Very rare: Disorientation, depression, insomnia, nightmare, irritability, psychotic disorder.
Nervous system disorders
Common: Headache, dizziness.
Rare: Somnolence.
Very rare: Paraesthesia, memory impairment, convulsion, anxiety, tremor, aseptic meningitis, taste disturbances, cerebrovascular accident.
Eye disorders
Very rare: Visual disturbance, vision blurred, diplopia.
Ear and labyrinth disorders
Common: Vertigo.
Very rare: Tinnitus, hearing impaired.
Cardiac disorders
Very rare: Palpitations, chest pain, cardiac failure, myocardial infarction.
Vascular disorders
Very rare: Hypertension, vasculitis.
Respiratory, thoracic and mediastinal disorders
Rare: Asthma (including dyspnoea).
Very rare: Pneumonitis.
Gastrointestinal disorders
Common: Nausea, vomiting, diarrhoea, dyspepsia, abdominal pain, flatulence, anorexia.
Rare: Gastritis, gastrointestinal haemorrhage, haematemesis, diarrhoea haemorrhagic, melaena, gastrointestinal ulcer (with or without bleeding or perforation).
Very rare: Colitis (including haemorrhagic colitis and exacerbation of ulcerative colitis or Crohn's disease), constipation, stomatitis, glossitis, oesophageal disorder, diaphragm-like intestinal strictures, pancreatitis.

Hepatobiliary disorders
Common: Transaminases increased.
Rare: Hepatitis, jaundice, liver disorder.
Very rare: Fulminant hepatitis
Skin and subcutaneous tissue disorders
Common: Rash.
Rare: Urticaria.
Very rare: Bullous eruptions, eczema, erythema, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), dermatitis exfoliative, loss of hair, photosensitivity reaction, purpura, allergic purpura, pruritus.
Renal and urinary disorders
Very rare: Acute renal failure, haematuria, proteinuria, nephrotic syndrome, interstitial nephritis, renal papillary necrosis.
General disorders and administration site conditions
Common: Injection site reaction, injection site pain, injection site induration.
Rare: Oedema, injection site necrosis.
Overdose and Treatment
Symptoms
There is no typical clinical picture resulting from diclofenac overdosage. Overdosage can cause symptoms such as vomiting, gastrointestinal haemorrhage, diarrhoea, dizziness, tinnitus or convulsions. In the event of significant poisoning, acute renal failure and liver damage are possible.
Therapeutic measures
Management of acute poisoning with NSAIDs, including diclofenac essentially consists of suppor tive measures and symptomatic treatment. Supportive measures and symptomatic treatment should be given for complications such as hypotension, renal failure, convulsions, gastrointestinal disorder, and respiratory depression.
Special measures such as forced diuresis, dialysis or haemoperfusion are probably of no help in eliminating NSAIDs, including diclofenac, due to the high protein binding and extensive metabolism.

Incompatibilities
As a rule, diclofenac sodium solution for injection should not be mixed with other injection solutions.
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.
Instructions for Use
To be injected either intramuscularly by deep intragluteal injection into the upper outer quadrant, or intravenously by slow infusion after dilution in accordance with the following instructions.
Depending on the intended duration of infusion, mix 100 to 500 mL of isotonic saline (sodium chloride 0.9% solution) or glucose 5% solution buffered with sodium bicarbonate injectable solution (0.5 mL of 8.4% or 1 mL of 4.2% or a corresponding volume of a different concentration) taken from a freshly opened container; add the contents of one diclofenac sodium injection ampoule to this solution. Only clear solutions should be used. If crystals or precipitates are observed, the infusion solution should not be used.
Storage Conditions
Finished product - Store below C
Each ampoule is for single use only. The solution should be used immediately after opening. Any unused contents should be discarded.

