

Dexamethasone 3.8 mg/ml solution for injection

dexamethasone

Information for the patient

Important information about this medicine

- **Dexamethasone is a steroid medicine**, prescribed for many different conditions including serious illnesses
- **You need to take it regularly** to get the maximum benefit
- **Don't stop taking this medicine** without talking to your doctor—you may need to reduce the dose gradually
- **Dexamethasone can cause side effects in some people** (read section 4: Possible side effects). Some problems such as mood changes (feeling depressed, or 'high'), or stomach problems can happen straight away. If you feel unwell, in any way, keep taking your medicine, **but see your doctor straight away**
- **Some side effects only happen after weeks or months**. These include weakness of arms and legs, or developing a rounder face (read Section 4 for more information)
- **If you take it for more than 3 weeks, in the UK, you will get a blue 'steroid card'**: always keep it with you and show it to any doctor or nurse treating you
- **Keep away from people who have chicken pox or shingles**, if you have never had them. They could affect you severely. If you do come into contact with chicken pox or shingles, **see your doctor straight away**

Now read the rest of this leaflet.

It includes other important information on the safe and effective use of this medicine that might be especially important for you.

- Read all of this leaflet carefully before you start using this medicine
- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or your pharmacist
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet:

1. **What Dexamethasone is and what it is used for**
2. **Before you have Dexamethasone**
3. **How you have Dexamethasone**
4. **Possible side effects**
5. **How to store Dexamethasone**
6. **Further 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 can be used to:

- Reduce inflammation
- Treat a number of different diseases of the immune system

2. Before you have Dexamethasone

Do not have Dexamethasone and tell your doctor if:

- You are allergic (hypersensitive) to dexamethasone or any other ingredients in this medicine (listed in section 6)
The signs of an allergic reaction include a rash, itching or shortness of breath
- You have an infection that affects the whole body
- You have an infection of a joint
- 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, talk to your doctor or pharmacist before having Dexamethasone.

Check with your doctor first:

- 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, 'Possible side effects').

- 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 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 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

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

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.

More important information about having this kind of medicine

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.

Taking other medicines

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

Talk to your doctor before having this medicine if you are pregnant, planning to become pregnant or are breast-feeding.

Driving and using machines

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

3. How you have Dexamethasone

Dexamethasone is normally given by a doctor. It will be given as an injection into a muscle or under your skin. It can also be given as an injection into a vein. The dose depends on your illness and how bad it is. The dose in adults is normally from 0.5 to 24mg daily, and in children 0.2 to 0.4mg/kg daily. Your doctor will decide the dose.

If you have 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

If you stop having Dexamethasone

It can be dangerous to stop having this medicine suddenly. If you need to stop this treatment, follow your doctor's advice. He or she may tell you to lower the amount of medicine you are having gradually until you stop having it altogether. If you stop having this medicine too quickly, your condition may get worse.

You may also feel a 'withdrawal symptom'. 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.

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

4. Possible side effects

Like all medicines, Dexamethasone 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.

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. Also, 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
- **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 has become worse, headache or problems with your vision (including eye pain or swelling)
- 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 out of the reach and sight of children
- Do not use Dexamethasone 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.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment

6. Further 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.

The Marketing Authorisation Holder is:

Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24, Ireland

The Manufacturer is:

N.V.Organon, PO Box 20, 5340 BH Oss, The Netherlands.

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Technical information for the healthcare professional

**NEW FORMULATION
CHANGE IN CONCENTRATION
STORE IN A REFRIGERATOR**

The following information is intended for the healthcare professional only:

This is an extract from the Summary of Product Characteristics (SmPC) to assist in the administration of Dexamethasone 3.8 mg/ml solution for injection.

The prescriber should be familiar with the **full SmPC** in order to determine the appropriateness of the use of the product in a particular patient. The full SmPC can be found on the electronic Medicines Compendium (eMC) website: <http://www.medicines.org.uk/emc/>.
The Patient Information Leaflet provided (see the other half of this leaflet) should be given to the patient.

