"Is There Pain?" Educational Program

PAIN MANAGEMENT IN AGED CARE FACILITIES

"Is There Pain?" Educational Program

Today's workshop
Presented by
Jolan Stokes

Pain and dementia

Workshop objectives

- To improve the ability to identify and assess pain in residents with dementia
- To understand the role of support staff and the family in pain management
- To recognise the value of an analgesic trial in non-verbal communicative residents suspected to be experiencing pain

Pain and dementia are both common in residents of aged care facilities

- Aged care residents are among the frailest and sickest people in the community[1,2]
- Prevalence of chronic conditions is common[1,3]

Medical condition	Prevalence amongst high care residents[3]
Dementia	60%
Chronic pain	40-80%
Sensory loss	80+%
Depression	30-40%

- Most (~95%) residents with dementia have moderate to severe dementia[2]

1. The Royal Australian College of General Practitioners. Medical care of older persons in residential aged care facilities. Edition 4. 2006.
2. Somers M *et al.* Aust Fam Physician 2010;39(6):413-416.
3. National Aged Care Alliance (NACA). NACA issues paper. The aged care – health care interface. 2003.

Chronic pain

- Common sources of chronic pain in the elderly:[1]
  - Musculoskeletal conditions (e.g. osteoarthritis, degenerative spine conditions)
  - Neuropathic pain secondary to diabetes or infection (shingles)
  - Cancer pain
- Many residents will have multiple sources of pain[1]
  - Painful procedures, wound care, rehabilitation[2]
- Chronic pain or its inadequate treatment is associated with:[1]
  - ↓ function
  - ↓ socialisation
  - ↑ falls
  - ↓ sleep
  - Mood changes
  - ↑ use of health resources

1. AGS Panel on the pharmacological management of persistent pain in older persons. JAGS. 2009;57(8):1331-1346.
2. . Herr K *et al.* Pain Manage Nurs 2011;12(4):230-250.

Pain is frequently underdiagnosed and undertreated[1-3]

- More pronounced amongst residents with impaired cognition and communication[1-3]
  - Identification of pain is lower in residents with cognitive impairment[3]
    - As the severity of impairment increases, the rate of pain identification decreases[3]
- Residents with cognitive impairment receive:[3]
  - Less prescribed analgesics from their doctor
  - Less nurse initiated analgesia
- Unrecognised or undertreated pain can lead to problematic behaviours and inappropriate use of psychotropics[4,5]

1. McClean WJ, Higginbotham NH. Med J Aust. 2002;177:17-20. 2. AGS Panel on the pharmacological management of persistent pain in older persons. JAGS. 2009;57(8):1331-1346. 3. The Australian Pain Society. Pain in residential aged care facilities. Management Strategies 2005.
4. Balfour JE, O'Rourke N. Pain Res Manag. 2003;8:198-204. 5. Haasum Y *et al.* Drugs Aging. 2011;28:283-293.

Psychotropics overprescribed in dementia

- Concern that antipsychotics are being overprescribed in dementia as a means of controlling behaviour[1,2]
- Identification of pain can be made more difficult due to the sedative properties of psychotropics[3]
- Pain as a potential source of behaviour change needs to be considered and ruled out before antipsychotics are used[1]

Sleep and sedation does not equate to no pain or pain relief[3]

1. National Prescribing Service. Health News and Evidence 2013.
2. Balfour JE, O'Rourke N. Pain Res Manag 2003;8(4):198-204.
3. Herr K *et al*. Pain Manage Nurs 2011;12(4):230-250.

Identifying and assessing pain

- Pain needs to be assessed regularly[1]
  - On admission
  - Significant changes in the resident's condition/behaviour
  - Routinely
- The best indicator of pain is the resident's own report[1-3]
- Residents able to report pain need to be asked regularly asked about pain[1]
- Pain needs to be elevated to the 5th vital sign[3]

1. The Australian Pain Society. Pain in residential aged care facilities. Management Strategies 2005.
2. AGS Panel on the pharmacological management of persistent pain in older persons. JAGS. 2009;57(8):1331-1346.
3. Australian and New Zealand Society for Geriatric Medicine. Pain in older people. 2012. Report No.: 21.