Manufactured for
BETA PHARMA LABORATUVAR ILAÇ SAN .VE TİC .LTD .ŞTİ
MOLLA GURANI MAH. TURGUT OZAL MILLET
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For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

BETACLON

Diclofenac Sodium Injection

For IV/IM Use

Pharmacodynamics
Mechanism of action
Diclofenac sodium is a non-steroidal compound with pronounced antirheumatic, anti-inflammatory, analgesic and antipyretic properties. Inhibition of prostaglandin biosynthesis, which has been demonstrated in experiments, is considered fundamental to its mechanism of action. Prostaglandins play a major role in causing inflammation, pain and fever. Diclofenac sodium in vitro does not suppress proteoglycan biosynthesis in cartilage at concentrations equivalent to those reached in humans.

Pharmacodynamic effects
In rheumatic diseases, the anti-inflammatory and analgesic properties of diclofenac sodium elicit a
clinical response characterised by marked relief from signs and symptoms such as pain at rest, pain on movement, morning stiffness, and swelling of the joints, as well as by an improvement in function.
Diclofenac sodium has also been found to exert a pronounced analgesic effect in moderate and severe pain of non-rheumatic origin, an effect which sets in within 15 to 30 minutes.
Diclofenac sodium has also been shown to have a beneficial effect in migraine attacks.
In post-traumatic and post-operative inflammatory conditions, diclofenac sodium rapidly relieves both spontaneous pain and pain on movement and reduces inflammatory swelling and wound oedema.
When used concomitantly with opioids for the management of post-operative pain, diclofenac sodium significantly reduces the need for opioids.
Diclofenac sodium injection are particularly suitable for initial treatment of inflammatory and degenerative rheumatic diseases, and of painful conditions due to inflammation of non-rheumatic origin.

Pharmacokinetics
Absorption
After administration of 75 mg diclofenac by intramuscular injection, absorption sets in immediately, and mean peak plasma concentrations of about 2.5 micrograms/mL (8 micromol/L) are reached after about 20 minutes. The amount absorbed is in linear proportion to the size of the dose.
When 75 mg diclofenac is administered as an intravenous infusion over 2 hours, mean peak plasma concentrations are about 1.9 micrograms/mL (5.9 micromol/L). Shorter infusions result in higher peak plasma concentrations, while longer infusions give plateau concentrations proportional to the infusion rate after 3 to 4 hours. In contrast, plasma concentrations decline rapidly once peak levels have been reached following intramuscular injection or administration of gastro-resistant tablets or suppositories.
The area under the concentration curve (AUC) after intramuscular or intravenous administration is about twice as large as it is following oral or rectal administration, because about half the active substance is metabolised during its first passage through the liver ("first pass" effect) when administered via the oral or rectal routes. Pharmacokinetic behaviour does not change after repeated administration. No accumulation occurs provided the recommended dosage intervals are observed.

Distribution
99.7% of diclofenac is bound to serum proteins, mainly to albumin (99.4%). The apparent volume of distribution calculated is 0.12 to 0.17 L/kg. Diclofenac enters the synovial fluid, where maximum concentrations are measured 2 to 4 hours after peak plasma values have been attained. The apparent half-life for elimination from the synovial fluid is 3 to 6 hours. Two hours after reaching peak plasma values, concentrations of the active substance are already higher in the synovial fluid than in the plasma, and they remain higher for up to 12 hours.

Biotransformation
Biotransformation of diclofenac takes place partly by glucuronidation of the intact molecule, but mainly by single and multiple hydroxylation and methoxylation, resulting in several phenolic metabolites (3'-hydroxy-,4'-hydroxy-,5-hydroxy-,4',5-dihydroxy- and 3'-hydroxy-4'-methoxy-diclofenac), most of which are converted to glucuronide conjugates. Two of these phenolic metabolites are biologically active, but to a much smaller extent than diclofenac.

Elimination
Total systemic clearance of diclofenac from plasma is 263 ±56 mL/min (mean value ±SD). The terminal half-life in plasma is 1 to 2 hours. Four of the metabolites, including the two active ones, also have short plasma half-lives of 1 to 3 hours. One metabolite, 3'-hydroxy-4'-methoxy-diclofenac has a much longer plasma half-life. However, this metabolite is virtually inactive.