Dexamethasone 3.8 mg/ml solution for injection contains dexamethasone base in the form of the salt, dexamethasone sodium phosphate.

Each vial contains 1 ml of solution. Each 1 ml of solution contains 3.8 mg dexamethasone base (as sodium phosphate). This is equivalent to 5.0 mg dexamethasone sodium phosphate.

PREPARATION AND OTHER HANDLING INSTRUCTIONS

Dexamethasone solution for injection may be diluted with the following solutions for injection or infusion:

- Sodium Chloride 0.9% infusion, Glucose 5% Infusion, Compound Sodium Lactate Infusion, Hartmann's Solution for Injection, Ringer-Lactate Solution for Injection, Ringer's Solution for Injection, Sorbitol 5% Injection, Invert Sugar 10% Injection and Rheomacrodex

Using the above infusion fluids, Dexamethasone solution for injection can also be injected into the infusion line without causing precipitation of the ingredients.

For single use only.

Discard any unused solution after use.

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

The product should only be used when the solution is clear and particle free.

DOSAGE AND ADMINISTRATION

Dosage

Note: All dose recommendations stated in this section are expressed as mg dexamethasone base.

In general, glucocorticoid dosage depends on the severity of the condition and response of the patient. Under certain circumstances (e.g. in stress), extra dosage adjustments may be necessary. If no favourable response is noted within a couple of days, glucocorticoid therapy should be discontinued.

Adults and Elderly

Once the disease is under control the dosage should be reduced or tapered off to the lowest suitable level under continuous monitoring and observation of the patient.

For acute life-threatening situations (e.g. anaphylaxis, acute severe asthma) substantially higher dosages may be needed. Cerebral oedema (adults): initial dose 8 - 16 mg IV followed by 5 mg IV or IM every 6 hours, until a satisfactory result has been obtained. In brain surgery these dosages may be necessary until several days after the operation. Thereafter, the dosage has to be tapered off gradually. Increase of intracranial pressure associated with brain tumours can be counteracted by continuous treatment.

For local treatment, the following dosages can be recommended:

- intra-articularly: 1.6-3 mg large joints
0.6-0.8 mg small joints
- intrabursally: 1.6-3 mg;
- in tendon sheaths: 0.3-0.8mg

The frequency of these injections may vary from every 3 - 5 days to every 2 - 3 weeks. For rectal drip in cases of ulcerative colitis: 4 mg diluted in 120 ml saline.

Suggested doses for children

Dosage requirements are variable and may have to be changed according to individual needs. Usually 0.2 mg/kg to 0.4 mg/kg of body weight daily.

Please refer to Table 1 for assistance when calculating any required dosage.

Table 1. Concentration vs. Volume

Desired concentration (mg dexamethasone base)	Required volume of product* (ml)
3.8	1.00
4	1.05
8	2.10
12	3.15
16	4.20

* Dexamethasone 3.8 mg/ml solution for injection

Method of administration

Dexamethasone solution for injection may be administered intravenously (IV), subcutaneously (SC), intramuscularly (IM), by local injection or as a rectal drip.

For administration by IV infusion: see section on 'Preparation and Other Handling Instructions'. With IV administration high plasma levels can be obtained rapidly.

Rapid IV injection of massive doses of glucocorticoids may sometimes cause cardiovascular collapse; the injection should therefore be given slowly over a period of several minutes.

Intra-articular injections should be given under strictly aseptic conditions.

WARNINGS

In post-marketing experience tumour lysis syndrome (TLS) has been reported very rarely in patients with haematological malignancies following the use of dexamethasone alone or in combination with other chemotherapeutic agents. Patients at high risk of TLS should be monitored closely and appropriate precautions taken.

