1.3.1.1.1 PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS

S4

1. NAME OF THE MEDICINE

ASPELONE 15 mg per 5 ml liquid

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml liquid of ASPELONE contains prednisolone sodium phosphate equivalent to 15 mg prednisolone base.

Preservatives:

Sodium methyl parahydroxybenzoate 0,21 % *m/v*

Sodium propyl parahydroxybenzoate 0,022 % *m/v*

Contains sugar: Sorbitol liquid (70 %) 2,5 g/5 ml, glycerol 0,5 g/5ml

Contains sweetener: Saccharin sodium 7,5 mg/5 ml

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Liquid

ASPELONE is a clear, pinkish-red liquid, free from foreign particles with a sweet raspberry odour.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

ASPELONE is indicated for the relief of symptoms associated with inflammatory conditions, where a steroid is indicated.

4.2. Posology and method of administration

Posology

Adults

DOSING REQUIREMENT MAY VARY DEPENDING ON THE SPECIFIC DISEASE, ITS SEVERITY AND THE RESPONSE OF THE PATIENT. DOSAGES SHOULD THEREFORE BE MODIFIED TO SUIT EACH PATIENT.

The usual dose of ASPELONE is about 3 mg to 60 mg daily in divided doses and it varies according to the disease being treated.

ASPELONE may be given daily as a single dose after breakfast or as a double dose on alternate days.

Some patients may require higher initial doses, where low doses should be sufficient in less severe situations.

Careful adjustment of the initial dose may be required to obtain a satisfactory response and this dose should be maintained thereafter.

Gradually discontinue the treatment if spontaneous remission occurs in a chronic condition.

Paediatric population

When prescribing doses for infants and children, one should not only adhere to ratios indicated by age or body weight but should also consider the guidelines followed when prescribing doses in adults.

The usual paediatric daily dose of ASPELONE is 0,5 mg to 2 mg per kg of body weight or 15 to 60 mg per square metre of body surface area in three divided doses.

Method of administration

For oral administration.

4.3. Contraindications

ASPELONE is contraindicated in:

- Patients with hypersensitivity to prednisolone, other corticosteroids or to any excipients in ASPELONE (see section 6.1).
- Patients with osteoporosis, oesophagitis, gastritis, peptic ulcer, acute psychosis or severe psychoneuroses.
- Patients with systemic fungal infections, or in patients with uncontrolled, systemic or local bacterial or viral infections.
- Patients with active or doubtfully quiescent tuberculosis, except, very rarely, as adjuncts to anti-tubercular treatment.
- Patients with acute viral infections such as herpes zoster or ocular herpes simplex.
- Patients receiving high-dose ASPELONE should not be immunised with live vaccines for up to 3 months after steroid therapy.
- Pregnant or breastfeeding women (see section 4.6).

4.4. Special warnings and precautions for use

Withdrawal

Patients who have received more than physiological doses of systemic corticosteroids, such as prednisolone, as in ASPELONE, (approximately 7,5 mg prednisolone or equivalent), for greater than three 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, such as prednisolone, as in ASPELONE is reduced. Clinical assessment of disease activity may be needed during withdrawal. If the disease is unlikely to relapse on withdrawal of systemic corticosteroids, such as prednisolone, as in ASPELONE, but there is uncertainty about HPA suppression, the dose of systemic corticosteroid, such as prednisolone, as in ASPELONE, may be reduced rapidly to physiological doses. Once a daily dose equivalent to 7,5 mg (2,5 ml) prednisolone, as in ASPELONE, is reached, dose reduction should be slower to allow the HPA axis to recover.

Abrupt withdrawal of systemic corticosteroid treatment, such as prednisolone, as in ASPELONE, which has continued up to three weeks is appropriate if it is considered that the disease is unlikely to relapse.

Abrupt withdrawal of doses of up to 40 mg daily of prednisolone, as in ASPELONE, or equivalent for three 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, such as ASPELONE should be considered even after courses lasting three weeks or less:

- Patients who have had repeated courses of systemic corticosteroids, such as prednisolone, as in ASPELONE, particularly if taken for greater than three 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 or have been stopped following prolonged therapy, may need to be temporarily reintroduced.
- Patients receiving doses of systemic corticosteroids, greater than 40 mg daily of prednisolone, as in ASPELONE (or equivalent).
- Patients repeatedly taking doses in the evening.

