Synchrony Pharma Ltd launches Dexamethasone oral solution range

Dexamethasone 10mg/5ml and 20mg/5ml **NOW available**[1,2]

Provides flexibility in dosing whilst minimising the administrative burden of tablet formulations for patients receiving high daily doses[1,2]

- **10mg/day:**
  1 X 5 ml Dexamethasone 2mg/ml
  vs 5 X 2mg oral tablets
- **20mg/day:**
  1 X 5ml Dexamethasone 4mg/ml
  vs 10 X 2mg oral tablets
- **40mg/day:**
  2 X 5ml Dexamethasone 4mg/ml
  vs 20 X 2mg oral tablets

- Dexamethasone 10mg/5ml oral solution 50ml
- Dexamethasone 20mg/5ml oral solution 50ml

Available through Phoenix and Alloga

10mg/5ml	EAN code: 5060231320266	PIP code: 1242767
20mg/5ml	EAN code: 5060231320273	PIP code: 1242775

Synchrony Pharma contact details
Phone: +44(0) 1438791091
Email: information@synchronypharma.com

Synchrony Pharma

Prescribing Information

PRESCRIBING INFORMATION FOR DEXAMETHASONE 10 mg/ 5ml and 20mg/5ml Oral Solution
ACTIVE INGREDIENT(S): Dexamethasone sodium phosphate
Please refer to the Summary of Product Characteristics (SmPC) before prescribing. **INDICATIONS:** Dexamethasone is a corticosteroid. It is designed for use in certain endocrine and non-endocrine disorders, in certain cases of cerebral oedema and for diagnostic testing of adrenocortical hyperfunction. **Please refer to SmPC for a full list of indications. DOSAGE & ADMINISTRATION: Adults:** The dosage should be titrated to the individual response and the nature of the disease. In order to minimise side effects, the lowest effective possible dosage should be used. The initial dosage varies from 0.5 – 9mg (0.125ml to 2.25ml) a day depending on the disease being treated. In more severe diseases, doses higher than 9mg may be required. The initial dosage should be maintained or adjusted until the patient's response is satisfactory. **Elderly:** Treatment of elderly patients, particularly if long term, should be planned bearing in mind the more serious consequences of the common side effects of corticosteroids in old age. **Please refer to SmPC for full details CONTRAINDICATIONS:** Hypersensitivity to the active substance or to any of the excipients. Systemic infection unless specific anti-infective therapy is employed. Systemic fungal infections. Stomach ulcer or duodenal ulcer. Infection with tropical worms. **SPECIAL WARNINGS & PRECAUTIONS:** Patients should carry "steroid treatment" cards. Treatment with Dexamethasone Oral Solution should only be implemented in the event of the strongest indications and if necessary, additional targeted antiinfective treatment administered. In addition, treatment with Dexamethasone Oral Solution should only be implemented under strong indications and if necessary, additional specific treatment must be implemented. **Please refer to SmPC for full details.** Dexamethasone Oral Solution must only be used under urgent indication and under appropriate monitoring. Upon interruption or discontinuation of long-term glucocorticoid administration, consideration should be given to the exacerbation or recurrence of the underlying disease, acute adrenal insufficiency and corticosteroid withdrawal syndrome. Consideration should also be given to certain viral diseases (chickenpox, measles), Tumour Lysis syndrome, Visual disturbances. Preterm neonates: available evidence suggests long-term neurodevelopmental adverse events after early treatment (<96 hours) of premature infants with chronic lung disease at starting doses of 0.25 mg/kg twice daily. Paediatric population: corticosteroids cause a dose-dependent inhibition of growth in infancy, childhood, and adolescence, which may be irreversible. Therefore, during long-term treatment with Dexamethasone Oral Solution, the indication should be very strongly presented in children and their growth rate should be checked regularly. Use in the elderly: The adverse effects of systemic corticosteroids can have serious consequences especially in old age, mainly osteoporosis, hypertension, hypokalaemia, diabetes, susceptibility to infection and skin atrophy. Close clinical monitoring is required to prevent life-threatening reactions. Influence of diagnostic tests: Glucocorticoids can suppress skin reaction to allergy testing. They can also affect the nitroblue tetrazolium test for bacterial infections and cause false-negative results. Note on doping: the use of doping tests when taking Dexamethasone Oral Solution can lead to positive results. Excipient Warnings**:** This medicinal product contains Liquid Maltitol and Sorbitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine. **SIDE EFFECTS: Serious side-effects**: The incidence of anticipated adverse effects, such as the suppression of the hypothalamic-pituitary-adrenal axis correlates with the relative potency of the substance, dose, time of day of administration and duration of treatment. During a short-term therapy, in compliance with the