a medicine used to treat fungal infections).
- Phenytoin (a medicine used to treat seizures).

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

**Taking Cataflam with food and drink (sugar-coated tablets and soft capsules only)**

Cataflam sugar-coated tablets and soft capsules should be swallowed whole with a glass of water or other liquid.

It is recommended to take Cataflam sugar-coated tablets and soft capsules before meals or on an empty stomach.
Older people

Elderly patients may react more strongly to Cataflam than other adults. Therefore, they should follow the doctor’s instructions particularly carefully and take the minimum number of injections, tablets, suppositories, that provides relief of symptoms. It is especially important for elderly patients to report undesirable effects promptly to their doctor.

Children and adolescents

Solution for injection

Cataflam solution for injection must not be used in children and adolescents (below 18 years of age).

Sugar-coated tablets and soft capsules

Cataflam sugar-coated tablets and soft capsules must not be given to children and adolescents below 14 years of age. In children below 14 years of age, other forms of diclofenac such as oral drops or suppositories could be used, as determined by the doctor. Cataflam must not be given to children less than 1 year old.

Suppositories

Because of their strength, Cataflam suppositories of 75 mg must not be given to children and adolescents (below 18 years of age). Cataflam suppositories must not be given to children under 12 months of age.

Pregnancy and breast-feeding

You should tell your doctor if you are pregnant or think that you may be pregnant. You should not take Cataflam solution for injection, sugar-coated tablets, soft capsules or suppositories, while pregnant unless absolutely necessary.

As with other anti-inflammatory medicines, you must not receive Cataflam solution for injection, or take sugar-coated tablets, soft capsules or suppositories, during the last 3 months of pregnancy, as it could harm your unborn child or cause problems at delivery.

You should tell your doctor if you are breast-feeding.

You should not breast-feed if you are taking Cataflam solution for injection, sugar-coated tablets, soft capsules or suppositories, as it might be harmful for your infant.

Ask your doctor or pharmacist for advice before taking any medicines.

Your doctor will discuss with you the potential risk of taking Cataflam during pregnancy or breast-feeding.
Women of child-bearing potential
Cataflam may make it more difficult to become pregnant. You should not receive Cataflam solution for injection, or take sugar-coated tablets, soft capsules or suppositories, unless necessary if you are planning to become pregnant or if you have problems to become pregnant.

Driving and using machines
Cataflam is unlikely to affect the ability to drive, use machines or carry out other activities that need careful attention.

Information about some of the ingredients of Cataflam sugar-coated tablets
Cataflam 25 mg and 50 mg sugar-coated tablets contain sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3 How to take Cataflam
Follow your doctor’s instructions carefully. Do not exceed the recommended dose.

How much Cataflam to take
Do not exceed the recommended dose prescribed by your doctor. It is important that you use the lowest dose that controls your pain and that you do not receive Cataflam solution for injection, or take sugar-coated tablets, soft capsules or suppositories, for longer than necessary.
Your doctor will tell you exactly how many ampoules, sugar-coated tablets, soft capsules or suppositories, of Cataflam to take. Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

Adults
Solution for injection
In adults, usually one ampoule a day is given for two days at the most; in some cases, two ampoules may be given a day. If further treatment with Cataflam is needed, this can be given for example in the form of Cataflam tablets or suppositories.

Sugar-coated tablets
The usual daily dose at the start of the treatment is generally 100 to 150 mg. In milder cases, 75 to 100 mg daily is usually sufficient. The total daily dose should usually be taken in 2 or 3 separate doses, as applicable. Do not exceed 150 mg per day.
In painful menstrual periods, start treatment with a single dose of 50 mg as soon as you feel the first symptoms. Continue with 50 mg up to three times a day for a few days, as needed. If 150 mg a day does not provide sufficient pain relief over 2 to 3 menstrual periods, your doctor may recommend you to start with a dose of 100 mg and take up to 200 mg a day divided into 2 or 3 separate doses during your next menstrual periods. Do not exceed 200 mg per day.