Adrenal cortical atrophy develops during prolonged therapy and may persist for years after stopping treatment. Withdrawal of corticosteroids, such as ASPELONE, 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. During prolonged therapy any intercurrent illness, trauma or surgical procedure will require a temporary increase in dosage; if corticosteroids, such as ASPELONE have been stopped following prolonged therapy they may need to be temporarily re-introduced (see section 4.8).

Risk of bradycardia

Bradycardia is a rare but serious adverse effect of corticosteroids, such as prednisolone, as in ASPELONE, that may be both symptomatic and asymptomatic. It is most likely to occur with high doses of corticosteroids, such as prednisolone, as in ASPELONE, however, bradycardia can occur even with standard doses of oral corticosteroids, such as prednisolone, as in ASPELONE, and is reversible with dose reduction or discontinuation. Furthermore, patients with pre-existing cardiac or renal problems or electrolyte imbalance are at high risk of experiencing bradycardia (see section 4.8).

The degree of risk may be increased by the concomitant use of other medicines that causes bradycardia as an adverse event.

Pheochromocytoma Crisis

Pheochromocytoma crisis, which can be fatal, has been reported after administration of systemic corticosteroids. Corticosteroids, as in ASPELONE should only be administered to patients with suspected or identified pheochromocytoma after an appropriate risk/benefit evaluation.

Suppression of the HPA axis

Suppression of the HPA axis and other 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 alternate days. Frequent patient review is required to appropriately titrate the dose against disease activity (see section 4.2).

Infections

Suppression of the inflammatory response and immune function increases the susceptibility to infections and their severity. The resultant opportunistic infections may be fatal. 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.

Chickenpox

Chickenpox is of particular concern since this normally minor illness may be fatal in immunosuppressed patients. Patients 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. If the patient is a child, parents must be given the above advice. Passive immunisation with varicella zoster immunoglobulin (VZIG) is

needed by exposed non-immune patients who are receiving systemic corticosteroids such as prednisolone, as in ASPELONE, or who have used them within the previous three 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, such as prednisolone, as in ASPELONE, should not be stopped and the dose may need to be increased.

Measles exposure

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

Live vaccines

Live vaccines should not be given to individuals with impaired immune responsiveness caused by high doses of corticosteroids, such as prednisolone, as in ASPELONE. The antibody response to other vaccines may be diminished (see section 4.3).

Kaposi's sarcoma

Kaposi's sarcoma has been reported to occur in patients receiving corticosteroid, such as prednisolone, as in ASPELONE, therapy. Discontinuation of corticosteroids, such as prednisolone, as in ASPELONE, may result in clinical remission.

Chronic immunosuppression

Chronic immunosuppression (e.g. in the setting of organ transplantation), has been associated with an increased risk of malignancy.

Other conditions

Due to the possibility of fluid retention, care must be taken when corticosteroids, such as prednisolone, as in ASPELONE are administered to patients with renal insufficiency or hypertension or congestive heart failure.

Corticosteroids, such as prednisolone, as in ASPELONE may worsen diabetes mellitus, hypertension, glaucoma and epilepsy and therefore patients with these conditions or a family history of them should be monitored frequently.

Care is required and frequent patient monitoring necessary where there is a previous steroid myopathy, hypothyroidism or recent myocardial infarction.

Liver failure

In patients with liver failure, blood levels of corticosteroid, such as prednisolone, as in ASPELONE may be increased, as with other medicines which are metabolised in the liver. Frequent patient monitoring is therefore necessary.

Use in the elderly

Systemic ASPELONE should be used with caution in the elderly and in patients with heart failure, a recent myocardial infarction, hypertension, diabetes mellitus, epilepsy, glaucoma, hypothyroidism, heart failure, osteoporosis, peptic ulceration, psychoses or severe affective disorders and renal impairment, susceptibility to infection and thinning of the skin (see section 4.3).

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

Long term treatment

Patients on long-term corticosteroid treatment, such as prednisolone, as in ASPELONE, should be assessed on a regular basis for hypertension, hypokalaemia, glycosuria, gastric discomfort and mental disturbances. They may require potassium supplementation and their dietary intake of sodium may need to be reduced.

