

**Dexamethasone Sodium Phosphate Injection USP 4mg/ml,  
8mg/2ml, 20mg/5ml, 100mg/10ml, 120mg/30ml**

**Package leaflet: Information for the patient**

**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, ask your doctor or pharmacist.
  - If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
1. What is in this leaflet
  2. What Dexamethasone is and what it is used for
  3. What you need to know before you use Dexamethasone
  4. How you use Dexamethasone
  5. Possible side effects
  6. How to store Dexamethasone
  7. Contents of the pack and other information

**1. What Dexamethasone is and what it is used for**

The name of your medicine is Dexamethasone. This belongs to a group of medicines called corticosteroids.

Corticosteroids are hormones that are found naturally in your body that help to keep you healthy and well. Boosting your body with extra corticosteroid, such as Dexamethasone, is an effective way to treat various illnesses involving inflammation in the body. Dexamethasone lowers inflammation, which could otherwise go on making your condition worse. You must take this medicine regularly to get maximum benefit from it.

Dexamethasone is given by injection to patients unable to take a tablet form of the medicine. When given into a vein or muscle, dexamethasone reduces inflammation and suppresses the immune system and is used normally for patients with:

- severe allergic reactions causing swelling of the face and throat, low blood pressure and collapse (angioneurotic oedema and anaphylaxis), severe exacerbation of bronchial asthma (such as status asthmaticus), hypersensitivity reaction to other medications
- shock caused by infection or severe tuberculosis (also with anti-infective treatments e.g. antibiotics)
- raised pressure in the skull caused by tumours or infantile spasms

Dexamethasone can be used

- to control cerebral oedema (swelling in the brain) caused by brain tumour or after neurosurgery, but not in cases of head trauma.

Sometimes, the injection is given into the painful area itself e.g. inflammation of the joints (rheumatoid arthritis and osteoarthritis).

## **2. What you need to know before you use Dexamethasone**

### **Do not use Dexamethasone:**

- if you are allergic to dexamethasone or any of the other ingredients of this medicine (listed in section 6). The signs of an allergic reaction include a rash, itching or shortness of breath
- if you have an infection that affects the whole body
- if you have an infection of a joint
- if you have unstable joints. This is a condition where joints, such as the knee, can suddenly give way.

Do not have this medicine if any of the above apply to you.

### **Warnings and precautions**

Talk to your doctor or pharmacist before using Dexamethasone:

- If you have ever had severe depression or manic depression (bipolar disorder). This includes having had depression before while taking steroid medicines like Dexamethasone
- If any of your close family has had these illnesses

If either of these applies to you, talk to a doctor before having this medicine.

### **Mental problems while having Dexamethasone**

Mental health problems can happen while having steroids like Dexamethasone (see also section 4).

- These illnesses can be serious
- Usually they start within a few days or weeks of starting the medicine
- They are more likely to happen at high doses
- Most of these problems go away if the dose is lowered or the medicine is stopped. However, if problems do happen, they might need treatment

Talk to a doctor if you (or someone taking this medicine), show any signs of mental problems. This is particularly important if you are depressed, or might be thinking about suicide. In a few cases, mental problems have happened when doses are being lowered or stopped.

### **Take special care with Dexamethasone**

Before you have Dexamethasone, tell your doctor if:

- You have had allergic reactions with a corticosteroid treatment. Severe allergic reactions (including shock) have been seen with injected corticosteroids.
- You have a cancer of the blood because you may be at risk of a very rare, potentially life-threatening condition resulting from a sudden breakdown of tumour cells.
- You have symptoms of tumour lysis syndrome such as muscle cramping, muscle weakness, confusion, visual loss or disturbances and shortness of breath, in case you

suffer from haematological malignancy

- You have kidney or liver problems
- You have high blood pressure or heart disease
- You have diabetes or there is a family history of diabetes
- You have thinning of the bones (osteoporosis), particularly if you are a female who has been through the menopause
- You have had muscle weakness with this or other steroids in the past
- You have raised eye pressure (glaucoma) or there is a family history of glaucoma
- You have a stomach (peptic) ulcer
- You have mental problems or you have had a mental illness which was made worse by this type of medicine such as ‘steroid psychosis’
- You have epilepsy
- You have migraines
- You have an infection with parasites
- You have tuberculosis (TB)
- You have stunted growth
- You have ‘Cushing’s syndrome’
- You have had a head injury
- You have had a stroke
- Contact your doctor if you experience blurred vision or other visual disturbances.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before having Dexamethasone.