In migraine, start treatment with a single dose of 50 mg, as soon as you feel the first signs of an impending attack. In cases where pain relief within 2 hours after the first dose is not sufficient, a further dose of 50 mg may be taken. If needed, further doses of 50 mg may be taken at intervals of 4 to 6 hours. Do not exceed 200 mg per day.

**Soft capsules**

The usual daily dose at the start of the treatment is generally 100 to 150 mg. In milder cases, 50 to 100 mg daily may be sufficient. The total daily dose should usually be taken in 2 or 3 separate doses, as applicable. Do not exceed 150 mg per day.

In painful menstrual periods, start treatment with a single dose of 50 mg as soon as you feel the first symptoms. Continue with 50 mg up to three times a day for a few days, as needed. If 150 mg a day does not provide sufficient pain relief over 2 to 3 menstrual periods, your doctor may recommend you to start with a dose of 100 mg and take up to 200 mg a day divided in 2 or 3 separate doses during your next menstrual periods. Do not exceed 200 mg per day.

In migraine, start treatment with a single dose of 50 mg, as soon as you feel the first signs of an impending attack. In cases where pain relief within 2 hours after the first dose is not sufficient, a further dose of 50 mg may be taken. If needed, further doses of 50 mg may be taken at intervals of 4 to 6 hours. Do not exceed 200 mg per day.

**Suppositories**

The usual daily dose at the start of the treatment is generally 100 to 150 mg. In milder cases, 75 to 100 mg daily is usually sufficient. The total daily dose should usually be divided into 2 or 3 separate doses, as applicable. Do not exceed 150 mg per day.

In painful menstrual periods, start treatment with a dose of 50 mg as soon as you feel the first symptoms. Continue with 50 mg up to three times a day for a few days, as needed. If 150 mg a day does not provide sufficient pain relief over 2 to 3 menstrual periods, your doctor may recommend you to start with a dose of 100 mg and take up to 200 mg a day divided into 2 or 3 separate doses during your next menstrual periods. Do not exceed 200 mg per day.
Children and adolescents

Sugar-coated tablets
For adolescents aged 14 years or over, a daily dose of 75 to 100 mg is usually sufficient. The total daily dose should usually be taken in 2 or 3 separate doses, as applicable. Do not exceed 150 mg per day.
In migraine, Cataflam sugar-coated tablets must not be used by children and adolescents (below 18 years of age).

Soft capsules
For adolescents aged 14 years or over, a daily dose of 50 to 100 mg may be sufficient.
The total daily dose should usually be taken in 2 or 3 separate doses, as applicable. Do not exceed 150 mg per day.
In migraine, Cataflam soft capsules must not be used by children and adolescents (below 18 years of age).

Suppositories
Children aged 1 year or over and adolescents should be given 0.5 to 2 mg per kilogram of body weight daily, depending on the severity of the disorder. For adolescents aged 14 or over, 75 to 100 mg daily is usually sufficient, in divided doses.
The total daily dose should usually be divided into 2 to 3 separate doses, as applicable. Do not exceed 150 mg per day.
Example: A child weighing 20 kilograms would thus be given a daily dose of 10 to 40 mg.
Within this dose range, up to 3 suppositories of 12.5 mg may be given per day.
In cases where the suppositories of 12.5 mg or 25 mg do not allow accurate dosing e.g. in very young children, Cataflam can also be used in the form of oral drops, as decided by the doctor.

When to take Cataflam

Sugar-coated tablets and soft capsules
Take the tablets or soft capsules on an empty stomach.

Suppositories
It is best to take the suppositories after emptying your bowels.
How to take Cataflam

Solution for injection
The solution is drawn from the ampoule into a syringe and injected deep into your buttock muscle.

