Suboxone® Sublingual Film
buprenorphine/naloxone

INDIVIOR sponsored training session for healthcare professionals

PHARMACY TRAINING:

Practical applications in the use of Suboxone® FILM in community pharmacy

Wednesday 14th September 2022 | 18:30-19:15 BST
Join us Online

Dear colleague,

We are pleased to invite you to an educational training session where Duncan Hill (Specialist pharmacist in substance misuse) will be sharing his real-world insights of prescribing and dispensing Suboxone® FILM focusing on the patient experience.

During the training, Duncan will discuss practical elements of dispensing Suboxone® FILM as well as patient feedback

At the end of the training, there will be a live Q&A session during which you will have the opportunity to submit questions to Duncan.

We are looking forward to your active participation in what promises to be an informative and engaging training session.

CLICK HERE TO SEND AN EMAIL AND REGISTER YOUR INTEREST

FACULTY

Mr. Duncan Hill
Qualified Pharmacist Independent Prescriber
Member of the Scottish Specialist Pharmacists in Substance Misuse group

Timing	Session
10 min	Welcome and introductions
20 min	Training in depth
10 min	Q&A and closing

Adverse events should be reported. Reporting forms and information can be found at **www.mhra.gov.uk/yellowcard.** Adverse events with this product can also be reported to PatientSafetyRoW@indivior.com and **0808 234 9243.**

This symposium is for healthcare professionals only. Indivior products will be discussed; Prescribing Information and adverse event reporting information can be found below.

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INDIVIOR Focus on you.