If you develop an infection while you are having this medicine, you should talk to your doctor. Please tell any doctor, dentist or person who may be giving you treatment that you are currently taking steroids or have taken them in the past.

If you are living in the UK, you should always carry a blue ‘steroid card’ which gives clear guidance on the special care to be taken when you are taking this medicine. Show this to any doctor, dentist or person who may be giving you treatment. Even after your treatment has finished you must tell anyone who is giving you treatment that you have taken steroids in the past.

Do not use Dexamethasone for the treatment of Acute Respiratory Distress Syndrome (ARDS; a serious lung disease) if you have been diagnosed with this condition for over 2 weeks.

### **Dexamethasone and viral infections**

While you are having this kind of medicine, you should not come into contact with anyone who has chicken pox, shingles or measles if you have not had these illnesses. This is because you may need specialist treatment if you get these diseases. If you think you may have had exposure to any of these diseases, you should talk to your doctor straight away. You should also tell your doctor if you have ever had infectious diseases such as measles or chicken pox and if you have had any vaccinations for these conditions in the past.

Please tell a doctor or anyone giving you treatment, such as at a hospital, if:

You have an accident

You are ill

You need any surgery. This includes any surgery you may have at your dentist's

You need to have a vaccination

If any of the above apply to you, you should tell your doctor or the person treating you even if you have stopped having this medicine.

### **Children**

If a child is having this medicine, it is important that the doctor monitors their growth and development regularly.

Dexamethasone should not be routinely given to premature babies with respiratory problems.

### **Other medicines and Dexamethasone**

- Please tell your doctor if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. Other medicines can affect the way Dexamethasone works or Dexamethasone can affect the way they work. In particular:

- Medicines to treat heart and blood problems, such as warfarin, high blood pressure medicine, and water tablets (diuretics)
- Antibiotics such as rifampicin and rifabutin
- Medicines that are broken down in the body by an enzyme in the liver (CYP 3A4) such as HIV protease inhibitors (e.g. indinavir) or certain antibiotics (e.g. erythromycin)
- Some medicines may increase the effects of Dexamethasone and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat)
- Medicines to treat epilepsy, such as phenytoin, carbamazepine, phenobarbitone and primidone
- Medicines that control pain or lower inflammation, such as aspirin or phenylbutazone
- Medicines used to treat diabetes
- Medicines used to lower potassium levels
- Medicines used to treat myasthenia
- Anti-cancer treatments, such as aminoglutethimide
- Ephedrine used to relieve symptoms of a blocked nose
- Acetazolamide used for glaucoma
- Carbenoxolone sometimes used for ulcers.

### **Pregnancy and breast-feeding**

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

### **Driving and using machines**

Dexamethasone is not likely to affect you being able to drive or use any tools or machines.

Dexamethasone contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium- free'.

### **3. How you have Dexamethasone**

Dexamethasone is normally given by a doctor or a nurse. It will be given as an injection into a muscle, tendon or joint. It can also be given as an injection into a vein. The dose depends on your illness and how bad it is. Your doctor will decide the correct dosage for you and how and when the injection will be given

### **If you use more Dexamethasone than you should**

If you think you have been given too much Dexamethasone, tell your doctor straight away. The following effects may happen:

- Swelling of the throat
- Skin reaction
- Difficulty breathing

Since the injection will be given to you by a doctor or nurse, it is unlikely that you will be given too much or that you will miss a dose. If you think you have been given too much or that

you have missed a dose, please contact your doctor immediately.

### **If you stop using Dexamethasone**

It can be dangerous to have your treatment with Dexamethasone Injection stopped abruptly. After prolonged therapy your body may have gotten used to the administration of this medicine and may have reduced the normal production of hormones like the one contained in this medicine. How your treatment is stopped will depend on the disease you are being treated for and how much Dexamethasone Injection you have been given. If you need to stop this treatment, follow your doctor's advice.. If you stop having this medicine too quickly, your condition may get worse.

It may be necessary to reduce the amount of medicine you are given gradually until you stop having it altogether. Your doctor has to make sure that the disease you have been treated for is unlikely to relapse. Dosage reduction must be adjusted if you are subjected to unusual stress (e.g. another illness, trauma or surgical procedures).