Sugar-coated tablets and soft capsules
Cataflam sugar-coated tablets and soft capsules should be swallowed whole with a glass of water or other liquid, preferably before meals or on an empty stomach. Do not divide or chew the tablets or soft capsules.

Suppositories
Cataflam suppositories are wrapped in foil. Before inserting the suppository, take off all the foil and moisten the suppository with cold water. Lie down on your side and use your finger to push the suppository well up into the rectum. If the suppository is too soft to insert, chill it in the refrigerator for a few minutes or hold it under cold water before taking off the foil. Do not cut the suppositories apart, as incorrect storage conditions may have led to uneven distribution of the active substance.

Never take suppositories by mouth.

How long to take Cataflam
Follow your doctor’s instructions exactly.
If you take Cataflam for more than a few weeks, you should make sure to visit your doctor for regular check-ups, to ensure that you are not suffering from unnoticed undesirable effects.
If you have questions about how long to take Cataflam, talk to your doctor or your pharmacist.

If you take more Cataflam than you should
If you have accidentally taken too much Cataflam, tell your doctor or pharmacist or go to the hospital emergency unit at once.

You may require medical attention.

If you forget to take Cataflam
If you forget to take a dose, take one as soon as you remember. If it is nearly time for your next dose, you should simply take the next tablet at the usual time. Do not double the next dose to make up for the one you missed.
4 Possible side effects

As with all medicines, patients taking Cataflam can experience side effects, although not everybody gets them.

Some side effects could be serious

*These uncommon side effects may affect between 1 and 10 in every 1000 patients, especially when taking a high daily dose (150 mg) for a long period of time*

- Sudden and oppressive chest pain (signs of myocardial infarction or heart attack).
- Breathlessness, difficulty of breathing when lying down, swelling of the feet or legs (signs of cardiac failure).

*These rare or very rare side effects may affect from less than 1 to 10 in every 10,000 patients*

- Spontaneous bleeding or bruising (signs of thrombocytopenia).
- High fever, frequent infections, persistent sore throat (signs of agranulocytosis).
- Difficulty of breathing or swallowing, rash, itching, hives, dizziness (signs of hypersensitivity, anaphylactic and anaphylactoid reactions).
- Swelling mainly of the face and throat (signs of angioedema).
- Disturbing thoughts or moods (signs of psychotic disorders).
- Impaired memory (signs of memory impairment).
- Seizures (signs of convulsions).
- Anxiety.
- Stiff neck, fever, nausea, vomiting, headache (signs of aseptic meningitis).
- Sudden and severe headache, nausea, dizziness, numbness, inability or difficulty to speak, weakness or paralysis of limbs or face (signs of cerebrovascular accident or stroke).
- Difficulty of hearing (signs of hearing impaired).
- Headache, dizziness (signs of high blood pressure, hypertension).
- Rash, purplish-red spots, fever, itching (signs of vasculitis).
- Sudden difficulty of breathing and feeling of tightness in chest with wheezing or coughing (signs of asthma or Pneumonitis if fever).
- Vomiting of blood (signs of hematemesis) and/or black or bloody stools (signs of gastrointestinal hemorrhage).
- Bloody diarrhea (signs of diarrhea hemorrhagic).
- Black stools (signs of melena).
- Stomach pain, nausea (signs of gastrointestinal ulcer).
- Diarrhea, abdominal pain, fever, nausea, vomiting (signs of colitis, including hemorrhagic colitis and exacerbation of ulcerative colitis or Crohn’s disease).
- Severe upon stomach pain (signs of pancreatitis).
- Yellowing of the skin or eyes (signs of jaundice), nausea, loss of appetite, dark urine (signs of hepatitis/liver failure).
- Flu-like symptoms, feeling tired, muscles aches, increased liver enzymes in blood test results (signs of liver disorders including fulminant hepatitis, hepatic necrosis, hepatic failure).
- Blister (signs of dermatitis bullous).
- Red or purple skin (possible signs of blood vessel inflammation), skin rash with blisters, blistering of the lips, eyes and mouth, skin inflammation with flaking or peeling (signs of erythema multiforme or if fever signs of Stevens-Johnson syndrome or toxic epidermal necrolysis).
- Skin rash with flacking or peeling (signs of dermatitis exfoliative).
- Increased sensitivity of the skin to sun (signs of photosensitivity reaction).
- Purple skin patches (signs of purpura or Henoch-Schonlein purpura if caused by an allergy).
- Swelling, feeling weak, or abnormal urination (signs of acute renal failure).
- Excess of protein in the urine (signs of proteinuria).
- Swollen face or abdomen, high blood pressure (signs of nephrotic syndrome).
- Higher or lower urine output, drowsiness, confusion, nausea (signs of tubulointerstitial nephritis).
- Severely decreased urine output (signs of renal papillary necrosis).
- Generalized swelling (signs of edema).