About 60% of the administered dose is excreted in the urine as the glucuronide conjugate of the intact molecule and as metabolites, most of which are also converted to glucuronide conjugates. Less than 1% is excreted as unchanged substance. The rest of the dose is eliminated as metabolites through the bile in the faeces.

Characteristics in patients
No relevant age-dependent differences in the drug's absorption, metabolism or excretion have been observed. In patients suffering from renal impairment, no accumulation of the unchanged active substance can be inferred from the single-dose kinetics when applying the usual dosage schedule. At a creatinine clearance of <10 mL/min, the calculated steady-state plasma levels of the hydroxy metabolites are about 4 times higher than in normal subjects. However, the metabolites are ultimately cleared through the bile. In patients with chronic hepatitis or non-decompensated cirrhosis, the kinetics and metabolism of diclofenac are the same as in patients without liver disease.

Indication
Intramuscular injection
Treatment of:
- Exacerbations of inflammatory and degenerative forms of rheumatism: rheumatoid arthritis, ankylosing spondylitis, osteoarthritis, spondylarthritis, painful syndromes of the vertebral column, non-articular rheumatism.
- Acute attacks of gout.
- Renal colic and biliary colic.
- Post-traumatic and post-operative pain, inflammation and swelling.

Intravenous infusion
- Treatment or prevention of post-operative pain in a hospital setting.

Recommended Dosage
As a general recommendation, the dose should be individually adjusted and the lowest effective dose given for the shortest possible duration.

Adults
Diclofenac sodium solution for injection should not be given for more than 2 days; if necessary, treatment can be continued with diclofenac sodium tablets or suppositories.

Intramuscular injection
The following directions for intramuscular injection must be followed in order to avoid damage to a nerve or other tissue at the injection site.
The dose is generally one 75 mg ampoule daily, given by deep intragluteal injection into the upper outer quadrant. In

severe cases (e.g. colic), the daily dose can exceptionally be increased to two injections of 75 mg, separated by an interval of a few hours (one into each buttock). Alternatively, one ampoule of 75 mg can be combined with other pharmaceutical forms of diclofenac sodium (e.g. tablets, suppositories) up to a total maximum daily dose of 150 mg.

Intravenous infusion
Diclofenac sodium solution for injection must not be given as an intravenous bolus injection. Immediately before starting an intravenous infusion, diclofenac sodium solution for injection must be diluted with saline 0.9% or glucose 5% infusion solution buffered with sodium bicarbonate according to the instructions given in section Instructions for Use.
Two alternative dosage regimens of diclofenac sodium solution for injection are recommended. For the treatment of moderate to severe post-operative pain, 75 mg should be infused continuously over a period of 30 minutes to 2 hours. If necessary, treatment may be repeated after a few hours, but the dose should not exceed 150 mg within any period of 24 hours.
For the prevention of post-operative pain, a loading dose of 25 mg to 50 mg should be infused after surgery over 15 minutes to 1 hour, followed by a continuous infusion of about 5 mg per hour up to a maximum daily dose of 150 mg.

Children and adolescents
Because of their dosage strength, the ampoules of diclofenac sodium solution for injection are not suitable for children and adolescents.
Mode of Administration
Intravenous infusion
Intramuscular injection

Contraindications
- Known hypersensitivity to the active substance or to any of the excipients.
- Active gastric or intestinal ulcer, bleeding or perforation.
- Last trimester of pregnancy
- Severe hepatic, renal or cardiac failure
- Like other non-steroidal anti-inflammatory drugs (NSAIDs), diclofenac sodium is also contraindicated in patients in whom attacks of asthma, urticaria, or acute rhinitis are precipitated by acetylsalicylic acid or other NSAIDs.