Pain identification – the verbal resident

- Residents with mild to moderate dementia and verbal communication skills can reliably report pain[1,2]

Use a quiet area with minimal distraction[3]	Make eye contact with the resident[4]	Ask about current pain[1]
Ask simple open-ended questions[4]	Allow the resident sufficient time to understand and answer[4]	Use at least two questions phrased differently[1,4]

Importantly, don't dismiss behaviours as 'just being part of dementia'. If you believe the resident has understood the question, accept their report as true.[4]

1. McClean WJ. Nursing & Residential Care 2003;5(10):481-483. 2. Monroe TB *et al*. Geriatr Gerontol Int 2013.
3. Smith SD. Nurs Times 2007, 103(30):26-27.
4. The Australian Pain Society. Pain in residential aged care facilities. Management Strategies. 2005.

Discussion point:

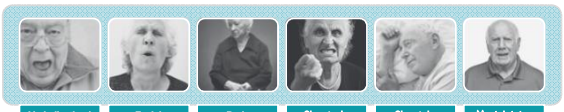
What questions do you use to assess pain in verbally communicative patients with mild to moderate dementia?

When assessing the severity of pain use verbal descriptors, e.g. mild, moderate, severe or small, medium, big[1,2]

1. McClean WJ. Nursing & Residential Care 2003;5(10):481-483.
2. The Australian Pain Society. Pain in residential aged care facilities. Management Strategies. 2005.

Pain identification – the non-verbal resident

- Increased need to rely upon non-verbal cues
- Staff observation and informant reporting of behaviours that may signal pain:[1]



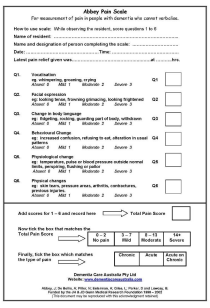
Verbalisation/ vocalisations	Facial expressions	Body movements	Changes in interpersonal interactions	Changes in activity patterns or routines	Mental status changes
e.g. whimpering, groaning, calling out	e.g. frowning, looking tense, grimacing	e.g. fidgeting, rocking, guarding of a body part	e.g. aggressive, combative, withdrawn, socially inappropriate	e.g. refusing food, appetite change, increased rest periods or wandering	e.g. crying, increased confusion, distress, irritability

1. The Australian Pain Society. Pain in residential aged care facilities. Management Strategies. 2005.

Use a validated tool to assess pain

THE ABBEY PAIN SCALE[1,2]

- Specifically designed to measure key behaviours which may signify pain in residents who can't verbally communicate[2]
- To be performed multiple times over a 24-hour period[2]
- Note: this tool cannot distinguish between pain and other forms of distress that may be the source of the observed behaviours[3]
- If analgesics are initiated based on the use of this tool, ongoing assessment using this scale is essential[3]



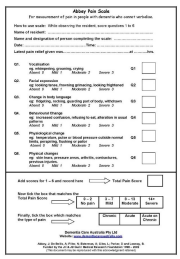
1. Abbey J *et al*. Int J Palliat Nurs. 2004;10:6-13.
2. Abbey J *et al*. The Abbey Pain Scale. For measurement of pain in patients who cannot verbalise. Imperial College Healthcare 2007.
3. The British Pain Society. National Guidelines No. 8 The assessment of pain in older people. 2007.

Tips on using the Abbey Pain Scale[1]

Observe and record while the resident is being moved e.g. during pressure area care, and at rest e.g. during sleep

Complete the scale immediately following the procedure and record the results (including time of assessment and actions taken) in the resident's notes

If you suspect pain, advocate for the resident to be assessed by their doctor



If an analgesic trial is commenced, assess the resident's response to the new therapy regularly e.g. hourly until the resident appears comfortable, then every 4 hours for 24 hours

If there is no improvement, notify the resident's doctor of the pain scores and actions taken. Advocate for a comprehensive re-assessment of all facets of the residents condition and care

1. Abbey J *et al.* The Abbey Pain Scale. For measurement of pain in patients who cannot verbalise. Imperial College Healthcare 2007.

