Itzenal (alimemazine tartrate) 7.5mg/5ml, 30mg/5ml Oral Solution, Sugar-Free, Prescribing Information.
Prescribers should consult the SmPC before prescribing.

Presentation: Each 5ml of oral solution contains 7.5mg or 30mg alimemazine tartrate.
Excipients with known effect: sodium methyl parahydroxybenzoate: 1.35 mg per 1 ml dose.

Indication: Itzenal has a central sedative effect comparable to that of chlorpromazine but largely devoid of the latter's anti adrenaline action. It has powerful antihistamine and anti-emetic actions. In the management of urticaria and pruritus.
In pre-medication as a sedative before anaesthesia in children aged between 2 to 7 years.

Dosage and administration: Not recommeneded for infants less than 2 years old. DO NOT exceed the recommended dose. Urticaria and pruritus*: Adults*: 10 mg two or three times daily; up to 100 mg per day. *Elderly:* 10 mg once or twice daily. *Children over 2 years of age*: 2.5 - 5mg three or four times daily. 7.5mg/5ml oral solution is recommended. As a sedative before anaesthesia: *Children aged 2 – 7 years*: Maximum recommended dosage is 2 mg per kg bodyweight 1 – 2 hours before the operation.

Method of administartion: Oral use. Oral syringe and a 'press-in' syringe/bottle adaptor are provided.

Fertility, pregnancy and lactation: Pregnancy: Should be avoided in pregnancy unless the physician considers it essential. Breast-feeding: Phenothiazines may be excreted in human milk; breast-feeding should be discontinued during treatment. Fertility: No data available.

Contraindications: Hypersensitivity to phenothiazines or to any of the excipients, hepatic or renal disfunction, epilepsy, Parkinson's disease, hypothyroidism, phaeochromocytoma, myasthenia gravis, history of narrow angle glaucoma, history of agranulocytosis, prostatic hypertophy. Children < 2 years of age.

Special warnings and precautions: Strongly advise patients not to consume alcoholic beverages or medicines containing alcohol. Avoid exposure to sunlight. *Use with caution in:* Elderly or volume depleted patients who are more susceptible to orthostatic hypotension, elderly patients presenting chronic constipation (risk of paralytic ileus), elderly patients with possible prostatic hypertrophy, elderly patients in hot and cold weather (risk of hyper/hypothermia), patients with certain cardiovascular diseases, patients with seizures. *Paediatric population*: Contraindicated in children/infants less than 2 years of age due to the risk of marked sedation and respiratory depression. There is a risk of post-operative restlessness, especially if the child is in pain. This medicine contains sodium methyl parahydroxybenzoate and may cause allergic reactions (possibly delayed). Alimemazine 7.5mg/5ml Oral Solution contains less than 23 mg sodium per 10 ml dose, Alimemazine 30mg/5ml Oral Solution contains less than 23mg sodium per 8.5ml dose, essentially both presentations are 'sodium-free'.

Drug interactions: Alcohol, anxiolytics, hypnotics, opiates, barbiturates, and other sedatives, tricyclic antidepressants, MAOIs, antihypertensive drugs, antimuscarinics, amphetamine, levodopa, clonidine, guanethidine, adrenaline, anticholinergic drugs, antacids, anti-Parkinson, lithium, high doses of phenothiazines reduce the response to hypoglycaemic agents, the dosage of which may have to be raised. Adrenaline must not be used in patients overdosed with phenothiazines.

Effects on ability to drive/use machines: Patients should be warned about drowsiness during the early days of treatment and advised not to drive or operate machinery.

Undesirable effects: Mild leukopenia, agranulocytosis, hyperprolactinaemia, neuroleptic malignant syndrome, insomnia, agitation, extrapyramidal effects (acute dystonias or dyskinesias, akathisia, Parkinsonism, tardive dyskinesia), convulsions, dizziness, headache, drowsiness, accommodation disorders, cardiac arrhythmias (including atrial arrhythmia, atrio-ventricular block, ventricular tachycardia and ventricular fibrillation), hypotension or pallor, postural hypotension, nasal congestion, respiratory depression, constipation, dry mouth, jaundice, contact skin sensitisation, skin rashes, photosensitivity in patients on high doses, urine retention, paradoxical excitement, electrocardiogram changes. Prescribers should consult the SmPC in relation to other adverse reactions.

Pack size and UK list price:
Itzenal 7.5 mg/ 5ml Oral Solution (PL 17780/0889), pack size: 100ml, £89.00
Itzenal 30 mg/ 5ml oral solution (PL 17780/0890), pack size: 100ml, £99.00

Legal Category: POM

Marketing Authorisation Holder: Zentiva Pharma UK Limited, 12 New Fetter Lane, London EC4A 1JP, United Kingdom

Date of preparation: 13 May 2022 **Ref:** 19793

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 Zentiva via email to PV-United-Kingdom@zentiva.com or via phone on 0800 090 2408.