Warnings and Precautions
Precaution:
Severe cutaneous reactions, including Stevens - Johnson syndrome and toxic epidermal necrolysis (Lyell's syndrome), have been reported with diclofenac sodium. Patients treated with diclofenac sodium should be closely monitored for signs of hypersensitivity reactions. Discontinue diclofenac sodium immediately if rash occurs.

Warning
RISK OF GI ULCERATION, BLEEDING AND PERFORATION WITH NSAID
Serious GI toxicity such as bleeding, ulceration and perforation can occur at any time, with or without warning symptoms, in patients treated with NSAID therapy. Although minor upper GI problems (e.g. dyspepsia) are common, usually developing early in theraphy, prescribers should remain alert for ulceration and bleeding in patients treated with NSAIDs even in the absence of previous GI tract symptoms.
Studies to date have not identified any subset of patients not at risk of developing peptic ulceration and bleeding. Patients with prior history of serious GI events and other risk factors associated with peptic ulcer disease (e.g. alcoholism, smoking, and corticosteroid therapy) are at increased risk. Elderly or debilitated patients seem to tolerate ulceration or bleeding less than other individuals and account for most spontaneous reports for fatal GI events.
As with other NSAIDs, allergic reactions, including anaphylactic/anaphylactoid reactions, can also occur in rare cases with diclofenac without earlier exposure to the drug.
Like other NSAIDs, diclofenac sodium may mask the signs and symptoms of infection due to its pharmacodynamic properties.
The concomitant use of diclofenac sodium with systemic NSAIDs including cyclooxygenase-2 selective inhibitors, should be avoided due to the absence of any evidence demonstrating synergistic benefits and the potential for additive undesirable effects.
Caution is indicated in the elderly on basic medical grounds. In particular, it is recommended that the lowest effective dose be used in frail elderly patients or those with a low body weight.

Pre-existing asthma
In patients with asthma, seasonal allergic rhinitis, swelling of the nasal mucosa (i.e. nasal polyps), chronic obstructive pulmonary diseases or chronic infections of the respiratory tract (especially if linked to allergic rhinitis-like symptoms), reactions on NSAIDs like asthma exacerbations (so-called intolerance to analgesics / analgesics-asthma), Quincke's oedema or urticaria are more frequent than in other patients. Therefore, special precaution is recommended in such patients (readiness for emergency). This is applicable as well for patients who are allergic to other substances, e.g. with skin reactions, pruritus or urticaria.
Special caution is recommended when diclofenac sodium is used parenterally in patients with bronchial asthma because symptoms may be exacerbated.

Gastrointestinal effects
To reduce the risk of GI toxicity in patients with a history of ulcer, particularly if complicated with haemorrhage or perforation, and in the elderly, the treatment should be initiated and
maintained at the lowest effective dose.
Combination therapy with protective agents (e.g. proton pump inhibitors or misoprostol) should be considered for these patients, and also for patients requiring concomitant use of medicinal products containing low-dose acetylsalicylic acid (ASA)/aspirin or other medicinal products likely to increase gastrointestinal risk.
Patients with a history of GI toxicity, particularly the elderly, should report any unusual abdominal symptoms (especially GI bleeding). Caution is recommended in patients receiving concomitant medications which could increase the risk of ulceration or bleeding, such as systemic corticosteroids, anticoagulants, anti-platelet agents or selective serotonin-reuptake inhibitors.
Close medical surveillance and caution should also be exercised in patients with ulcerative colitis or Crohn's disease, as their condition may be exacerbated.

Hepatic effects
Close medical surveillance is required when prescribing diclofenac sodium to patients with impaired hepatic function, as their condition may be exacerbated.
As with other NSAIDs, including diclofenac, values of one or more liver enzymes may increase. During prolonged treatment with diclofenac sodium, regular monitoring of hepatic function is indicated as a precautionary measure. If abnormal liver function tests persist or worsen, if clinical signs or symptoms consistent with liver disease develop, or if other manifestations occur (e.g. eosinophilia, rash), diclofenac sodium should be discontinued. Hepatitis may occur with use of diclofenac without prodromal symptoms.
Caution is called for when using diclofenac sodium in patients with hepatic porphyria, since it may trigger an attack.