Potentially severe psychiatric adverse reactions may occur with systemic steroids. Symptoms typically emerge within a few days or weeks of starting the treatment. Risks may be higher with high doses/systemic exposure, although dose levels do not allow prediction of the onset, type severity or duration of reactions. Most reactions recover after either dose reduction or withdrawal, although specific treatment may be necessary. Please seek advice if worrying psychological symptoms develop, especially if depressed mood or suicidal ideation is suspected. Please also be alert to possible psychiatric disturbances that may occur either during or immediately after dose tapering/withdrawal of systemic steroids, although such reactions have been reported infrequently.

Take particular care when considering the use of systemic corticosteroids in patients with existing or previous history of severe affective disorders in themselves or in their first degree relatives (Including depressive or manic-depressive illness and previous steroid psychosis).

Undesirable effects may be minimised by using the lowest effective dose for the minimum period, and by administering the daily requirement as a single morning dose or whenever possible as a single morning dose on alternative days. Frequent patient review is required to appropriately titrate the dose against disease activity.

After parenteral administration of glucocorticoids serious anaphylactoid reactions have occasionally occurred, particularly in patients with a history of allergy. If such an anaphylactoid reaction occurs, the following measures are recommended: immediate slow IV injection of 0.1 - 0.5 ml of adrenaline (solution of 1:1000: 0.1 - 0.5 mg adrenaline dependent on body weight), IV administration of aminophylline and artificial respiration if necessary.

Corticosteroids should not be used for the management of head injury or stroke because it is unlikely to be of any benefit and may even be harmful.

When treating Acute Respiratory Distress Syndrome (ARDS), therapy with corticosteroids should start within the first 2 weeks of onset of ARDS.

Preterm neonates

Available evidence suggests long-term neurodevelopment adverse events after early treatment (<96 hours) of premature infants with chronic lung disease at starting doses of 0.25 mg/kg twice daily.

Dexamethasone withdrawal

Adrenal cortical atrophy develops during prolonged therapy and may persist for years after stopping treatment. Withdrawal of corticosteroids after prolonged therapy must therefore always be gradual to avoid acute adrenal insufficiency, being tapered off over weeks or months according to the dose and duration of treatment.

In patients who have received more than physiological doses of systemic corticosteroids (approx. 1 mg dexamethasone) for greater than 3 weeks, withdrawal should not be abrupt. How dose reduction should be carried out depends largely on whether the disease is likely to relapse as the dose of systemic corticosteroids is reduced. Clinical assessment of disease activity may be needed during withdrawal. If the disease is unlikely to relapse on withdrawal of systemic corticosteroids but there is uncertainty about HPA suppression, the dose of systemic corticosteroid may be reduced rapidly to physiological doses. Once a daily dose of 1 mg dexamethasone is reached, dose reduction should be slower to allow the HPA-axis to recover. Abrupt withdrawal of systemic corticosteroid treatment, which has continued up to 3 weeks is appropriate if it is considered that the disease is unlikely to relapse. Abrupt withdrawal of doses of up to 6 mg daily of dexamethasone for 3 weeks is unlikely to lead to clinically relevant HPA-axis suppression in the majority of patients. In the following patient groups, gradual withdrawal of systemic corticosteroid therapy should be *considered* even after courses lasting 3 weeks or less:

- Patients who have had repeated courses of systemic corticosteroids, particularly if taken for greater than 3 weeks.
- When a short course has been prescribed within one year of cessation of long-term therapy (months or years).
- Patients who may have reasons for adrenocortical insufficiency other than exogenous corticosteroid therapy.
- Patients receiving doses of systemic corticosteroid greater than 6 mg daily of dexamethasone.
- Patients repeatedly taking doses in the evening.

During prolonged therapy any intercurrent illness, trauma or surgical procedure will require a temporary increase in dosage; if corticosteroids have been stopped following prolonged therapy they may need to be temporarily re-introduced.