dosage recommendations and close monitoring of patients, the risk of side effects is low. The undesirable effects can include, infections and infestations, Blood and lymphatic system disorders, immune system disorders, endocrine disorders, metabolism and nutrition disorders, psychiatric disorders, nervous system disorders, eye disorders, cardiac disorders, respiratory, thoracic and mediastinal disorders, gastrointestinal disorders, skin and subcutaneous disorders, musculoskeletal and connective tissue disorders, reproductive and breast disorders, general disorders and administration site conditions, injury and poisoning and procedural complications **Refer to SmPC for full details of side effects. PREGNANCY:** Dexamethasone crosses the placenta. There is no evidence that corticosteroids result in an increased incidence of congenital abnormalities, such as cleft palate/ lip in man. Long-term or repeated corticosteroid therapy in pregnancy increases the risk of intrauterine growth retardation. Dexamethasone should be prescribed during pregnancy and particularly in the first trimester only if the benefit outweighs the risks for the mother and child. **LACTATION:** Glucocorticoids are excreted in breast milk. There are no known risks to infants. Nevertheless, extra caution should be exercised regarding its indication during pregnancy. Should the relevant condition require higher doses, treatment should be discontinued. **INTERACTIONS:** Concomitant administration of dexamethasone with inducers of CYP3A4, such as phenytoin, barbiturates, ephedrine, rifabutin, carbamazepine and rifampicin may lead to decreased plasma concentrations of dexamethasone and the dose may need to be increased. Concomitant administration of inhibitors of CYP3A4 such as ketoconazole, ritonavir and erythromycin may lead to increased plasma concentrations of dexamethasone. Co-treatment with CYP3A inhibitors, including cobicistat-containing products, 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 side-effects, in which case patients should be monitored for systemic corticosteroid side-effects. These interactions may also interfere with dexamethasone suppression tests, which therefore should be interpreted with caution during administration of substances that affect the metabolism of dexamethasone. Antibiotics: Macrolide antibiotics have been reported to cause a significant decrease in corticosteroid clearance. Anticholinesterases: Concomitant use of anticholinesterase agents and corticosteroids may produce severe weakness in patients with myasthenia gravis. If possible, anticholinesterase agents should be withdrawn at least 24 hours before initiating corticosteroid therapy. Colestyramine: Colestyramine may decrease the absorption of dexamethasone. Estrogens, including oral contraceptives: Estrogens may decrease the hepatic metabolism of certain corticosteroids, thereby increasing their effect. Aminoglutethimide: Decrease of dexamethasone efficacy, due to its metabolism increase. An adjustment of dexamethasone dosage may be required. Gastrointestinal topicals, antacids, charcoal: A decrease in digestive absorption of glucocorticoids have been reported with prednisolone and dexamethasone. Therefore, glucocorticoids should be taken separately from gastrointestinal topicals, antacids or charcoal, with an interval between treatment of at least two hours. **Refer to SmPC for full details of the Effects of dexamethasone on other medicinal products,** to include**;** Salicylates, NSAIDs, Hypoglycaemic agents (e.g. insulin), Anti-hypertensives, Diuretics, Amphotericin B injection, Potassium depleting agents, Corticosteroids, Teracosactide, Carbenoxolone, Cardiac glycosides, Sultopride, Antitubercular drugs, Ciclosporin, Thalidomide, Praziquantel, Oral anticoagulants, Sulfonylureas, Metformin, Isoniazid **LEGAL CATEGORY:** POM.
PRESENTATIONS, PACK SIZES, PRODUCT LICENCE NUMBERS & BASIC NHS COSTS: Amber (Type III) glass bottle, with child-resistant, tamper-evident screw cap with an LDPE liner, a 3ml graduated oral dosing syringe and a "press-in" syringe/bottle adaptor. Pack size: 30ml or 50ml. Not all pack sizes may be marketed. **PL 39280/0019 and PL39280/0020**

FURTHER INFORMATION AVAILABLE FROM THE MARKETING AUTHORISATION HOLDER: Synchrony Pharma Ltd., Business & Technology Centre, Bessener Drive, Stevenage, SG1 2DX, UK.

Prescribing information last revised: February 2020
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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/ yellowcard. Adverse events should also be reported to Synchony Pharma Ltd on 01438 791091 or at pv@synchronypharma.com.

References

1. Dexamethasone 10mg/5ml Oral Solution SmPC, February 2020
2. Dexamethasone 20mg/5ml Oral Solution SmPC, February 2020

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Date of preparation: October 2020

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