Renal effects
As fluid retention and oedema have been reported in association with NSAID therapy, including diclofenac particular caution is called for in patients with impaired cardiac or renal function, history of hypertension, the elderly, patients receiving concomitant treatment with diuretics or medicinal products that can significantly impact renal function, and in those patients with substantial extracellular volume depletion from any cause, e.g. before or after major surgery. Monitoring of renal function is recommended as a precautionary measure when using diclofenac sodium in such cases. Discontinuation of therapy is usually followed by recovery to the pre-treatment state.

Haematological effects
During prolonged treatment with diclofenac sodium, as with other NSAIDs, monitoring of the blood count is recommended. Like other NSAIDs, diclofenac sodium may temporarily inhibit platelet aggregation. Patients with defects of haemostasis should be carefully monitored.

Effects on ability to drive and use machines
Patients experiencing visual disturbances, dizziness, vertigo, somnolence or other central nervous system disturbances while taking diclofenac sodium should refrain from driving or using machines.

Interactions with Other Medicaments
The following interactions include those observed with diclofenac sodium enteric-coated tablets
and/or other pharmaceutical forms of diclofenac.

Lithium
If used concomitantly, diclofenac may raise plasma concentrations of lithium. Monitoring of the serum lithium level is recommended.

Digoxin
If used concomitantly, diclofenac may raise plasma concentrations of digoxin. Monitoring of the serum digoxin level is recommended.

Diuretics and antihypertensive agents
Like other NSAIDs, concomitant use of diclofenac with diuretics or antihypertensive agents (e.g. beta-blockers, angiotensin converting enzyme (ACE) inhibitors) may cause a decrease in their antihypertensive effect. Therefore, the combination should be administered with caution and patients, especially the elderly, should have their blood pressure periodically monitored. Patients should be adequately hydrated and consideration should be given to monitoring of renal function after initiation of concomitant therapy and periodically thereafter, particularly for diuretics and ACE inhibitors due to the increased risk of nephrotoxicity. Concomitant treatment with potassium-sparing drugs may be associated with increased serum potassium levels, which should therefore be monitored frequently.

Other NSAIDs and corticosteroids
Concomitant administration of diclofenac and other systemic NSAIDs or corticosteroids may increase the frequency of gastrointestinal undesirable effects.
Anticoagulants and anti-platelet agents
Caution is recommended since concomitant administration could increase the risk of bleeding. Although clinical investigations do not appear to indicate that diclofenac affects the action of anticoagulants, there are isolated reports of an increased risk of haemorrhage in patients receiving diclofenac and anticoagulants concomitantly. Close monitoring of such patients is therefore recommended.
Selective serotonin reuptake inhibitors (SSRIs)
Concomitant administration of systemic NSAIDs, including diclofenac, and SSRIs may increase the risk of gastrointestinal bleeding.

Antidiabetics
Clinical studies have shown that diclofenac can be given together with oral antidiabetic agents without influencing their clinical effect. However, there have been isolated reports of both hypoglycaemic and hyperglycaemic effects necessitating changes in the dosage of the antidiabetic agents during treatment with diclofenac. For this reason, monitoring of the blood glucose level is recommended as a precautionary measure during concomitant therapy.

Methotrexate
Caution is recommended when NSAIDs, including diclofenac, are administered less than 24 hours before or after treatment with methotrexate, since blood concentrations of methotrexate may rise and the toxicity of this substance be increased.

Ciclosporin
Diclofenac, like other NSAIDs, may increase the nephrotoxicity of ciclosporin due to the effect on renal prostaglandins. Therefore, it should be given at doses lower than those that would be used in patients not receiving ciclosporin.

Quinolone antibacterials
There have been isolated reports of convulsions which may have been due to concomitant use of quinolones and NSAIDs.