Engage support staff assistance[1]

Registered nurses are primarily responsible for pain assessment, but support staff can help by:

- Familiarising themselves with common pain behaviours
- Ensuring the resident's basic needs are met e.g. are they hungry, thirsty, hot or cold, lonely, fearful or needing the toilet?
- Providing comfort measures e.g. massage or repositioning the resident
- Monitoring the resident's response to prescribed pain treatments for continued pain behaviours
- Notifying a nurse if basic needs and comfort measures have been tried and are ineffective.

1. Alliance of State Pain Initiatives. Detecting discomfort in dementia: focus on behaviours. 2006.

The importance of family as partners

- Family members can play a key role in the resident's care
  - However family dynamics can also make it difficult for nurses to provide optimal support[1]
- Holding family care meetings (starting from admission) can help decrease the resident's and family's concerns regarding illness and treatments[2]
- During meetings it is important to:
  - Promote a friendly and comfortable environment[2]
  - Make information clear and easy to understand[2]
  - Address any knowledge gaps[2]
  - Provide written information where needed[2]
  - Explain that if pain is suspected, your duty of care is to ensure all residents are as free as possible from pain[3]
  - Encourage family members to report any changes they may observe with the resident

1. Hudson PL *et al.* J Palliat Med 2004;7(1):19-25.2. Hudson P *et al.* BMC Palliat Care 2008;7:12.
3. Herr K *et al.* Pain Manage Nurs 2011;12(4):230-250.

When opioids are considered for the treatment of moderate to severe chronic pain, apply universal precautions[1,2]

1. Support the diagnosis with appropriate differential.
2. Support the psychological assessment and risk of addictive disorders.
3. Check informed consent has been obtained.
4. Agree on treatment with your resident / carer. Opioids form one component of a multimodal pain management plan.[3]
5. Pre- and post-intervention assessment of pain level and function.
6. Opioid therapy initiated on a trial basis (4-6 weeks) for first-time patients.[4-6]
7. Conduct regular reassessments of pain score and level of function.
8. Regularly assess the '6 As' of pain medicine.[1,2,6]
   - Analgesia
   - Activity
   - Affect
   - Adverse events
   - Aberrant behaviour
   - Accurate prescription records
9. Support periodic review of pain diagnosis and comorbid conditions.
10. Keep complete documentation.[7]

Adapted from Gourlay DL and Heit HA. Universal precautions revisited: managing the inherited pain patient. Pain Med 2009;10(S2):S115–S123. For more information please refer to full publication.

1. Gourlay DL, Heit HA. Pain Med 2009;10(S2):S115–S123. 2. Gourlay DL *et al.* Pain Med 2005;6(2):107-112
3. Analgesic Expert Group Therapeutic Guidelines Analgesic Version 6, 2012. 4. Grazzotti PJ, Goucke CR. Med J Aust 1997;167(1):30-34
5. Australian Medicines Handbook 2014. 6. Cohen ML, Wodak AD. Medicine Today 2010;11(2):10-18. 7. DeRemer CE *et al.* South Med J 2011;104(9):629-633

Multimodal pain management[1]

Non-pharmacotherapies (cognitively impaired & normal cognition)
- Heat/cold (mild)
- Vibration (mild)
- Massage
- Mobilising exercises
- Passive relaxation

Non-pharmacotherapies (normal cognition)
- Coping skills
- Problem solving
- Strengthening exercises
- TENS

Pharmacotherapies
- Paracetamol
- NSAIDs
- Adjuvants
- Opioids

1. The Australian Pain Society. Pain in residential aged care facilities. Management strategies. 2005.

Analgesic trial[1]

- If the resident with dementia has a condition known to be painful, e.g. osteoarthritis, or is undergoing a painful procedure, an analgesic trial may be appropriate[1]
  - Check basic needs and comfort measures have been addressed
- Analgesia is based on the suspected severity of pain considering the cause of the pain and analgesic history[1]
  - Mild to moderate pain, commence trial with paracetamol (up to 4000mg/day)
    - If behaviours improve continue paracetamol and continue with non-pharmacotherapies
  - If behaviours unchanged request a pain management review by the resident's doctor