Psychiatric adverse reactions

Patients and/or carers should be warned that potentially severe psychiatric adverse reactions may occur with systemic steroids, such as prednisolone, as in ASPELONE (see section 4.8). Symptoms typically emerge within a few days or weeks of starting the treatment. Risks may be higher with high doses/systemic exposure (see section 4.2), although dose levels do not allow prediction of the onset, type, severity or duration of reactions. Most adverse reactions resolve after either dose reduction or withdrawal of the medicine, although specific treatment may be necessary. Patients/carers should be encouraged to seek medical advice if worrying psychological symptoms develop, especially if depressed mood or suicidal ideation is suspected. Patients/carers should also be alert to possible psychiatric disturbances that may occur either during or immediately after dose tapering/withdrawal of systemic steroids, such as prednisolone, as in ASPELONE, although such reactions have been reported infrequently.

Particular care is required when considering the use of systemic corticosteroids, such as prednisolone, as in ASPELONE in patients with existing or a previous history of severe affective disorders in themselves or in their first-degree relatives. These would include depressive or manic-depressive illness and previous steroid psychosis (see section 4.3).

Visual disturbance

Visual disturbance may be reported with systemic corticosteroids, such as prednisolone, as in ASPELONE, 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 corticosteroids, such as prednisolone, as in ASPELONE.

Scleroderma renal crisis

Caution is required in patients with systemic sclerosis because of an increased incidence of (possibly fatal) scleroderma renal crisis with hypertension and decreased urinary output observed with a daily dose of 15 mg or more prednisolone, such as prednisolone, as in ASPELONE. Blood pressure and renal function (s-creatinine) should therefore be routinely checked. When renal crisis is suspected, blood pressure should be carefully controlled.

Anticoagulants

ASPELONE alters the response to anti-coagulants and increases the requirements for anti-diabetic or anti-hypertensive medicines (see section 4.5).

Myasthenia gravis

ASPELONE may lead to a reduced effect of antimuscarinics in the treatment of myasthenia gravis (see section 4.5).

Tumour lysis syndrome

In post marketing experience tumour lysis syndrome (TLS) has been reported in patients with malignancies, including haematological malignancies and solid tumours, following the use of systemic corticosteroids alone, including ASPELONE, or in

combination with other chemotherapeutic medicines. Patients at high risk of TLS, such as patients with tumours that have a high proliferative rate, high tumour burden and high sensitivity to cytotoxic medicines, should be monitored closely and appropriate precautions should be taken.

Paediatric population

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

Excipients

Sorbitol

ASPELONE contains sorbitol and glycerol and may have a laxative effect.
The additive effect of concomitantly administered medicines containing sorbitol (or fructose) and dietary intake of sorbitol (or fructose) should be taken into account. The content of sorbitol in medicines for oral use may affect the bioavailability of other medicines for oral use administered concomitantly.

Patients with hereditary fructose (sorbitol) intolerance (HFI) must not be given ASPELONE unless strictly necessary.

Propylene glycol

Co-administration with any substrate for alcohol dehydrogenase such as ethanol may induce serious adverse effects in neonates and in children less than 5 years old.

Medical monitoring is required in patients with impaired renal or hepatic functions because various adverse events attributed to propylene glycol have been reported such as renal dysfunction (acute tubular necrosis), acute renal failure and liver dysfunction.

Preservatives:

ASPELONE contains sodium methyl parahydroxybenzoate and sodium propyl parahydroxybenzoate and may cause allergic reactions (possibly delayed).

4.5. Interaction with other medicines and other forms of interaction

Co-treatment with CYP3A inhibitors, including cobicistat-containing medicines, is expected to increase the risk of systemic side effects. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid, such as prednisolone, as in ASPELONE, side effects, in which case patients should be monitored for systemic corticosteroid, such as prednisolone, as in ASPELONE, side effects.

Rifampicin, rifabutin, carbamazepine, barbiturates, phenobarbitone, immunosuppressants, phenytoin, primidone, ephedrine and aminoglutethimide enhance the metabolism of corticosteroids, such as prednisolone, as in ASPELONE and its therapeutic effects may be reduced.

Mifepristone may reduce the effect of corticosteroids, such as prednisolone, as in ASPELONE for 3 to 4 days.