If you experience any of these, **tell your doctor straight away.**

**Some side effects are common**

*These side effects may affect between 1 and 10 in every 100 patients*
Headache, dizziness, vertigo, nausea, vomiting, diarrhea, indigestion (signs of dyspepsia), abdominal pain, flatulence, loss of appetite (signs of decreased appetite), abnormal liver function test results (e.g. level of transaminases increased), skin rash, skin reaction such as redness or swelling at the site of injection (injection site reaction) (solution for injection only), injection site pain (solution for injection only), injection site induration (solution for injection only), application site irritation (suppositories only).

Some side effects are rare
These side effects may affect between 1 and 10 in every 10,000 patients
Drowsiness (signs of somnolence), stomach pain (signs of gastritis), liver disorder, itchy rash (signs of urticaria), dead tissue at the site of injection (signs of injection site necrosis) (solution for injection only), painful rectum (sometimes with bleeding and discharge, signs of proctitis) (suppositories only).

Some side effects are very rare
These side effects may affect less than 1 in 10,000 patients
Low level of red blood cells (anemia), low level of white blood cells (leukopenia), disorientation, depression, difficulty sleeping (signs of insomnia), nightmares, irritability, tingling or numbness of the hands or feet (signs of paresthesia), trembling (signs of tremor), taste disorders (signs of dysgeusia), vision disorders (signs of visual impairment, vision blurred, diplopia), noises in ears (signs of tinnitus), constipation, mouth sores (signs of stomatitis), swollen, red and sore tongue (signs of glossitis), disorder of the tube that carries food from the throat to the stomach (signs of esophageal disorder), upper abdomen cramp specially after eating (signs of intestinal diaphragm disease), palpitations, chest pain, itchy, red and burning rash (signs of eczema), skin reddening (signs of erythema), hair loss (signs of alopecia), itching (signs of pruritus), blood in urine (signs of hematuria), injection site abscess (solution for injection only), anal itching and pain, fresh red blood on stools, or tender lumps near the anus (signs of haemorrhoids) (suppositories only).

If any of these affects you severely, tell your doctor.

If you notice any other side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

If you take Cataflam for more than a few weeks, you should make sure to visit your doctor for regular check-ups, to ensure that you are not suffering from unnoticed undesirable effects.
5  **Storing Cataflam**

- Do not use after the expiry date shown on the box.
- Store below 30°C.
- Store in the original package. For Cataflam soft capsules, **always keep the blister in the original package**, in order to protect from moisture and light.
- Keep out of the reach and sight of children.

6  **Further information**

**What Cataflam is**

**Solution for injection**

- The **active substance** in Cataflam solution for injection is diclofenac potassium.
- The **other ingredients** are sodium metabisulphite (E 223), disodium edetate dihydrate, mannitol, benzyl alcohol, propylene glycol, potassium hydroxide and water for injection.

