Tapclob® (clobazam) 5mg/5ml and 10mg/5ml Oral Suspension Prescribing Information
See Summary of Product Characteristics (SPC) before prescribing.

Presentation: Oral suspension with raspberry odour, containing 5 mg or 10 mg of clobazam per 5 ml of suspension. **Indications:** Clobazam is a 1,5-benzodiazepine indicated as adjunctive therapy in epilepsy in adults or children over 2 years of age, if standard treatment with one or more anticonvulsants has failed. Clobazam oral suspension should only be used in children from 6 month to 2 years old, under exceptional situations, where there is a clear epilepsy indication. See SPC for details relating to short-term relief of severe anxiety and adjunctive use in schizophrenic or other psychotic illness (including dosing guidance). **Dosage and administration*:*** *For oral use only. Shake the bottle thoroughly before use. Once titrated to an effective dose of clobazam, patients should remain on their treatment and care should be exercised when changing between different formulations.* If low doses are required, the 5mg/5ml strength product is the most suitable presentation. If high doses are required, the 10mg/5ml strength product is the most suitable presentation. ***Treatment of epilepsy in association with one or more other anticonvulsants:*** The oral suspension is suitable for any epilepsy patient in whom the clinician feels an oral suspension is preferable to clobazam tablets. In all cases, treatment should be initiated at the lowest effective dose with gradual dose increments under careful observation. *Adults*: Start with 20-30 mg/day, increasing as necessary up to a maximum of 60 mg daily. *Elderly:* Treatment requires low initial doses and gradual dose increments under careful observation. Paediatric population aged 6 years and above: Treatment requires low initial doses and gradual dose increments under careful observation. Start at 5mg daily with a maintenance dose of 0.3 to 1mg/kg body weight daily. *Paediatric population aged 2 and above*: Initial: 5 mg/day (aged 6 years and above) or 0.1 mg/kg/day for younger patients. The dose may be increased slowly by steps of 0.1 to 0.2 mg/kg/day at 7 days intervals, until the required clinical effect is achieved or side effects occur. Maintenance dose: usually 0.3 to 1 mg/kg/day. The daily dose can be taken in divided doses or as single dose at night. *Paediatric population aged 6 month-2 years*: Clobazam oral suspension should only be used in children from 6 months to 2 years old, under exceptional situations, when there is a clear epilepsy indication. Use 0.1mg/kg/day and titrate upwards very slowly (increasing not more often than every 5 days) to achieve required clinical effect, in divided doses twice daily. Re-assess within 4 weeks and regularly thereafter to evaluate the need for continued treatment. A break in therapy may be beneficial if drug exhaustion develops, recommencing therapy at a low dose. At the end of treatment (including in poor-responding patients), since the risk of withdrawal phenomena/rebound phenomena is greater after abrupt discontinuation of treatment, it is recommended to gradually decrease the dosage. **Contra-Indications:** Hypersensitivity to the active substance, benzodiazepines or to any of the excipients; history of drug or alcohol dependence; myasthenia gravis; severe respiratory insufficiency; sleep apnoea syndrome; severe hepatic insufficiencies; during the first trimester of pregnancy and in breast-feeding women. Benzodiazepines must not be given to children without careful assessment of the need for their use. Clobazam must not be used in children between the ages of 6 months and 2 years, other than in exceptional cases for anticonvulsant treatment where there is a compelling indication. **Warnings and precautions:** Amnesia may occur with benzodiazepines. In case of loss or bereavement psychological adjustment may be inhibited by benzodiazepines. Special caution is necessary if clobazam is used in patients with myasthenia gravis, spinal or cerebellar ataxia or sleep apnoea. A dose reduction may be necessary. Use with extreme caution in patients with personality disorders. Use of benzodiazepines may lead to the development of physical and psychological dependence therefore the duration of treatment should be as short as possible. Once physical dependence has developed, abruptly stopping treatment will lead to withdrawal symptoms (or rebound phenomena). A withdrawal syndrome may also occur when abruptly changing over from a benzodiazepine with a long duration of action (eg. clobazam) to one with a short duration of action. Monitor respiratory function in patients with chronic or acute severe respiratory insufficiency and consider a dose reduction. In patients with impairment of renal or hepatic function, responsiveness to clobazam and susceptibility to adverse effects are increased, and a dose reduction may be necessary. In long-term treatment renal and hepatic function must be checked regularly. In the treatment of epilepsy, consider that tolerance (decrease in efficacy) may occur. Due to the sorbitol content, do not give to patients with rare hereditary problems of fructose intolerance. The medicine also contains sodium methyl and propyl hydroxybenzoates which may cause allergic reactions (signs include rash, swallowing or breathing problems and swelling of the lips, face, throat or tongue). **Interactions:** At high doses, an enhancement of central depressive effect may occur when used with antipsychotics (neuroleptics), hypnotics, anxiolytics/sedatives, antidepressant agents, narcotic analgesics, anticonvulsant drugs,