1. Herr K *et al.* Pain Manage Nurs 2011;12(4):230-250.

S.B.A.R. - Situation

- 80-year-old resident
- Moderate dementia
- Transferred recently to this aged care facility
- During transfers, becomes combative
  - Especially when trying to mobilise
  - Unusually loud vocalisations
  - Shouting in her native language
- Sleep patterns appear to be interrupted, waking up hourly

S.B.A.R. - Background

- Italian lady, with very little English
- Moderate dementia
- Medical history
  - Osteoarthritis of the knees
  - Congestive heart failure
- Medications
  - CHF: beta-blocker, digoxin, thiazide diuretic
  - Pain: modified-release paracetamol (2 x 665mg TDS)

Discussion Point

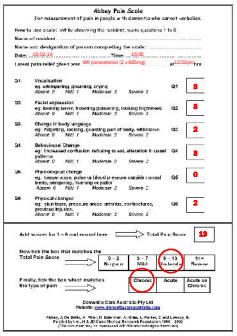
How would you assess pain in this resident?

S.B.A.R. – Assessment[1-3]

1. McClean W.J. Nursing & Residential Care 2003;5(10):481-483. 2. Monroe TB *et al.* Geriatr Gerontol Int 2013. 3. The Australian Pain Society. Pain in residential aged care facilities. Management Strategies. 2005.

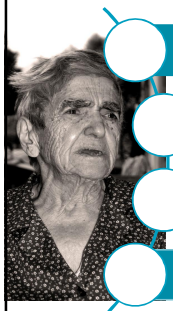
S.B.A.R. - Assessment

- The Abbey Pain Scale is used to assess the resident at rest and during transfers over a 24-hour period[1]
- During rest, her scores are between 6 and 8
- With movement, scores range between 12 and 14
- Suggests she may be experiencing moderate to severe pain
- Other potential causes are assessed – no signs of infection, constipation or dehydration



1. The Australian Pain Society. Pain in residential aged care facilities. Management Strategies. 2005.

S.B.A.R. - Recommendation



- Document assessments in the resident's notes
- Discuss the case with her GP
- Suggest a trial of additional analgesics with ongoing review
- Include the resident's family in the management plan (e.g. schedule a family meeting)

Outcome

- Resident's GP decision was to:
  - Initiate a trial of NORSPAN® 5µg/hr patches
  - Continue paracetamol use
- At the end of the second week of the trial:
  - Abbey Pain Scores have improved (rest 1-3, movement 3-5)
  - Resident is not combative during transfers
  - Therapy is well tolerated
- This represents a positive analgesic trial, confirming the clinical suspicion of inadequately controlled pain
  - Current analgesics are to be continued and physiotherapist to assess the resident for appropriate physical therapies

Final Thoughts

- Pain needs to be assessed regularly[1]
- Residents able to report pain need to be regularly asked about current pain[1,2]
- If verbally non-communicative, validated tools should be used to support observational assessments of pain[1]
- Importantly, don't dismiss behaviour changes as "just being part of dementia"[1]
- An analgesic trial should be considered if the resident with dementia has signs suggesting inadequately controlled pain, especially if:[3]
  - Have a condition known to be painful, e.g. osteoarthritis, or
  - Had a painful procedure

1. The Australian Pain Society. Pain in residential aged care facilities. Management Strategies. 2005.
2. McClean W.J. Nursing & Residential Care. 2003;5:428-430.
3. Herr K *et al*. Pain Manage Nurs 2011;12(4):230-250.

Questions

Mundipharma Pty Limited

ABN 87 081 322 509, 50 Bridge Street, Sydney NSW 2000

Before prescribing any product mentioned in this presentation, please refer to the relevant Product Information and to State and Federal regulations.
Product Information for NORSPAN® patch, TARGIN® tablets, ***OxyContin***® tablets, ***OxyNorm***® capsules and oral liquid are available at this workshop and from Mundipharma Pty Limited. http://www.mundipharma.com.au/Products.aspx

PBS Information: NORSPAN® patches, ***OxyContin***® tablets, TARGIN® tablets. Restricted Benefit. Chronic severe disabling pain not responding to non-narcotic analgesics. Authority required for increased maximum quantities and/or repeats. Refer to PBS schedule for full restricted benefit and authority information.