Erythromycin and ketoconazole may inhibit the metabolism of some corticosteroids, such as prednisolone, as in ASPELONE.

Ciclosporin increases plasma concentration of prednisolone, as in ASPELONE. The same effect is possible with ritonavir.

Estrogens and other oral contraceptives may potentiate the effects of glucocorticoids, such as prednisolone, as in ASPELONE and dosage adjustments may be required if oral contraceptives are added to or withdrawn from a stable dosage regimen.
Plasma levels of corticosteroids, such as prednisolone, as in ASPELONE, may be elevated by oral contraceptives.
ASPELONE increases the requirements for anti-diabetic or anti-hypertensive medicines (see section 4.4).
The desired effects of hypoglycaemic medicines (including insulin), anti-hypertensives and diuretics are antagonised by corticosteroids, such as prednisolone, as in ASPELONE.
The growth promoting effect of somatotropin may be inhibited by the concomitant use of corticosteroids, such as prednisolone, as in ASPELONE.
Steroids, such as prednisolone, as in ASPELONE may reduce the effects of anticholinesterases/antimuscarinics in the treatment of myasthenia gravis and cholecystographic x-ray media.
The efficacy of coumarin anticoagulants and warfarin may be enhanced by concurrent corticosteroid, such as prednisolone, as in ASPELONE, therapy and close monitoring of the INR or prothrombin time is required to avoid spontaneous bleeding.

Concomitant use of aspirin and Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) with corticosteroids, such as prednisolone, as in ASPELONE, increases the risk of gastrointestinal bleeding and ulceration.
The renal clearance of salicylates is increased by corticosteroids, such as prednisolone, as in ASPELONE withdrawal may result in salicylate intoxication.

Serum concentrations of salicylates may be reduced.

Hypokalaemia may result from concurrent administration with potassium-depleting diuretics such as the thiazides, furosemide, or bronchodilator therapy with xanthines or beta$_2$-receptor agonists.

The hypokalaemic effects of acetazolamide, loop diuretics, and carbenoxolone, are enhanced by corticosteroids, such as prednisolone, as in ASPELONE. The risk of hypokalaemia is increased with theophylline and amphotericin. Corticosteroids, such as prednisolone, as in ASPELONE should not be given concomitantly with amphotericin, unless required to control reactions.

The risk of hypokalaemia also increases if high doses of corticosteroids, such as prednisolone, as in ASPELONE are given with high doses of bambuterol, fenoterol, formoterol, ritodrine, salbutamol, salmeterol and terbutaline.

The toxicity of cardiac glycosides is increased if hypokalaemia occurs with corticosteroids, such as prednisolone, as in ASPELONE.

Concomitant use with methotrexate may increase the risk of haematological toxicity. High doses of corticosteroids, such as prednisolone, as in ASPELONE, impairs the immune response therefore live vaccines should be avoided (see also section 4.3 and 4.4).

4.6. Fertility, pregnancy and lactation

The use of ASPELONE is contraindicated in pregnancy and lactation (see section 4.3).

Pregnancy

The ability of corticosteroids such as prednisolone, as in ASPELONE, to cross placenta varies between individual medicines, however, 88 % of prednisolone, as in ASPELONE, is inactivated as it crosses the placenta.

Administration of corticosteroids, such as prednisolone, as in ASPELONE to pregnant animals can cause abnormalities of foetal development including cleft palate, intra-uterine growth retardation and effects on brain growth and development. There is no evidence that corticosteroids, such as prednisolone, as in ASPELONE, result in an increased incidence of congenital abnormalities, such as cleft palate / lip. However, when administered for prolonged periods or repeatedly during pregnancy, corticosteroids, such as prednisolone, as in ASPELONE, may increase the risk of intrauterine growth retardation.

Hypoadrenalism may, in theory, occur in the neonate following prenatal exposure to corticosteroids, such as prednisolone, as in ASPELONE but usually resolves spontaneously following birth and is rarely clinically important. Depression of hormone levels has been described in pregnancy but the significance of this finding is not clear.

Breastfeeding

Corticosteroids, such as prednisolone, as in ASPELONE are excreted in small amounts in breast milk.