SUBOXONE SUBLINGUAL FILM 2 MG/0.5 MG and 8 MG/2 MG

ABBREVIATED PRESCRIBING INFORMATION

Please refer to the Summary of Product Characteristics before prescribing.
Indication: Substitution treatment for opioid drug dependence, within a framework of medical, social and psychological treatment. Naloxone is intended to deter intravenous abuse. For adults and adolescents aged over 15 years who have agreed to be treated for addiction.
Presentation: Sublingual film containing buprenorphine hydrochloride, equivalent to 2 mg or 8 mg buprenorphine base, and naloxone hydrochloride dihydrate equivalent to 0.5 mg or 2 mg, respectively of naloxone.
Dosage and administration: Treatment must be under the supervision of a physician experienced in the management of opioid dependence/addiction. A clinical strategy for reviewing and ending treatment should be agreed in advance with the patient. Induction must only commence when there are clear objective signs of mild-to-moderate withdrawal (e.g. on the Clinical Opiate Withdrawal Scale [COWS] scale).
Precautions before induction: Baseline liver function tests and documentation of viral hepatitis status are recommended prior to commencing therapy. Thereafter, monitor liver function regularly.
Patients dependent on heroin or short-acting opioids: Give the first dose of Suboxone not less than 6 hours after opioids were last used. Patients receiving methadone: before beginning therapy, reduce methadone to a maximum of 30 mg/day. Give the first dose of Suboxone not less than 24 hours after methadone was last used. Buprenorphine may precipitate withdrawal in patients dependent on methadone.
Induction: Two Suboxone 2 mg/0.5 mg sublingual films, which can be repeated up to twice on day 1, depending on the patient's requirement. Sublingual administration is recommended for induction. Daily supervision is recommended during the induction phase.
Dosage adjustment and maintenance: Following induction on day 1, titrate the dose according to the clinical and psychological status of the patient, up to a maximum single, daily dose of 24 mg buprenorphine. Once induction is complete, patients can switch between sublingual and buccal administration.
Less than daily dosing: After stabilisation, the frequency of dosing may be decreased to every other day or 3 times per week. Dose adjustment will be required. The dose given on any one day should not exceed 24 mg.
Medical withdrawal: After stabilisation, the dosage may be reduced gradually to a lower maintenance dose; in some cases, treatment may be discontinued.
Switching between sublingual tablet and film: When switching between Suboxone film and Suboxone sublingual tablets (or *vice versa*), careful monitoring is required as dose adjustment may be necessary. Combining or alternating different formulations is not advised.
Elderly: Safety and efficacy has not been established in patients >65 years of age.
Hepatic impairment: Use lower initial doses and careful dose titration in patients with mild-to-moderate impairment. Do not use in severe impairment.
Renal impairment: Caution is required in patients with severe renal impairment (creatinine clearance <30 ml/min).
Paediatrics: The safety and efficacy of buprenorphine/naloxone in children below the age of 15 years have not been established. No data are available.
Method of administration: Suboxone film is only for sublingual and/or buccal administration and must be placed under the tongue or inside the cheek until completely dissolved. The film is not to be swallowed.
Contraindications: Hypersensitivity to buprenorphine, naloxone or any other component of the film; severe respiratory or hepatic insufficiency; acute alcoholism or delirium tremens; concomitant administration of opioid antagonists (naltrexone, nalmefene).
Warnings and precautions:
Drug dependence, tolerance, potential for abuse and diversion: Can occur similar to other opioids. Closely monitor patients to minimise the risk. Suboptimal treatment may prompt medication misuse, which can lead to overdose or treatment dropout. Naloxone is included to deter misuse and abuse.
Seizures: May lower seizure threshold in patients with a history of seizure disorder.
Respiratory depression: Reports of death, particularly in combination with benzodiazepines or when not used according to prescribing information. Deaths have also been reported through concomitant ingestion with other depressants such as alcohol or other opioids. Use with care in asthma or respiratory insufficiency. Potentially fatal respiratory depression can occur in children and people not tolerant to opioids. Warn patients to store medication out of reach and never take in front of children. Contact emergency unit in case of accidental ingestion or suspicion of ingestion.
Central nervous system (CNS) depression: Drowsiness, particularly with alcohol or concomitant CNS depressants may occur. Benzodiazepines or other sedative medications should be used at the lowest effective dose and for the shortest duration required.
Serotonin syndrome: Concomitant administration with other serotonergic agents may result in serotonin syndrome, a potentially life-threatening condition. Careful clinical observation is advised during treatment initiation or escalation. Consider dose reduction or discontinuation of therapy depending on symptom severity.
Dependence: Chronic administration produces opioid-type dependence. Do not stop abruptly because this may result in a delayed withdrawal syndrome.