PBS Information: ***OxyNorm***® capsules, ***OxyNorm***® liquid. Restricted Benefit. Severe disabling pain not responding to non-narcotic analgesics. Authority Required (increased maximum quantities and/or repeats). Refer to PBS schedule for full restricted benefit and authority required information

®: NORSPAN, TARGIN, OXYCONTIN and OXYNORM are Registered Trademarks

TARGIN® tablets
Minimum Product Information

OPIOID THERAPY SHOULD ONLY BE PRESCRIBED AS PART OF A MULTIMODAL PAIN MANAGEMENT PLAN

INDICATIONS The management of moderate to severe chronic pain unresponsive to non-narcotic analgesia. The naloxone component in a fixed combination with oxycodone is indicated for the therapy and/or prophylaxis of opioid-induced constipation.

CONTRAINDICATIONS Hypersensitivity to opioids, naloxone and any of the excipients or any situation where opioids are contraindicated; moderate to severe hepatic impairment; severe respiratory depression with hypoxia; elevated carbon dioxide levels in the blood; *cor pulmonale*; cardiac arrhythmias; uncontrolled bronchial asthma; severe chronic obstructive pulmonary disease; non-opioid induced paralytic ileus; pregnancy; lactation; severe CNS depression; increased cerebrospinal or intracranial pressure; brain tumour or head injury (due to the risk of increased intracranial pressure); uncontrolled convulsive disorders; suspected surgical abdomen; delayed gastric emptying; alcoholism; *delirium tremens*; concurrent administration of MAO-inhibitors and for 2 weeks after their cessation.

PRECAUTIONS Most important hazard of opioid preparations is respiratory depression; occurs most frequently in overdose situations, the elderly, the debilitated and in those suffering from conditions accompanied by hypoxia when even moderate doses may be dangerous. Use with extreme caution in patients with substantially decreased respiratory reserve, pre-existing respiratory depression, chronic obstructive pulmonary disease. Use with caution in hypothyroidism (may need to reduce dose); elderly, infirm or debilitated patients; mild hepatic impairment; renal impairment; severely impaired pulmonary function; opioid dependence; hypotension; hypertension; hypovolaemia; biliary tract disease; pancreatitis; inflammatory bowel disorders; prostatic hypertrophy; adrenocortical insufficiency (Addison's disease); toxic psychosis; myxoedema; opioid-induced paralytic ileus; pre-existing cardiovascular disease; epileptic disorders or predisposition to convulsions; patients on long-term higher doses of opioids switching to TARGIN® tablets; chronic non-cancer pain; prior history of substance abuse. Not recommended in patients with galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption; for the treatment of withdrawal symptoms; patients with cancer associated with peritoneal carcinomatosis or sub-occlusive syndrome in advanced stages of digestive and pelvic cancers. Tolerance and physical dependence tend to develop upon repeated administration. Withdraw gradually. Parenteral or intranasal abuse in opioid-dependent individuals is expected to produce marked withdrawal symptoms. Parenteral venous injection may be fatal. Reduce dosage to ½ to ¼ of the usual dose in elderly patients who are infirm or debilitated and in patients with renal failure (CLcr<60mL/min) or mild hepatic impairment. May impair ability to drive and operate machinery. May produce positive results in sports agency drug testing procedures. Not recommended for immediate pre-operative use and post-operative for 24 hours after surgery. Do not use within 24 hours of cordotomy or other pain-relieving surgery

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TARGIN® tablets
Minimum Product Information

INTERACTIONS Anticholinergic agents, antihypertensives, CNS depressants (antidepressants, sedatives, hypnotics, general anaesthetics, phenothiazines or other tranquilizers, alcohol, other opioids, anti-histamines, anti-emetics, neuroleptics etc.), coumarin derivatives, metoclopramide, non-selective MAOIs or within 14 days of stopping treatment (caution is advised with selective MAOIs), neuromuscular blocking agents, opioid agonist analgesics and mixed agonist/antagonist analgesics, drugs that affect the P450 enzyme system (CYP3A4, CYP2D6).