Patients should carry 'steroid treatment' cards which give clear guidance on the precautions to be taken to minimise risk and which provide details of prescriber, drug, dosage and the duration of treatment.

Anti-inflammatory/Immunosuppressive effects and Infection

Suppression of the inflammatory response and immune function increases the susceptibility to infections and their severity. The clinical presentation may often be atypical, and serious infections such as septicaemia and tuberculosis may be masked and may reach an advanced stage before being recognised.

Appropriate antimicrobial therapy should accompany glucocorticoid therapy when necessary e.g. in tuberculosis and viral and fungal infections of the eye.

Chickenpox is of particular concern since this normally minor illness may be fatal in immunosuppressed patients.

Patients (or parents of children) without a definite history of chickenpox should be advised to avoid close personal contact with chickenpox or herpes zoster and if exposed they should seek urgent medical attention. Passive immunisation with varicella zoster immunoglobulin (VZIG) is needed by exposed non-immune patients who are receiving systemic corticosteroids or who have used them within the previous 3 months; this should be given within 10 days of exposure to chickenpox. If a diagnosis of chickenpox is confirmed, the illness warrants specialist care and urgent treatment. Corticosteroids should not be stopped and the dose may need to be increased.

Measles

Patients should be advised to take particular care to avoid exposure to measles and to seek immediate medical advice if exposure occurs; prophylaxis with intramuscular normal immunoglobulin may be needed.

Live vaccines should not be given to individuals with impaired immune responsiveness. The antibody response to other vaccines may be diminished.

Special precautions

Particular care is required when considering the use of systemic corticosteroids in patients with the following conditions and frequent patient monitoring is necessary:

- a. Osteoporosis (post-menopausal females are particularly at risk)
- b. Hypertension or congestive heart failure
- c. Existing or previous history of severe affective disorders (especially previous steroid psychosis)
- d. Diabetes mellitus (or a family history of diabetes)
- e. History of tuberculosis, since glucocorticoids may induce reactivation
- f. Glaucoma (or a family history of glaucoma)
- g. Previous corticosteroid-induced myopathy
- h. Liver failure
- i. Renal insufficiency
- j. Epilepsy
- k. Gastro-intestinal ulceration
- l. Migraine
- m. Certain parasitic infestations in particular amoebiasis
- n. Incomplete statural growth since glucocorticoids on prolonged administration may accelerate epiphyseal closure
- o. Patients with Cushing's syndrome

In the treatment of conditions such as tendinitis or tenosynovitis care should be taken to inject into the space between the tendon sheath and the tendon as cases of ruptured tendon have been reported.

Use in children

Corticosteroids cause dose-related growth retardation in infancy, childhood and adolescence, which may be irreversible.

Dexamethasone has been used 'off label' to treat and prevent chronic lung disease in preterm infants. An association between the use of dexamethasone in preterm infants and the

development of cerebral palsy has been suggested. In view of this possible safety concern, an assessment of the risk:benefit should be made on an individual patient basis.

Use in the Elderly

The common adverse effects of systemic corticosteroids may be associated with more serious consequences in old age. Close clinical supervision is required to avoid life-threatening reactions.

Please see SmPC section 4.5 for interaction with other medicinal products and other forms of interaction.

OVERDOSE

It is difficult to define an excessive dose of a corticosteroid as the therapeutic dose will vary according to the indication and patient requirements. Massive IV corticosteroid doses given as a pulse in emergencies are relatively free from hazardous effects.

Exaggeration of corticosteroid related adverse effects may occur. Treatment should be asymptomatic and supportive as necessary.

STORAGE

As packaged for sale

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

Following dilution with infusion fluids (see 'PREPARATION AND OTHER HANDLING INSTRUCTIONS'):

Chemical and physical in-use stability of dilutions has been demonstrated for at least 24 hours, at 25°C (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 dilution has taken place in controlled and validated aseptic conditions.

MARKETING AUTHORISATION HOLDER

Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24, Ireland
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