Statement on Usage During Pregnancy and Lactation
Pregnancy
The use of diclofenac in pregnant women has not been studied. Therefore, diclofenac sodium should not be used during the first two trimesters of pregnancy unless the potential benefit to the mother outweights the risk to the foetus. As with other NSAIDs, use of diclofenac during the third trimester of pregnancy is contraindicated owing to the possibility of uterine inertia and/or premature closure of the ductus arteriosus. Animal studies have not shown any directly or indirectly harmful effects on pregnancy, embryonal/foetal development, parturition or postnatal development.

Lactation
Like other NSAIDs, diclofenac passes into the breast milk in small amounts. Therefore, diclofenac sodium should not be administered during breast feeding in order to avoid undesirable
effects in the infant.

Fertility
As with other NSAIDs, the use of diclofenac sodium may impair female fertility and is not recommended in women attempting to conceive. In women who have difficulties conceiving or who are undergoing investigation of infertility, withdrawal of diclofenac sodium should be considered.

Adverse Effects / Undesirable Effects
Adverse effects:
Dermatological: Occasional - rashes or skin eruptions.
Cases of hair loss, bullous eruptions, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), and photosensitivity reactions have been reported.
Patients experiencing visual disturbances, dizziness, vertigo, somnolence or other central nervous system disturbances while taking diclofenac sodium, should refrain from driving or using machines.
The following undesirable effects include those reported with diclofenac sodium injection and/or other pharmaceutical forms of diclofenac, with either short-term or long-term use.

Infections and infestations
Very rare: Injection site abscess. Adverse effects:
Dermatological: Occasional - rashes or skin eruptions.
Cases of hair loss, bullous eruptions, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), and photosensitivity reactions have been reported.
Patients experiencing visual disturbances, dizziness, vertigo, somnolence or other central nervous system disturbances while taking diclofenac sodium, should refrain from driving or using machines.
The following undesirable effects include those reported with diclofenac sodium injection and/or other pharmaceutical forms of diclofenac, with either short-term or long-term use.
Infections and infestations
Very rare: Injection site abscess.

Blood and lymphatic system disorders
Very rare: Thrombocytopenia, leukopenia, anaemia (including haemolytic and aplastic anaemia), agranulocytosis.
Immune system disorders
Rare: Hypersensitivity, anaphylactic and anaphylactoid reactions (including hypotension and shock).
Very rare: Angioneurotic oedema (including face oedema).
Psychiatric disorders

Not known (Frequency cannot be estimated from the available data)
- A secondary infection that may not respond to the antibiotic previously prescribed.
- Form of anaemia where red blood cells are destroyed (haemolytic anaemia).
- Severe decrease in white blood cells (agranulocytosis).
- Convulsions.
- Vertigo (spinning sensation).
- Inflammation of the pancreas (pancreatitis). The signs include severe pain in the stomach which spreads to your back.
- Inflammation of the mucus lining of the mouth (stomatitis).
- Inflammation of the tongue (glossitis). The signs include swelling, redness and soreness of the tongue.
- Problems with your gallbladder, which may cause pain, feeling sick and being sick.
- A neurological condition that may occur in neonates with severe jaundice (kernicterus).
- Kidney problems caused by deposits of calcium ceftriaxone. There may be pain when passing water (urine) or low output of urine.
- A false positive result in a Coombs' test (a test for some blood problems).
- A false positive result for galactosaemia (an abnormal build up of the sugar galactose).
- Ceftriaxone may interfere with some types of blood glucose tests - please check with your doctor.

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:

5. How to store Ceftriaxone injection
Keep out of the sight and reach of children.
Do not use Ceftriaxone injection after the expiry date which is printed on the label and carton.

Do not store above 25°C. Your doctor, pharmacist or nurse will know how to store Ceftriaxone Injection properly.

6. Contents of the pack and other information
What Ceftriaxone injection contains
Each vial contains 250mg, 1g, or 2g ceftriaxone (as ceftriaxone sodium).
The vials contain no other ingredients.