ADVERSE EFFECTS Typical of full opioid agonists and tend to reduce with time. Common side effects (incidence ≥1%) include agitation, anorexia, asthenic conditions, abdominal pain, bronchospasm, chills, constipation, decrease in blood pressure, diarrhoea, dizziness, drug withdrawal syndrome, dry mouth, dyspepsia, faintness, fever, gastritis, headache, hepatic enzymes increased, hiccup, hot flush*, hyperhidrosis, insomnia*, mood changes, muscle spasms, muscle twitching, myalgia, nausea, orthostatic hypotension, pharyngitis, pruritus, rash, somnolence*, ureteric spasm, urinary abnormalities, urinary tract infection, vertigo, voice alteration, vomiting.

DOSAGE AND ADMINISTRATION Must be swallowed whole and not broken, chewed or crushed. Taking broken, chewed or crushed TARGIN® tablets could lead to the rapid release and absorption of a potentially toxic dose of oxycodone that could be fatal *Adults*: Usual starting dose (opioid-naïve patients, or patients with moderate to severe chronic pain uncontrolled by weaker opioids): one 10/5 mg TARGIN® tablet 12-hourly. Patients with renal or mild hepatic impairment: one 5/2.5 mg TARGIN® tablet 12-hourly. Titrate cautiously (every 1-2 days if necessary) to achieve pain relief. Maximum recommended daily dose: 80/40 mg (one 40/20 mg TARGIN® tablet 12-hourly). *Children*: Not recommended in patients below 12 years of age.

Please review Product Information before prescribing. Product Information is available from Mundipharma Pty Limited, 50 Bridge Street, Sydney, NSW 2000. Phone 1800 188 009.

TGA APPROVAL DATE 5 March 2010

DATE OF FIRST INCLUSION ON ARTG 12 May 2010

DATE OF MOST RECENT AMENDMENT 28 December 2011

*Please note changes to Product Information.
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NORSPAN® Transdermal Drug Delivery System Minimum Product Information

OPIOID THERAPY SHOULD ONLY BE USED AS PART OF A MULTIMODAL PAIN MANAGEMENT PLAN
NAME OF THE MEDICINE Buprenorphine.
INDICATIONS Management of moderate to severe pain.
CONTRAINDICATIONS Hypersensitivity to buprenorphine or patch components, *myasthenia gravis*, *delirium tremens*, pregnancy, severely impaired respiratory function, concurrent non-selective MAO inhibitors (or within 14 days of their administration), treatment of opioid dependence or withdrawal.

PRECAUTIONS Use with caution in convulsive disorders, head injury, shock, reduced level of consciousness of uncertain origin, intracranial lesions or increased intracranial pressure, severe hepatic impairment, history of seizure disorder*,* hypotension, hypovolaemia, biliary tract disease, pancreatitis, inflammatory bowel disorders, prostatic hypertrophy, adrenocortical insufficiency, chronic renal and hepatic disease, following abdominal surgery, in debilitated patients, known or suspected drug or alcohol abuse problems, serious mental illness, intravenous administration of buprenorphine, congenital or medication-induced QT prolongation, driving or operating machinery, pregnancy (Category C), lactation. Do not use in immediate post-operative period, within 24 hours of cordotomy or other pain-relieving surgery. Reduce dosage in hypothyroidism and monitor severely febrile patients for enhanced drug absorption. Physical dependence and withdrawal syndrome may develop. Do not use in opioid-dependent patients. Increased alanine aminotransferase levels have been noted

INTERACTIONS Contraindicated in patients concurrently receiving non-selective MAO inhibitors or within 14 days of stopping treatment. Caution is advised with the newer selective MAO inhibitors. CNS depressants (sedatives, hypnotics, general anaesthetics, opioids, phenothiazines, centrally acting anti-emetics, benzodiazepines, alcohol) can cause respiratory depression, hypotension and profound sedation or coma. Some general anaesthetics (halothane) and other drugs can decrease hepatic elimination of buprenorphine. CYP3A4 inhibitors (protease inhibitors, azole antimycotics, calcium channel antagonists, macrolide antibiotics) might increase buprenorphine levels. Enzyme inducers (phenobarbitone, carbamazepine, phenytoin, rifampicin) could lead to increased clearance and reduced efficacy. Buprenorphine has also been shown to be a CYP2D6 inhibitor *in vitro*. INR levels may potentially increase with concurrent warfarin.

