B. PACKAGE LEAFLET

Package leaflet: Information for the patient

Dexamethasone 3.8 mg/ml solution for injection
Dexamethasone

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 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.

What is in this leaflet

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. Dexamethasone is a synthetic glucocorticoid (adrenocortical hormone).

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).

Dexamethasone is used as a treatment of coronavirus disease 2019 (COVID-19) in adult and adolescent patients (aged 12 years and older with body weight at least 40 kg) with difficulty breathing and need of oxygen therapy.

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

If dexamethasone is given to a prematurely born baby, monitoring of heart function and structure is needed.

Treatment with this medicine may cause pheochromocytoma crisis, which can be fatal. Pheochromocytoma is a rare tumor of the adrenal glands Crisis can occur with the following symptoms: headaches, sweating, palpitations, and hypertension. Contact your doctor immediately if you experience any of these signs.

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 you have or are suspected of having pheochromocytoma (a tumor of the adrenal glands).

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

You should not stop taking any other steroid medications unless your doctor has instructed you to do.

Talk to your doctor, pharmacist or nurse before you take Dexamethasone.

General precautions regarding steroid use in specific diseases, masking infection, concomitant medicines etc. in line with current recommendations.

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.

New born babies of mothers who received Dexamethasone near the end of pregnancy may have low blood sugar levels after birth.

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.

Take Dexamethasone as only as prescribed by your doctor. Your doctor will decide how long you should take dexamethasone for. Check with your doctor or pharmacist if you are not sure.

<u>For the treatment of Covid-19</u>

Adult patients are recommended to be given [IV] 6 mg once a day for up to 10 days.

Use in adolescents

Paediatric patients (adolescents of 12 years of age or older) are recommended to be given [IV] 6 mg once a day for up to 10 days.

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, thickening of the heart muscle (hypertrophic cardiomyopathy) in prematurely born babies, that generally returns to normal after stopping treatment (frequency not known).
- **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. You can also report side effects directly via the national reporting system Yellow Card Scheme. Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

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.

The Marketing Authorisation Holder and Manufacturer
Aspen Pharma Trading Limited, 3016 Lake Drive, Citywest Business Campus, Dublin 24, Ireland

The Manufacturers:
Delpharm Saint Remy, Rue de l'Isle, Saint Remy Sur Avre, 28380, France.

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:
United Kingdom
24 Hour Helpline +441748 823 391 (free phone UK only 0800 0087 392)

This leaflet was last revised in August 2022

The following information is intended for healthcare professionals 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

Posology

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): initially 8.3 mg (2.2 mL) dexamethasone

solution for injection intravenously followed by 3.3 mg (0.9 mL) intramuscularly every 6 hours until symptoms of cerebral oedema subside. Response is usually noted within 12 to 24 hours: dosage may be reduced after 2 to 4 days and gradually discontinued over a period of 5 to 7 days.

For local treatment, see section 4.2 of the SmPC.

Paediatric population

Dosage requirements are variable and may have to be changed according to individual needs.

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), intramuscularly (IM) or by local injection (intra-articular or soft tissue).

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

Serious neurologic events, some resulting in death, have been reported with epidural injection of corticosteroids. Specific events reported include, but are not limited to, spinal cord infarction, paraplegia, quadriplegia, cortical blindness, and stroke. These serious neurologic events have been reported with and without use of fluoroscopy. The safety and effectiveness of epidural administration of corticosteroids have not been established, and corticosteroids are not approved for this use.
Severe allergic reactions. Rare instances of anaphylactoid/anaphylactic reactions with a possibility of shock have occurred in patients receiving parenteral corticosteroid therapy. Appropriate precautionary measures should be taken with patients who have a history of allergic reactions to corticosteroids.

Tumor lysis syndrome. In post-marketing experience tumour lysis syndrome (TLS) has been reported in patients with haematological malignancies following the use of dexamethasone alone or in combination with other chemotherapeutic agents. Patients at high risk of TLS such as patients with high proliferative rate, high tumour burden, and high sensitivity to cytotoxic agents, should be monitored closely and appropriate precaution 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, treat the patient with adrenaline and positive pressure ventilation.

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 immunoglobin may be needed.

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

Visual disturbance
Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

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.

<u>Paediatric population</u>
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.

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

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

This leaflet was last revised in February 2024