Chiesi
People and ideas for innovation in healthcare

1 August 2020

Dear Doctor

Diacomit® (stiripentol) 250 mg and 500 mg capsules and powder for oral suspension: PBS listing 1 August 2020[1]

Chiesi Australia is pleased to inform you that as of 1 August 2020, Diacomit® will be listed on the Pharmaceutical Benefits Scheme (PBS) under the following restriction:[1]

Authority Required - Streamlined*

Indication:

- Severe myoclonic epilepsy of infancy (Dravet syndrome)

Clinical criteria:

- Patient must have, or have had, generalised tonic-clonic or generalised clonic seizures that are not adequately controlled with a benzodiazepine and valproate, AND
- The treatment must be as adjunctive therapy to a benzodiazepine and valproate

Treatment criteria:

- Must be treated by a neurologist if treatment is being initiated; or
- Must be treated by a neurologist if treatment is being continued/re-initiated; or
- Must be treated by a paediatrician in consultation with a neurologist if treatment is being continued; or
- Must be treated by a general practitioner in consultation with a neurologist if treatment is being continued.

STIRIPENTOL (strength, form, pack size)	PBS item code	Max. Qty (Packs)	Max. Qty (Units)	No. of Repeats
250 mg capsule, 60	12103B	2	120	3
500 mg capsule, 60	12107F	2	120	3
250 mg powder for oral liquid, 60 sachets	12106E	2	120	3
500 mg powder for oral liquid, 60 sachets	12088F	2	120	3

The availability of Diacomit® in Australia is an important step forward in the management of childhood-onset epilepsy, and will lead to improved access for patients and their families living with Dravet syndrome.

To find out more about Diacomit®, please contact Medical Information on (03) 9077 4486 or email: medicalaffairs.au@chiesi.com

Kind regards,

Vivian Nguyen BPharm
Brand Manager – Neurology
M: +61 423 244 643
E: v.nguyen@chiesi.com

Dr James Micevski, BSc(Hons) PhD
Head of Medical Affairs
M: +61 433 771 183
E: j.micevski@chiesi.com

*Please refer to PBS schedule for full authority information.

DIACOMIT® (stiripentol)

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PBS Information: capsules and powder for oral suspension: Authority Required (Streamlined). Refer to PBS schedule for full authority information.

Please review the Product Information before prescribing, available at: www.emergehealth.com.au/PI/Diacomit

DIACOMIT Minimum Product Information. Indication: adjunctive treatment of generalised tonic clonic and clonic seizures associated with severe myoclonic epilepsy in infancy (SMEI, also known as Dravet syndrome) in patients whose seizures are not adequately controlled with a benzodiazepine (usually clobazam) and valproate. **Dosage and administration:** treatment should be initiated by a neurologist experienced in the diagnosis and management of epilepsy. **Recommended dosage:** 50 mg/kg/day, in two to three divided doses. **Dose escalation:** gradual, starting with 20 mg/kg/day for 1 week, then 30 mg/kg/day for 1 week. Further dosage escalation is age dependent: children < 6 years should receive an additional 20 mg/kg/day in the third week, thus achieving the recommended dose of 50 mg/kg/day in three weeks; children 6 - 12 years should receive an additional 10 mg/kg/day each week, thus achieving the recommended dose of 50 mg/kg/day in four weeks; children and adolescents ≥12 years should receive an additional 5 mg/kg/day each week until the optimum dose is reached based on clinical judgment. **Method of administration:** capsules should be swallowed whole and powder mixed in a glass of water and taken immediately; always take with food, avoid milk/dairy products, carbonated drinks, fruit juice, food and drinks containing caffeine or theophylline. **Contraindications:** Hypersensitivity to active ingredient or to any of the excipients; history of psychoses in the form of episodes of delirium. **Precautions:** children <3 years, adults, and elderly; pregnancy category B3; hepatic and renal impairment; driving or operating machinery; monitor liver function and blood count prior to starting treatment and every 6 months; suicidal ideation and behaviour; somnolence and drowsiness, when combined with other central nervous depressants. Dosage adjustment of concomitant clobazam or other anti-epileptic drugs could be considered. All patients treated with antiepileptic drugs, irrespective of indication, should be monitored for signs of suicidal ideation and behaviour, appropriate treatment should be considered at the onset of side effects. **Interactions:** benzodiazepines, non-benzodiazepines, barbiturates, bromides, neuroactive steroids; statins; immunosuppressants; substances metabolised by CYP2C19 and CYP3A4 e.g. citalopram, omeprazole, HIV drugs, antihistamines, calcium channel blockers, statins, oral contraceptives, codeine; carbamazepine, phenytoin, and phenobarbital have the potential to worsen seizure activity and should not be used with stiripentol in the management of Dravet syndrome; daily dosage of clobazam and/or valproate should be reduced according to the onset of side effects whilst on stiripentol therapy. **Adverse events:** *Very common:* Anorexia, loss of appetite, weight loss, insomnia, drowsiness, ataxia, hypotonia, dystonia. *Common:* neutropenia, persistent severe neutropenia, aggressiveness, irritability, behaviour disorders, opposing behaviour, hyperexcitability, sleep disorders, hyperkinesias, nausea, vomiting, raised γGT. Date of first approval: 13 September 2019. Date of most recent amendment: 28 February 2020.

Reference: 1. Stiripentol Public Summary Document, March 2020 PBAC Meeting, available at: https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/psd/2020-03/files/stiripentol-psd-march-2020.pdf

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Tel: +61 3 9077 4486 | Fax: +61 3 8672 0792 | Email: customerservice.au@chiesi.com | Website: www.chiesi.com.au

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DIACOMIT® (stiripentol)