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For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only

BETA-ROSS

Ceftriaxone 500 mg, 1g, Powder for Solution for Injection or Infusion
Ceftriaxone (as Ceftriaxone Sodium)

For IV/IM Use

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.
- 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

The name of your medicine is "Ceftriaxone Powder for Solution for Injection or Infusion" (referred to as Ceftriaxone injection throughout this leaflet).

1. What Ceftriaxone injection is and what it is used for
Ceftriaxone is an antibiotic given to adults and children (including newborn babies). It works by killing bacteria that cause infections. It belongs to a group of medicines called cephalosporins.

Ceftriaxone injection is used to treat infections of:
- the brain (meningitis).
- the lungs.
- the middle ear.
- the abdomen and abdominal wall (peritonitis).
- the urinary tract and kidneys.
- bones and joints.
- the skin or soft tissues.
- the blood.
- the heart.

It can be given:
- to treat specific sexually transmitted infections (gonorrhoea and syphilis).
- to treat patients with low white blood cell counts (neutropenia) who have fever due to bacterial infection.
- to treat infections of the chest in adults with chronic bronchitis.
- to treat Lyme disease (caused by tick bites) in adults and children including newborn babies from 15 days of age.
- to prevent infections during surgery.

2. What you need to know before you are given Ceftriaxone injection
You must not be given Ceftriaxone injection if:
- You are allergic to ceftriaxone
- You have had a sudden or severe allergic reaction to penicillin or similar antibiotics (such as cephalosporins, carbapenems or monobactams). The signs include sudden swelling of the throat or face which might make it difficult to breath or swallow, sudden swelling of the hands, feet and ankles, and a severe rash that develops quickly.
- You are allergic to lidocaine and you are to be given Ceftriaxone injection as an injection into a muscle.

Ceftriaxone injection must not be given to babies if:
- The baby is premature.
- The baby is newborn (up to 28 days of age) and has certain blood problems or jaundice(yellowing of the skin or the whites of the eyes) or is to be given a product that contains calcium into their vein.

Warnings and precautions
Talk to your doctor or pharmacist or nurse before you are given Ceftriaxone injection if:
• You have recently received or are about to receive products that contain calcium.
• You have recently had diarrhoea after having an antibiotic medicine.
• You have ever had problems with your gut, in particular colitis (inflammation of the bowel).
• You have liver or kidney problems.
• You have gall stones or kidney stones
• You have other illnesses, such as haemolytic anaemia (a reduction in your red blood cells that may make your skin pale yellow & cause weakness orbreathlessness).
• You are on a low sodium diet.

If you need a blood or urine test
If you are given Ceftriaxone for a long time, you may need to have regular blood tests. Ceftriaxone can affect the results of urine tests for sugar and a blood test known as the Coombs test. If you are having tests:
• Tell the person taking the sample that you have been given Ceftriaxone.

Children
Talk to your doctor or pharmacist or nurse before your child is administered Ceftriaxone if:
• He/she has recently been given or is to be given a product that contains calcium into their vein.

Other medicines and Ceftriaxone
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
In particular, tell your doctor or pharmacist if you are taking any of the following medicines:
• A type of antibiotic called an aminoglycoside.
• An antibiotic called chloramphenicol (used to treat infections, particularly of the eyes).

Pregnancy and 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 taking this medicine. The doctor will consider the benefit of treating you with Ceftriaxone against the risk to your baby.

Driving and using machines
Ceftriaxone can cause dizziness. If you feel dizzy, do not drive or use any tools or machines. Talk to your doctor if you experience these symptoms.

Ceftriaxone injection contains sodium
This medicine contains 0.9 mmol (250mg vial), 3.6 mmol (1g vial) or 7.2 mmol (2g vial) of sodium. This should be taken into consideration by patients on a controlled sodium diet. Tell your doctor or nurse if you are on a low sodium diet.

3. How Ceftriaxone injection is given
Ceftriaxone injection is usually given by a doctor or nurse. It can be given as a drip (intravenous infusion) or as an injection directly into a vein or into a muscle.
Ceftriaxone injection is made up by the doctor, pharmacist or nurse and will not be mixed with or given to you at the same time as calcium-containing injections.