**Sugar-coated tablets**

- The **active substance** in Cataflam sugar-coated tablets is diclofenac potassium.
- The **other ingredients** are magnesium stearate; povidone; silica colloidal anhydrous; sodium starch glycollate; maize starch; calcium phosphate; microcrystalline cellulose; polyethylene glycol 8000; red iron oxide (E 172) and titanium dioxide (E 171) (dispersed Anstead); talc; sucrose; imprint with printing ink brown for 25 mg and white for 50 mg.

**Soft capsules**

- The **active substance** in Cataflam soft capsules is diclofenac potassium.
- The **other ingredients** are:
  Macrogol 600/polyethylene glycol 600, glycerol 85%, gelatin, glycerol 85%, Polysorb 85/70/00, Quinoline Yellow 70% (E104, CI 47005), purified water, shellac, titanium dioxide, and propylene glycol.

**Suppositories**

- The **active substance** in Cataflam suppositories is diclofenac potassium.
- The **other ingredient** is hard fat.

This information might differ in some countries.
What Cataflam is/looks like and contents of the pack

Solution for injection
Cataflam is a solution for injection supplied in a clear, colorless glass ampoule.
The ampoule contains 3 mL of clear, colourless or pale yellow solution.
Each ampoule contains 75 mg of the active substance diclofenac potassium.

Sugar-coated tablets
Your medicine is called Cataflam and is supplied in the form of a sugar-coated tablets.
Cataflam 25 mg sugar coated tablet is a pale red, round biconvex tablet.
Cataflam 50 mg sugar coated tablet is a reddish-brown, round biconvex tablet.
Each tablet contains 25 mg or 50 mg of the active substance diclofenac potassium.

Soft capsules
Your medicine is called Cataflam and is supplied in the form of a soft capsule.
Cataflam soft capsules are transparent to yellow oval capsules, with white print of C50 on one side and NVR on the other side.
Each capsule contains 50 mg of diclofenac potassium.

Suppositories
Your medicine is called Cataflam and is supplied in the form of a suppository.
Description of the pharmaceutical form: country specific.
Each suppository contains 12.5, 25 or 75 mg of the active substance diclofenac potassium.
This information might differ in some countries.

Marketing Authorisation Holder
Saudi Pharmaceutical Distribution Company (Saphad).

Manufacturer
Manufactured by Novartis Kurtkoy, Turkey.
If you have any questions about this medicine, please contact your doctor or pharmacist.

7 Information for the healthcare professional

Solution for injection
To be injected deep intraglutetally into the upper outer quadrant. Each ampoule is for single use only. The solution for injection should be used immediately after opening. Any unused contents should be discarded.
As a rule, Cataflam solution for intramuscular injection should not be mixed with other injection solutions.

This leaflet was last approved on: 03-Sep-13
Infusion solutions of sodium chloride 0.9% or glucose 5% without sodium bicarbonate as an additive present a risk of supersaturation, possibly leading to formation of crystals or precipitates. Infusion solutions other than those recommended should not be used.

Intravenous infusions should be initiated immediately after preparing the infusion solutions (see above instructions). The infusion solutions should not be stored.

This leaflet was last approved on: country specific

7. To report any side effect(s):
   - Saudi Arabia:
     - National Pharmacovigilance Center (NPC)
       - Fax: +966-11-205-7662
       - Toll-Free: 800249000
       - E-mail: npc.drug@sfda.gov.sa
       - Website: www.sfda.gov.sa/npc

8. Council of Arab Health Ministers
   The following statements issued by the Council of Arab Health Ministers should be printed in the PIL.

   This is a Medicament
   - Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
   - Follow strictly the doctor’s prescription, the method of use and the instructions of the pharmacist who sold the medicament.
   - The doctor and the pharmacist are the experts in medicines, their benefits and risks.
   - Do not by yourself interrupt the period of treatment prescribed for you.
   - Do not repeat the same prescription without consulting your doctor.
   - Keep all medicaments out of reach of children.

   Council of Arab Health Ministers
   Union of Arab Pharmacists