Fertility

Corticosteroids, such as prednisolone, as in ASPELONE may cause irregular menstruation or amenorrhoea.

4.7. Effects on ability to drive and use machines

ASPELONE has no or negligible influence on the ability to drive or operate machinery.

Since adverse reactions such as dizziness, headache and blurred vision have been reported in patients receiving ASPELONE, patients should not drive, use machinery or perform any tasks that require concentration, until they are certain that ASPELONE does not adversely affect their ability to do so (see section 4.4 and 4.8).

4.8. Undesirable effects

a) Summary of the safety profile

The incidence of predictable undesirable effects, including hypothalamo-pituitary-adrenal (HPA) suppression, correlates with the relative potency of the medicine, dosage, timing of administration and the duration of treatment (see section 4.4).

The following side effects may be associated with the long-term systemic use of corticosteroids, such as prednisolone, as in ASPELONE.

b) Tabulated list of adverse reactions

System organ class	**Frequent**	**Less frequent**	**Frequency unknown** (cannot be estimated from the available data)
Infections and infestations			Septicaemia, tuberculosis, fungal infections, viral infections, increased susceptibility and severity of infections with suppression of clinical symptoms and signs, opportunistic infections, recurrence of dormant tuberculosis, may mask the signs and symptoms of infection

Neoplasms benign, malignant and unspecified (including cysts and polyps)			Kaposi's sarcoma
Blood and the lymphatic system disorders			Leucocytosis
Immune system disorders			Hypersensitivity including anaphylaxis
Endocrine disorders			Cushingoid manifestations, suppression of the HPA axis, impaired carbohydrate intolerance with increased requirement for anti-diabetic therapy, manifestation of latent diabetes mellitus, , acute adrenal insufficiency may result from rapid withdrawal after prolonged therapy
Metabolism and nutrition disorders	Increased appetite	Hyperglycaemia	Sodium and water retention, with oedema, disturbances in electrolyte balance and hypokalaemic alkalosis resulting from increased excretion of potassium, negative protein and calcium balance
Psychiatric disorders		Mental disturbances	Euphoric mood, psychological dependence, depressed mood, insomnia, aggravation of schizophrenia
Nervous system disorders			Dizziness, headache, aggravation of epilepsy, neurological disturbances
Eye disorders			Ocular changes involving glaucoma and cataracts, papilloedema, posterior subcapsular cataracts, central serous chorioretinopathy, exophthalmos, corneal or scleral thinning, exacerbation of ophthalmic viral or fungal diseases, blurred vision

Ear and labyrinth disorders			Vertigo
Cardiac disorders			Myocardial rupture following recent myocardial infarction, congestive cardiac failure (in susceptible patients), bradycardia (following high doses)
Vascular disorders			Benign intra-cranial hypertension, thromboembolic complications, hypertension, embolism
Respiratory, thoracic and mediastinal disorders			Hiccups
Gastrointestinal disorders			Acute pancreatitis, dyspepsia, nausea, vomiting, abdominal distension, abdominal pain, diarrhoea, oesophageal ulceration, candidiasis, peptic ulceration with perforation and haemorrhage
Skin and subcutaneous tissue disorders		Hyperhidrosis	Skin thinning, skin atrophy, skin striae, acne, telangiectasia, , rash, pruritus, urticaria, hirsutism
Musculoskeletal and connective tissue disorders	Spontaneous fractures, osteoporosis	Aseptic necrosis of the bone.	Muscular weakness, vertebral and long bone fractures, myopathy, myalgia, tendon rupture, contusion (bruising)
Renal and urinary disorders			Scleroderma renal crisis
Reproductive system and breast disorders			Menstrual irregularities, amenorrhoea
General disorders and administrative site conditions			Growth retardation in children, impaired healing, malaise, delayed wound healing
Investigations			Weight increased, nitrogen depletion

c) *Description of selected adverse reactions*

Neoplasms benign, malignant and unspecified (including cysts and polyps): Kaposi's sarcoma has been reported to occur in patients receiving corticosteroids, such as prednisolone, as in ASPELONE therapy. Discontinuation of ASPELONE may result in clinical remission.

Endocrine disorders: Large doses of ASPELONE may cause Cushingoid manifestations. These manifestations include moon-face, buffalo hump, flushing, ecchymosis, increased bruising, striae and acne, hypertension, hypokalaemia, glycosuria, gastric discomfort and mental disturbances.