anaesthetics and sedative antihistamines. Caution if used in patients with lithium intoxication. Alcohol can increase the bioavailability of clobazam by 50%. When adding clobazam to established anticonvulsants, determine the dosage of clobazam by monitoring the EEG and check the plasma levels of the other drugs (e.g. phenytoin, valproic acid, carbamazepine). The effects of muscle relaxants, analgesics and nitrous oxide may be enhanced. If clobazam is used concomitantly with narcotic analgesics, possible euphoria may be enhanced; this may lead to increased psychological dependence. Concurrent treatment with drugs that inhibit the CYP P450 system (e.g. cimetidine) may enhance and prolong the effect of clobazam. **Fertility, Pregnancy and Lactation:** Do not use in the first trimester of pregnancy (stop treatment if a woman intends to become pregnant or suspects that she is pregnant). See SPC for risks to the newborn (e.g. 'floppy infant syndrome' and withdrawal symptoms) if administered to the mother during the late phase of pregnancy or during labour. Avoid in breast feeding mothers as clobazam passes into breastmilk. **Effects on ability to drive and use machines:** This medicine can adversely affect the ability to drive and operate machinery. See SPC. **Undesirable effects:** Sedation, leading to fatigue and sleepiness, especially at the beginning of treatment and when higher doses are used. Drowsiness, dizziness or dryness of the mouth, constipation, loss of appetite, nausea, or a fine tremor of the fingers have been reported. These are more likely at the beginning of treatment and often disappear with continued treatment or a reduction in dose. *Paradoxical reactions especially in elderly and in children (discontinue if affected):* restlessness, irritability, difficulty in sleeping, anxiety, delusion, nightmare, hallucinations, suicidal tendencies. In this event, treatment with clobazam must be discontinued. Anterograde amnesia (especially at high doses). Amnesia may be associated with inappropriate behaviour. Respiratory depression (especially at high doses) may occur and is risky for patients with pre-existing compromised respiratory function (i.e., in patients with bronchial asthma) or brain damage. Isolated cases of skin reactions, such as rashes or urticaria, have been observed. Slowing of reaction time, ataxia, confusion and headaches may occasionally occur. Disorders of articulation, unsteadiness of gait and other motor functions, visual disorders (e.g, double vision), weight gain, or loss of libido may occur, particularly with high doses or in long-term treatment, however these reactions are reversible. Unmasking of pre-existing depression. Tolerance and physical and/or psychic dependence may develop, especially during prolonged use. Discontinuation of the therapy may result in withdrawal or rebound phenomena. Abuse of benzodiazepines. When used as an adjuvant in the treatment of epilepsy, restlessness and muscle weakness may occur rarely. As with other benzodiazepines, the therapeutic benefit must be balanced against the risk of habituation and dependence during prolonged use. Consult SPC for further information. **Overdose:** Induce vomiting (within 1 hour) if the patient is conscious or gastric lavage with airway protection if the patient is unconscious. If this is not beneficial, reduce absorption using activated charcoal. Consider flumazenil as a benzodiazepine antagonist. **Marketing authorisation number and Basic NHS Price:** Tapclob 5mg/5ml PL 00156/0322 (150ml bottle £90.00 and 250ml bottle £150.00); Tapclob 10mg/5ml PL 00156/0323 (150ml bottle £95.00 and 250ml bottle £158.34). **Marketing Authorisation Holder:** Martindale Pharmaceuticals Ltd T/A Martindale Pharma, Bampton Road, Harold Hill, Essex RM3 8UG. **Legal Category:** POM. **Further information:** Martindale Pharma, Bampton Road, Romford, RM3 8UG. Tel: 01277 266 600. **Date of Preparation:** June 2019.

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 Martindale Pharma, an Ethypharm Group Company. Tel: 01277 266 600. e-mail: drugsafety.uk@ethypharm.com