The usual dose
Your doctor will decide the correct dose of Ceftriaxone for you.The dose will depend on the severity and type of infection; whether you are on any other antibiotics; your weight and age; how well your kidneys and liver are working. The number of days or weeks that you are given Ceftriaxone depends on what sort of infection you have.

Adults, older people and children aged 12 years and over with a body weight greater than or equal to 50 kilograms (kg):
1 to 2 g once a day depending on the severity and type of infection. If you have a severe infection, your doctor will give you a higher dose (up to 4 g once a day). If your daily dose is higher than 2 g, you may receive it as a single dose once a day or as two separate doses.

Newborn babies, infants and children aged 15 days to 12 years with a body weight of less than 50 kg:
50-80 mg Ceftriaxone for each kg of the child's body weight once a day depending on the severity and type of infection. If you have a severe infection, your doctor will give you a higher dose up to 100 mg for each kg of body weight to a maximum of 4 g once a day. If your daily dose is higher than 2 g, you may receive it as a single dose once a day or as two separate doses.
Children with a body weight of 50 kg or more should be giventhe usual adult dose.

Newborn babies (0-14 days)
20 – 50 mg Ceftriaxone for each kg of the child's body weight once a day depending on the severity and type of infection. The maximum daily dose is not to be more than 50 mg for each kg of the baby's weight.

People with liver and kidney problems
You may be given a different dose to the usual dose. Your doctor will decide how much Ceftriaxone you will need and will check you closely depending on the severity of the liver and kidney disease.

If you are given more Ceftriaxone than you should
If you accidentally receive more than your prescribed dose, contact your doctor or nearest hospital straight away.

If you forget to use Ceftriaxone injection
If you miss an injection, you should have it as soon as possible. However, if it is almost time for your next injection, skip the missed injection. Do not take a double dose (two injections at the same time) to make up for a missed dose.

If you stop using Ceftriaxone injection
Do not stop taking Ceftriaxone unless your doctor tells you to. If you have any further questions on the use of this medicine, ask your doctor or nurse.

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Severe allergic reactions (not known, frequency cannot be estimated from the available data)
If you have a severe allergic reaction, tell a doctor straight away. The signs may include:
• Sudden swelling of the face, throat, lips or mouth. This can make it difficult to breathe or swallow.
• Sudden swelling of the hands, feet and ankles.

Severe skin rashes (not known, frequency cannot be estimated from the available data)
If you get a severe skin rash, tell a doctor straight away. The signs may include a severe rash that develops quickly, with blisters or peeling of the skin and possibly blisters in the mouth.

Other possible side effects:

Common (may affect up to 1 in 10 people)
• Abnormalities with your white blood cells (such as a decrease of leucocytes and an increase of eosinophils) and platelets (decrease of thrombocytes).
• Loose stools or diarrhoea.
• Changes in the results of blood tests for liver functions.
• Rash.

Uncommon (may affect up to 1 in 100 people)
• Fungal infections (for example, thrush).
• A decrease in the number of white blood cells (granulocytopenia).
• Reduction in number of red blood cells (anaemia).
• Problems with the way your blood clots. The signs may include bruising easily and pain and swelling of your joints.
• Headache.
• Dizziness.
• Feeling sick or being sick.
• Pruritis (itching).
• Pain or a burning feeling along the vein where Ceftriaxone has been given.
• Pain where the injection was given.
• A high temperature (fever).
• Abnormal kidney function test (blood creatinine increased).

Rare (may affect up to 1 in 1,000 people)
• Inflammation of the large bowel (colon). The signs include diarrhoea, usually with blood and mucus, stomach pain and fever.
• Difficulty in breathing (bronchospasm).
• A lumpy rash (hives) that may cover a lot of your body, feeling itchy and swelling.
• Blood or sugar in your urine.
• Oedema (fluid build-up).
• Shivering.