ADVERSE EFFECTS Adverse reactions are similar to those observed with other opioid analgesics and tend to reduce over time except for constipation. Very common (≥ 10%) adverse reactions include application site reaction (includes erythema, oedema, pruritus or rash at application site), constipation, dizziness, dry mouth, headache, nausea, pruritus, somnolence and vomiting. Common (≥ 1% to < 10%) adverse reactions include abdominal pain, anorexia, anxiety, asthenic conditions (including muscle weakness, lethargy, fatigue and malaise), chest pain, confusion, depression, diarrhoea, dysgeusia (taste disturbance), dyspepsia, dyspnoea, exanthema, insomnia, nervousness, pain, paraesthesia, peripheral oedema, rash, sweating, tiredness, tremor*,* vasodilatation.

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NORSPAN® Transdermal Drug Delivery System Minimum Product Information

DOSAGE AND ADMINISTRATION Adults: For transdermal use only over 7 days. The initial dose is 5 µg/hr, especially in opioid-naïve patients and during conversion from other opioids (up to 90 mg oral morphine-equivalents/day and combination analgesics). Titrate until adequate analgesia and improvement in function is achieved, continuing supplemental analgesics as required. Do not increase dose at less than 3-day intervals. To increase dose, remove current patch and apply a higher strength patch or a combination of patches at a different site **(the current site should not be used for 3-4 weeks)**. No more than two patches should be applied at the same time. Apply to intact, non-irritated, relatively hairless skin of upper outer arm, upper back, or upper or side of the chest, avoiding large scars. Use only water to clean skin, and dry before applying patch. Apply patch immediately after removal from pouch. Press firmly in place for 30 seconds. Bathing, showering or swimming should not affect the patch, however if edges start peeling off, tape down with skin tape. If patch falls off, apply a new one. Avoid exposing the application site to external heat sources as an increase in absorption may occur. On removal, fold used patch bringing adhesive sides together, and dispose of safely, out of reach of children. Serum concentrations will decrease gradually, and subsequent opioids should not be administered within 24 hours.

Monitor patients to assess the optimum dose and treatment duration. If adequate pain relief cannot be achieved at maximum patch doses, convert to around-the-clock strong opioid. No dosage adjustment is required in renal impairment, in mild to moderate hepatic impairment or in the elderly, but use with caution if at all in severe hepatic impairment as accumulation of buprenorphine may occur.

Not recommended in patients under 18 years of age.

Please review Product Information before prescribing. Product Information is available from Mundipharma Pty Limited, 50 Bridge Street, Sydney, NSW 2000. Phone 1800 188 009.

DATE OF FIRST INCLUSION ON ARTG 9 May 2005

DATE OF MOST RECENT AMENDMENT 18 March 2013

*Please note changes to Product Information.

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OxyContin® tablets Minimum Product Information

OPIOID THERAPY SHOULD ONLY BE PRESCRIBED AS PART OF A MULTIMODAL PAIN MANAGEMENT PLAN

INDICATIONS The management of moderate to severe chronic pain unresponsive to non-narcotic analgesia.

CONTRAINDICATIONS. Hypersensitivity to opioids, naloxone and any of the constituents of OxyContin® tablets, acute respiratory depression, *cor pulmonale*, cardiac arrhythmias, acute asthma or other obstructive airways disease, suspected mechanical gastrointestinal obstruction (e.g. bowel obstruction, strictures) or any diseases/conditions that affect bowel transit (e.g. ileus of any type), suspected surgical abdomen, severe renal impairment (creatinine clearance < 10 mL/min), severe hepatic impairment (refer to Special Risk Groups), delayed gastric emptying, acute alcoholism, brain tumour, increased cerebrospinal or intracranial pressure, head injury (due to risk of raised intracranial pressure), severe CNS depression, convulsive disorders, *delirium tremens*, hypercarbia, concurrent administration of MAOIs or within two weeks of discontinuation of their use. Not recommended for preoperative use or for the first 24 hours post-operatively. Pregnancy.