When the treatment is stopped too quickly, you may feel 'withdrawal symptoms'. These may include headache, problems with your vision (including pain or swelling in the eye), feeling or being sick, fever, pain in your muscles and joints, swelling in the inside of your nose, weight loss, itchy skin and conjunctivitis. Too rapid a reduction following

prolonged treatment can lead to insufficiency of hormone production in the adrenal gland and low blood pressure (symptoms of which can be tiredness, dizziness, headache, palpitation). In extreme cases, this may be fatal.

In a few cases, **mental health problems** have occurred when doses are being lowered or stopped

– see section 4 below.

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

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Dexamethasone can also cause side effects when you stop using it.

See section 3, 'If you stop having Dexamethasone'

#### **Serious side effects: tell a doctor straight away**

Steroids including Dexamethasone can cause serious mental health problems. These are common in both adults and children. They can affect about 5 in every 100 people taking medicines like Dexamethasone. These include:

- Feeling depressed, including thinking about suicide

- Feeling high (mania) or moods that go up and down
- Feeling anxious, having problems sleeping, difficulty in thinking or being confused and losing your memory
- Feeling, seeing or hearing things that do not exist. Having strange and frightening thoughts, changing how you act or having feelings of being alone

If you notice any of these problems, talk to a doctor straight away.

#### **If you have an allergic reaction to Dexamethasone see a doctor straight away**

An allergic reaction may include:

- Any kind of skin rash or itching of the skin
- Difficulty in breathing or collapse
- Swelling of the face, lips, tongue and/or throat with difficulty in swallowing or breathing (angioedema).

#### **If you get any of the following side effects see your doctor as soon as possible:**

- **Stomach and gut problems:** stomach ulcers which may perforate or bleed, indigestion, having more of an appetite than usual, diarrhoea, feeling or being sick
- **Inflamed pancreas:** this may cause severe pain in the back or tummy
- **Problems with salts in your blood** such as too much sodium or low potassium or calcium. You may have water retention
- **Heart and blood problems:** high blood pressure, blood

clots

- **Bone problems:** thinning of the bones (osteoporosis) with an increased risk of fractures, bone disease, damaged tendons, damage to the joint where the injection was given
- **Recurring infections** that get worse each time such as chicken pox and thrush
- **Skin problems:** wounds that heal more slowly, bruising, acne, sweating more than usual. Burning, redness and swelling where the injection was given. This does not last long
- **Eye problems:** increased pressure in the eye including glaucoma, eye disorders such as cataracts, eye infections, visual disturbances, loss of vision, blurred vision
- **Hormone problems:** irregular or missing periods, stunted growth in children and teenagers, swelling of the face (called a 'Cushingoid' or 'moon' face). It may affect your diabetes and you may notice you start needing higher doses of the medicine you take for diabetes. Your body may not be able to respond normally to severe stress such as accidents, surgery or illness, growth of extra body hair (particularly in women), increased appetite or weight gain
- **Nervous system problems:** fits or epilepsy may become worse, severe unusual headache with visual problems, being unable to sleep, feeling depressed, extreme mood swings, schizophrenia may become worse, headache or problems with your vision (including eye pain or swelling)

## Reporting of side effects

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

## 5. How to store Dexamethasone

Keep this medicine out of the sight and reach of children

Do not use this medicine after the expiry date which is stated on the label and carton after "EXP". The expiry date refers to the last day of that month.

Store in a refrigerator (2°C - 8°C). Do not freeze. Store in the original package

After first opening, the product should be used immediately to avoid microbial contamination. When diluted with infusion fluids, chemical and physical in-use stability of dilutions has been demonstrated for at least 24 hours, at 25°C (room temperature). If not used immediately, in-use storage 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 dilution has taken place in controlled and validated aseptic conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.





## **6. Contents of the pack and other information What Dexamethasone contains**

The active ingredient is dexamethasone (as sodium phosphate). Each 1 ml contains 3.8 mg dexamethasone (as sodium phosphate) which is equivalent to 5.0 mg dexamethasone sodium phosphate

The other ingredients are glycerol, disodium edetate, water for injections and sodium hydroxide or phosphoric acid

## **What Dexamethasone looks like and contents of the pack**

Dexamethasone is a clear, colourless liquid. It comes in vials containing 1 ml of solution. Vials are available in packs of 1 or 10. Not all pack sizes may be marketed.

## **7.Manufactured in India by:**

### **TAJ PHARMACEUTICALS LTD.**

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