Hepatitis and hepatic events: Cases of acute hepatic injury have been reported. In many cases, there was pre-existing mitochondrial impairment (genetic disease, liver enzyme abnormalities, infection with hepatitis B or C virus, alcohol abuse, anorexia, concomitant use of other potentially hepatotoxic medicines and ongoing injecting drug use. Consider these underlying factors before prescribing Suboxone and monitor during treatment.
Drug withdrawal syndrome: Avoid abrupt withdrawal. Taper the dose gradually to minimise withdrawal symptoms.
Precipitation of opioid withdrawal syndrome: Suboxone film can precipitate withdrawal in opioid-dependent patients, particularly if given less than 6 hours after the last use of heroin or other short-acting opioid, or less than 24 hours after the last dose of methadone. Monitor patients during the switch from buprenorphine or methadone, as withdrawal symptoms have been reported. Undertake induction when objective signs of withdrawal are evident. Withdrawal may also be associated with suboptimal dosing.
Hepatic impairment: Higher plasma levels of buprenorphine were found in patients with moderate and severe hepatic impairment. Patients should be monitored for signs and symptoms of opioid withdrawal, toxicity or overdose. Use with caution in moderate hepatic impairment.
Renal impairment: Renal elimination may be prolonged. Metabolites accumulate. Caution in creatinine clearance <30 ml/min.
General: May produce orthostatic hypotension. Caution in patients with head injury, intracranial lesions, conditions that raise cerebrospinal fluid pressure, history of seizures, hypotension, prostatic hypertrophy or urethral stenosis, myxoedema, hypothyroidism, adrenal cortical insufficiency, dysfunction of the biliary tract, or in elderly or debilitated patients. Miosis, changes in level of consciousness and attenuation of pain may make clinical assessment and management difficult.
Use in adolescents (15 to <18 years): Monitor patients more closely.
CYP3A4 inhibitors: May give rise to increased concentrations of buprenorphine, so a reduced dose may be needed.
Excipients: Do not give to patients with rare hereditary problems of fructose intolerance, due to the presence of maltitol liquid. Sunset yellow may cause allergic reactions.
Interactions: Should not be taken with alcohol or medications containing alcohol due to increase in sedative effect. Use cautiously with benzodiazepines, other CNS depressants, other opioid derivatives (e.g. methadone, analgesics, antitussives), certain antidepressants, sedative H_1-receptor antagonists, barbiturates, anxiolytics, neuroleptics, clonidine and related substances. Adequate analgesia may be difficult to achieve using a full opioid agonist and there is potential for overdose. Do not give naltrexone or nalmefene because this may precipitate sudden severe withdrawal. Use with CYP3A4 inhibitors (e.g. azole antifungals, protease inhibitors, macrolide antibiotics) or inducers (e.g. phenobarbital, carbamazepine, phenytoin, rifampicin) may require dose adjustment. Concomitant use of monoamine oxidase inhibitors may exaggerate the opioid effect. Use with caution with serotonergic medicinal products due to the risk of serotonin syndrome.
Pregnancy and breastfeeding: Use only if the benefit outweighs the risk. Administration of buprenorphine in the last 3 months of pregnancy may cause a delayed withdrawal syndrome in the neonate and use late in pregnancy may induce respiratory depression in the newborn. Monitor the neonate for several days. Discontinue breastfeeding during treatment.
Effects on ability to drive and use machines: May cause drowsiness, dizziness or impaired thinking. Caution patients about driving or operating hazardous machinery. Advise patients not to drive until they establish how they are affected.
Undesirable effects: The most commonly reported reactions in clinical trials were constipation and drug withdrawal symptoms. Some reports of seizure, vomiting, diarrhoea and elevated liver function tests were considered serious.
Very common (≥1/10): insomnia, headache, constipation, nausea, hyperhidrosis, drug withdrawal syndrome.
Common (≥1/100 to <1/10): influenza, infection, pharyngitis, rhinitis, anxiety, depression, decreased libido, nervousness, abnormal thinking, migraine, dizziness, hypertonia, paraesthesia, somnolence, amblyopia, lacrimal disorder, hypertension, vasodilatation, cough, abdominal pain, diarrhoea, dyspepsia, flatulence, oral mucosal erythema, vomiting, hepatic function abnormality, rash, pruritus, urticaria, back pain, arthralgia, muscle spasms, myalgia, urine abnormality, erectile dysfunction, asthenia, pain, chest pain, chills, pyrexia, malaise, pain, peripheral oedema, abnormal liver function test, decreased weight, and injury. Please refer to the Summary of Product Characteristics in relation to other undesirable effects.
Overdose: Ensure patients are aware of symptoms and requirement for immediate medical help. General supportive measures including close monitoring of respiratory and cardiac status. Institute symptomatic treatment of respiratory depression and transfer the patient to an environment with full resuscitation facilities. Use an opioid antagonist (i.e. naloxone).
Package quantities: 28 films in child-resistant individual sachets
NHS price: 2 mg/0.5 mg: £27.94; 8 mg/2 mg: £83.81
Legal category: CD (Sch 3), POM
Marketing authorisation numbers: PLGB 36699/0014/ and PLGB 36699/0016.
Further information is available on request from Indivior UK Limited, The Chapleo Building, Henry Boot Way, Priory Park, Hull, HU4 7DY, United Kingdom.
Job code: P-SBX-UK-00046 Date of preparation: May 2022

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