PRECAUTIONS The major risk of opioid excess is respiratory depression. Use with caution in patients with hypothyroidism (may need to reduce dose), debilitated elderly or infirm patients, opioid-dependent patients, hypotension, hypovolaemia, diseases of the biliary tract, pancreatitis, inflammatory bowel disorders, prostatic hypertrophy, adrenocortical insufficiency (Addison's disease), toxic psychosis, chronic pulmonary, renal or hepatic disease, myxedema, following abdominal surgery (discontinue use if paralytic ileus is suspected or occurs), underlying gastro-intestinal disorders, chronic non-malignant pain, a prior history of alcohol or substance abuse. OxyContin® tablets should not be taken by patients with swallowing difficulties. Oxycodone should not be used during pregnancy or lactation unless clearly needed (Category C). Tolerance and physical dependence tend to develop upon repeated administration. Withdraw gradually. Parenteral venous injection of the tablet constituents may be fatal. Reduce dosage in the elderly, debilitated patients and in patients with renal or hepatic impairment (one-third to one-half of usual starting dose). Reduce dose or change to another opioid in hyperalgesia that will not respond to an increase dose of oxycodone. May affect driving or operating machinery. Do not use in immediate pre-operative period, or within 24 hours of cordotomy or other pain-relieving surgery.

INTERACTIONS Anticholinergic agents, antihypertensives, CNS depressants (sedatives, hypnotics, general anaesthetics, phenothiazines, other tranquillisers, alcohol, other opioids, neuroleptic drugs, etc.), coumarin derivatives, metoclopramide, non-selective MAOIs or within 14 days of stopping such treatment (caution is advised with selective MAOIs), neuromuscular blocking agents, opioid agonist analgesics and mixed agonist/antagonist analgesics, drugs and dietary elements (grapefruit juice) that affect the P450 enzyme system (CYP3A4, CYP2D6).

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OxyContin® tablets Minimum Product Information

ADVERSE EFFECTS Adverse reactions are typical of full opioid agonists and tend to reduce with time, with the exception of constipation. Very common side effects (incidence ≥ 1/10) include constipation, dizziness, headache, nausea, pruritus, somnolence and vomiting. Common side effects (incidence ≥ 1/100 to < 1/10) include abdominal pain, abnormal dreams, anxiety, asthenic conditions, bronchospasm, chills, confusional state, decreased appetite, depression, diarrhoea, dry mouth, dyspepsia, dyspnoea, faintness, fever, gastritis, hiccup, hyperhidrosis, insomnia, nervousness, orthostatic hypotension, pharyngitis, rash, sedation, thinking abnormal, tremor, twitching and voice alteration.

DOSAGE AND ADMINISTRATION Must be swallowed whole and are not to be broken, chewed, crushed or dissolved. The tablets have been hardened to reduce the risk of being accidentally or intentionally broken, chewed or crushed. Taking cut, broken, chewed, crushed or dissolved OxyContin® tablets could lead to the rapid release and absorption of a potentially fatal dose of oxycodone. OxyContin® tablets should not be pre-soaked, licked or otherwise wetted prior to placing in the mouth and should be taken one tablet at a time with enough water to ensure complete swallowing immediately after placing it in the mouth. Rectal administration of OxyContin® tablets is not recommended. Do not administer OxyContin® tablets via nasogastric, gastric or other feeding tubes as it may cause obstruction of feeding tubes. Alcohol should be avoided while the patient is being treated with OxyContin® tablets. *Adults, elderly and children over 12 years*: Dose at 12-hourly intervals. Usual starting dose (opioid-naïve patients or patients presenting with moderate to severe pain uncontrolled by weaker opioids): one OxyContin® 10mg tablet 12-hourly. Patients with renal or hepatic impairment: Reduce starting dose by ¼ to ½. Titrate carefully (as frequently as once a day if necessary) to achieve pain relief. 10 mg of oral oxycodone is equivalent to 20 mg of oral morphine. **OxyContin® 80 mg tablets should only be used in opioid-tolerant patients. In opioid naïve patients, this tablet strength may cause fatal respiratory depression.** *Children*: Not recommended in patients under 12 years of age.

Please review Product Information before prescribing. Product Information is available from Mundipharma Pty Limited, 50 Bridge Street, Sydney, NSW 2000. Phone 1800 188 009.

DATE OF FIRST INCLUSION ON ARTG 22 October 2013

Thank You

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