Metabolism and nutrition disorders: Hyperglycaemia may occur with accentuation or precipitation of the diabetic state. Diabetic patients may also require more insulin.

Psychiatric disorders: A wide range of psychiatric reactions including affective disorders (such as irritable, euphoric, depressed and labile mood and suicidal thoughts), psychotic reactions (including mania, delusions, hallucinations and aggravation of schizophrenia), behavioural disturbances, irritability, anxiety, sleep disturbances, and cognitive dysfunction including confusion and amnesia have been reported. Reactions are common and may occur in both adults and children. In adults, the frequency of severe reactions has been estimated to be 5 to 6 %. Psychological effects have been reported on withdrawal of corticosteroids, such as prednisolone, as in ASPELONE; the frequency is unknown.

Scleroderma renal crisis: Amongst the different subpopulations the occurrence of scleroderma renal crisis varies. The highest risk has been reported in patients with diffuse systemic sclerosis. The lowest risk has been reported in patients with limited systemic sclerosis (2 %) and juvenile onset systemic sclerosis (1 %) (see section 4.4).

Withdrawal Symptoms

ASPELONE should be gradually discontinued after prolonged therapy as rapid withdrawal may cause acute adrenal insufficiency.

Too rapid a reduction of corticosteroid, such as prednisolone, as in ASPELONE, dosage following prolonged treatment can lead to acute adrenal insufficiency, hypotension and death (see section 4.4). A 'withdrawal syndrome' may also occur including fever, myalgia, arthralgia, rhinitis, conjunctivitis, painful itchy skin nodules and loss of weight. In some instances, withdrawal symptoms may involve or resemble a clinical relapse of the disease for which the patient has been undergoing treatment. Other effects that may occur during withdrawal or change of corticosteroid, such as prednisolone, as in ASPELONE therapy include benign intracranial hypertension with headache and vomiting and papilloedema caused by cerebral oedema. Latent rhinitis or eczema may be unmasked.

Paediatric population:

Increased intracranial pressure with papilloedema in children (pseudotumour cerebri) usually after treatment withdrawal.

Growth retardation in infancy, childhood and adolescence (see section 4.4).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine.

Healthcare providers are asked to report any suspected adverse reactions to

SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/ +27 (0)11 239-6200

4.9. Overdose

Symptoms

For symptoms of overdosage please see section 4.8.

Treatment

Treatment is symptomatic and supportive. Treatment is unlikely to be needed in cases of acute overdosage. Serum electrolytes should be monitored.

High systemic doses of corticosteroids, such as prednisolone, as in ASPELONE, caused by chronic use have been associated with adverse events such as neuropsychiatric disorders (psychosis, depression, hallucinations), cardiac dysrhythmias and Cushing's syndrome.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Category and Class: A 21.5.1 Corticosteroids and analogues

Pharmacotherapeutic group: Glucocorticoids

ATC code: H02AB06

Mechanism of action

Prednisolone is a synthetically derived glucocorticoid analogue used mainly for its anti-inflammatory effects.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Colour raspberry red (C.I.14720), dipotassium hydrogen phosphate (for pH adjustment), disodium edetate, flavour raspberry, glycerol, potassium dihydrogen phosphate (for pH adjustment), propylene glycol, purified water, saccharin sodium, sodium chloride, sodium methyl parahydroxybenzoate, sodium propyl parahydroxybenzoate, sorbitol liquid.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

24 months

6.4. Special precautions for storage

Store at or below 25 °C.

Protect from light.

Shake the bottle before use and keep well closed.

6.5. Nature and contents of container

100 ml is packed in a round amber glass bottle sealed with a white, tamper evident, expanded polyethylene lined polypropylene screw cap. The bottle is placed in a cardboard unit carton with a leaflet.

50 ml is packed in a round amber glass bottle sealed with a white, tamper evident, expanded polyethylene lined polypropylene screw cap. The bottle is placed in a cardboard unit carton with a leaflet.

Not all pack sizes may be marketed.

6.6. Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Tel: 0800 122 912

8. REGISTRATION NUMBER

41/21.5.1/0189

9. DATE OF FIRST AUTHORISATION

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